Report

India’s Pharmaceuticals Industry

1. OVERVIEW OF THE INDUSTRY

1.1 Background

"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."

Richard Gerster

The Indian pharmaceutical sector has come a long way, being almost non-existent before 1970 to a prominent provider of healthcare products, meeting almost 95 per cent of the country's pharmaceuticals needs.

The Industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously.

Playing a key role in promoting and sustaining development in the vital field of medicines, **Indian Pharma Industry** boasts of quality producers and many units approved by regulatory authorities in USA and UK. International companies associated with this sector have stimulated, assisted and spearheaded this dynamic development in the past 53 years and helped to put India on the pharmaceutical map of the world.

The Indian Pharmaceutical sector is highly fragmented with more than 20,000 registered units with severe price competition and government price control. It has expanded drastically in the last two decades.

There are about 250 large units that control 70 per cent of the market with market leader holding nearly 7 per cent of the market share and about 8000 Small Scale Units together which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units). These units produce the complete range of pharmaceutical formulations, i.e., medicines ready for consumption by patients and about 350 bulk drugs, i.e., chemicals having therapeutic value and used for production of pharmaceutical formulations.

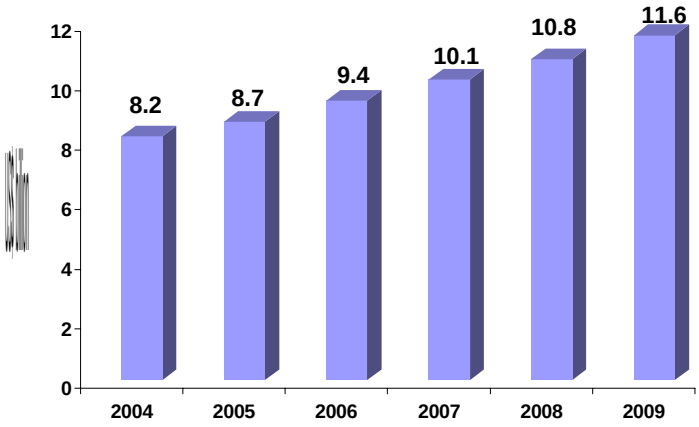
Following the de-licensing of the pharmaceutical industry, industrial licensing for most of the drugs and pharmaceutical products has been done away with. Manufacturers are free to produce any drug duly approved by the Drug Control Authority. Technologically strong and totally self-reliant, the pharmaceutical industry in India has low costs of production, low R&D costs, innovative scientific manpower, strength of national laboratories and an increasing balance of trade.

The total Indian production constitutes about 13 per cent of the world market in value terms and, 8 per cent 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 Japan- US$412, Germany- US$222 and USA- US$191.

1.2 Current Status

India's US$ 9.4 billion pharmaceutical industry is growing at the rate of 14 percent per year. It is one of the largest and most advanced among the developing countries. The Indian pharmaceutical industry can reach a market size of US$ 11.6 billion by 2009.



Source: Epsicom

A beginning has been made with the signing of General Agreement on Tariffs and Trade in January 2005 with which India began recognizing global patents. Soon after, the Indian pharmacy market became a sought after destination for foreign players. Foreign direct investment into the country's pharmacy industry touched US$ 172 million during 2005-06 having grown at a CAGR of 62.6 per cent during the period beginning 2002-06.

The sector recorded strong growth in the second quarter ended September 2006, driven by launch of new generic drugs with 180 days exclusivity period in the US market. The top ten pharmacy companies reported an impressive 57 per cent growth in consolidated net profit at US$ 314.3 million, as against US$ 200.7 million in the same quarter of the previous year, while consolidated net sales were up 51 per cent at US$ 1.7 billion.

Company	Profit(per cent)
Ranbaxy Labs	167.2
Dr Reddy's Labs	65.8
Cipla	5.2
Nicholas Piramal	473.9
Sun Pharma	35.8
Lupin	26.8
Cadila Healthcare	66.4
Torrent Pharma	313.7
Glenmark	74.5
Biocon	26.1

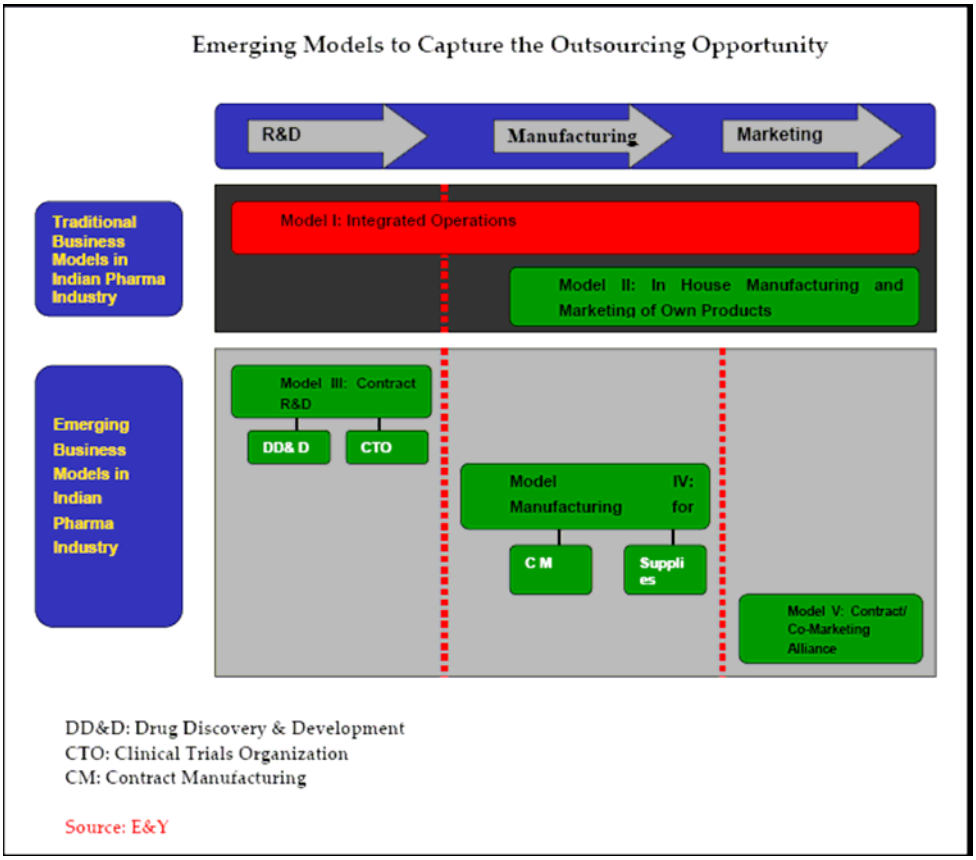
Total	57.2

There are 74 U.S. FDA-approved manufacturing facilities in India, more than in any other country outside the U.S, and in 2005, almost 20 per cent of all Abbreviated New Drug Applications (ANDA) to the FDA were filed by Indian companies.
Growth in other fields notwithstanding, generics are still a large part of the picture. London research company Global Insight estimates that India's share of the global generics market will have risen from 4 per cent to 33 per cent by 2007.

The focus of the Indian pharma companies is also shifting from process improvisation to drug discovery and R&D. the Indian companies are setting up their own R&D setups and are also collaborating with the research laboratories like CDRI, IICT etc.

1.3 The Changing Prescription

As per WTO, from the year 2005, India granted product patent recognition to all new chemical entities (NCEs) i.e., bulk drugs developed then onwards. This introduction of product patent regime from January 2005 is leading into long-term growth for the future which mandated patent protection on both products and processes for a period of 20 years. Under this new law, India will be forced to recognize not only new patents but also any patents filed after January 1, 1995. Under changed environment, the industry is being forced to adapt its business model to recent changes in the operating environment.



Indian pharmaceutical industry is mounting up the value chain. From being a pure reverse engineering industry focused on the domestic market, the industry is moving towards basic research driven, export oriented global presence, providing wide range of value added quality products and services, innovation, product life cycle management and enlarging their market reach. The old and mature categories like anti-infectives, vitamins, analgesics are de-growing while, new lifestyle categories like Cardiovascular, Central Nervous System (CNS), Anti Diabetic are expanding at double-digit growth rates.

The Indian companies are putting their act together to tap the generic drugs markets in the regulated high margin markets of the developed countries. The US market remains to be the most lucrative market for the Indian companies led by its market size and the intensity of blockbuster drugs going off patent. An estimated US$45 billion of drugs expected to go off patent by 2007 in US alone. The Indian pharmaceutical industry is also getting increasingly U.S. FDI compliant to harness the growth opportunities in areas of contract manufacturing and research. Indian companies such as Ranbaxy, Sun Pharma, and Dr. Reddy's are increasingly focusing on tapping the U.S. generic market.

Outsourcing in the fields of R&D and manufacturing is the next best event in the pharmaceutical industry. Spiraling cost, expiring patents, low R&D cost and market dynamics are driving the MNCs to outsource both manufacturing and research activities. India with its apt chemistry skills and low cost advantages, both in research and manufacturing coupled with skilled manpower will attract a lot of business in the days to come.

The Indian Government's decision to allow 100 percent foreign direct investment into the drugs and pharmaceutical industry is expected to aid the growth of contract research in the country.

MNCs in India is facing the problem of having a very high Drugs Price Control Order (DPCO) coverage, weakening their bottom lines as well as hindering their growth through the launch of new products. DPCO coverage is expected to be diluted further in the near future benefiting the MNCs.

1.4 Emerging Trend

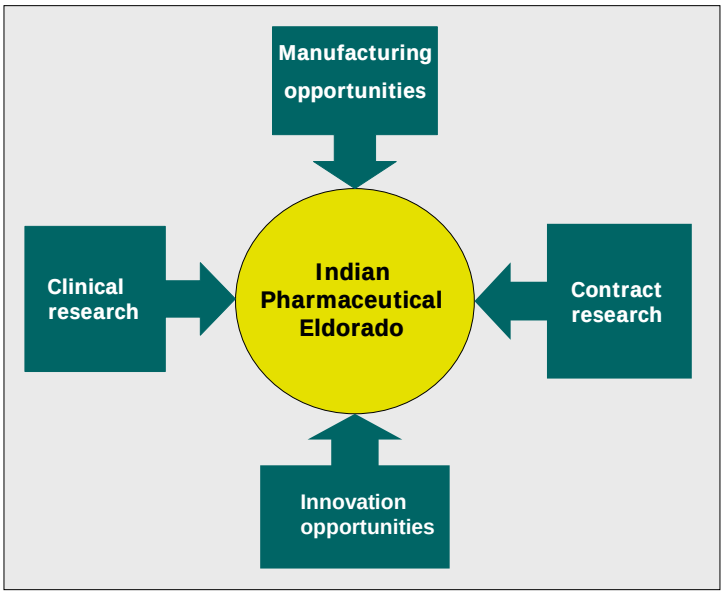
The Indian pharmaceutical industry is now discovering new opportunities of growth in clinical research, contract research, manufacturing and innovation opportunities. This path can lead the Indian pharmaceutical industry to huge success endeavors.

Indian Pharmaceutical Industry: Post 2005 scenario

- Global pharmacos expected to launch 200-250 new drugs over next 8-10 years totaling an estimated US$ 3-5 billion
- FDI inflow grew over six fold from US$ 60.7 mn in 2003 to US$ 340 mn, in fiscal year 2004
- Bristol Myers Squibb, Boehringer Ingelheim and Eisai without Indian presence earlier, have made recent foray
- Indian firms tying up with foreign companies to in-license drugs

Research & Development

Research & Development is the key to the future of pharmaceutical industry. The pharmaceutical advances for considerable improvement in life expectancy and health all over the world are the result of a steadily increasing investment in research. There is considerable scope for collaborative R & D in India. India can offer several strengths to the international R & D community. These strengths relate to availability of excellent scientific talents who can develop combinatorial chemistry, new synthetic molecules and plant derived candidate drugs.



The R & D expenditure by the Indian pharmaceutical industry is around 1.9 per cent of the industry's turnover, which is a little low as compared to foreign research based pharmaceutical companies. However, now that India is entering into the Patent protection area, many companies are spending relatively more on R & D.

When it comes to **clinical evaluation** at the time of multi-center trials, India is providing a strong base considering the real availability of clinical materials in diverse therapeutic areas. According to a survey by the Pharmaceutical Outsourcing Management Association and Bio/Pharmaceutical Outsourcing Report, pharmaceutical companies are utilizing substantially the services of **Contract Research Organizations** (CROs).

Indian Pharmaceutical Industry, with its rich scientific talents, provides cost-effective clinical trial research. It has an excellent record of development of improved, cost-beneficial chemical syntheses for various drug molecules. Some MNCs are already sourcing these services from their Indian affiliates.

Product development

For years, firms have made their ways into the global market by researching generic competitors to patented drugs and following up with litigation to challenge the patent. This approach remains untouched by the new patent regime and looks to increase in the future.

However, those that can afford it have set their sights on an even higher goal: **new molecule discovery**. Although the initial investment is huge, companies are lured by the promise of hefty profit margins and the recognition as a legitimate competitor in the global industry.

Small and medium enterprises

The excise structure changed so that companies now have to pay a 16 per cent tax on the maximum retail price of their products, as opposed to on the ex-factory price. Consequently, larger companies are cutting back on outsourcing and what business is left is shifting to companies with facilities in the four tax-free states - Himachal Pradesh, Jammu & Kashmir, Uttaranchal and Jharkhand. SMEs have been finding it difficult to find the funds to upgrade their manufacturing plants, resulting in the closure of many facilities.

In terms of the global market, India currently holds a modest 1-2 per cent share, but it has been growing at approximately 10 per cent per year. India gained its foothold on the global scene with its innovatively-engineered generic drugs and active pharmaceutical ingredients (API), and it is now seeking to become a major player in outsourced clinical research as well as contract manufacturing and research.

Multinational Success Stories

- Phase III study of **Zymar gatifloxacin** ophthalmic solution conducted by **Quintiles** in India has been accepted by FDA for approval to treat bacterial conjunctivitis.
- **Quintiles, India** is believed to be one of the most profitable subsidiaries (by operating profit margins) of Quintiles Transnational.
- **Pfizer, Novartis** and **Eli Lilly** and now **GSK** are all understood to be making India a global hub for their clinical research activities.

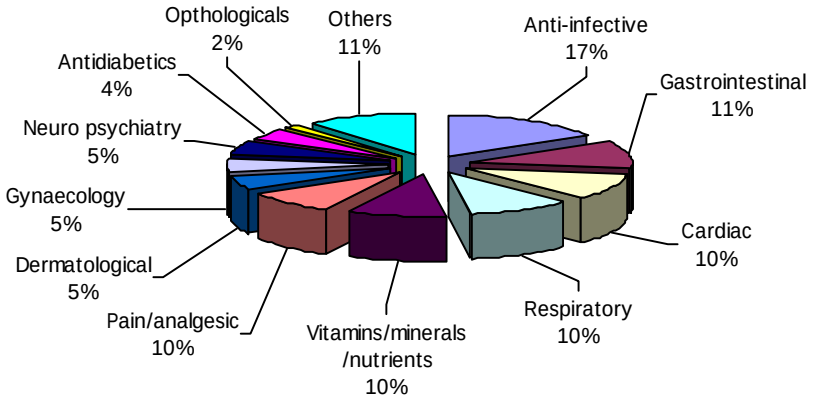
1.5 Domestic Demand

The industry has enormous growth potential. Factors listed below determine the rising demand for pharmaceuticals.

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

More than 85 per cent 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 Rs160 billion and it is growing at 10 per cent per annum.

Market Share of Different Pharmaceutical Product Categories



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. 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.

Category	Value (Rs bn)	Value Market Share (%)	Value growth (%)	Volume Growth (%)
Anti-infective	32.8	16.4	4	11
Gastrointestinal	21.8	10.9	8	9
Cardiac	20.7	10.3	18	15
Respiratory	20.4	10.2	9	6
Vitamins/minerals/nutrients	19.3	9.6	5	5
Pain/analgesic	19.1	9.5	8	9
Dermatological	10.8	5.4	8	4
Gynaecology	10.7	5.3	3	-1
Neuro psychiatry	10.6	5.3	10	6
Antidiabetics	8.8	4.4	11	16
Opthologicals	3.5	1.7	18	16
Others	22	11	-	-
Aggregate	200.5	100	8	9

Historically, 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.

1.6 Exports

Over 60 per cent of India's bulk drug production is exported. India's pharmaceutical exports are to the tune of Rs87 billion, of which formulations contribute nearly 55 per cent and the rest 45 per cent comes from bulk drugs. In financial year 2005, exports grew by 21 per cent. The Indian pharmaceutical market has been forecasted to grow to as much as US$ 25 billion by 2010 as per Organization of Pharmaceutical Producers of India (OPPI) estimates. However, Espicom's market projections forecast more modest but stable annual market growth of around 7.2 per cent, putting the market at US$ 11.6 billion by 2009.

Domestic pharmaceutical exports, growing at 30 per cent per annum, touched a new height of US$4.8 billion in the financial year 2006-07. The Year's exports will push the drug sectors contribution to India's Forx earnings to 7.75 per cent from the current 5 per cent. The growth in drug exports, despite the pressing generic competition in the global markets, is attributed to increased Abbreviated New Drug Applications (ANDAs) approvals in the US market and contribution from unconventional markets in Latin America, Australia and the emerging markets in the Middle East and African Region.

The export revenue now contributes almost half of the total revenue for the top three pharmaceutical majors: Dr Reddy's, Ranbaxy and Cipla.

The other major exporters are Wockhardt Limited, Sun Pharmaceutical Industries Ltd. and Lupin Laboratories. The formulations and exports are largely to developing nations in CIS, South East Asia, Africa and Latin America . In the last 3 years generic exports to developed countries have picked up. In the coming years, opening up of US generics market and anti AIDS market in Africa will boost exports.

Revenue from Export

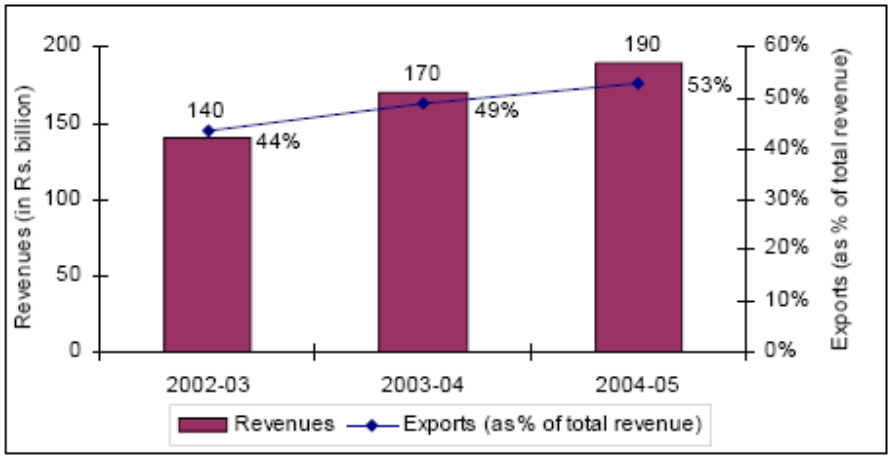
India accounts for less than two per cent of the world market for pharmaceuticals, with an estimated market value of US$10.4 billion in 2007 at consumer prices, or around US$9 per capita.

India currently represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year, compared to 7 percent annual growth for the world market overall. Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value, and its drug exports have been growing 30 percent annually. Cipla, Nicholas Piramal, Ranbaxy, Zydus Cadila, Dr. Reddy's are the few Indian pharmaceutical companies, which are known at the global level due to their quality products.

The Indian market for over-the-counter medicines (OTCs) is worth about $940 million and is growing 20 percent a year, or double the rate for prescription medicines. The industry's exports were worth more than $3.75 billion in 2004-05 and they have been growing at a

compound annual rate of 22.7 percent over the last few years, according to the government's draft National Pharmaceuticals Policy for 2006, published in January 2006. The Policy estimates that, by the year 2010, the industry has the potential to achieve $22.40 billion in formulations, with bulk drug production going up from $1.79 billion to $5.60 billion.

Graph 1: Trend in Revenue and Export Contributions for the Sample



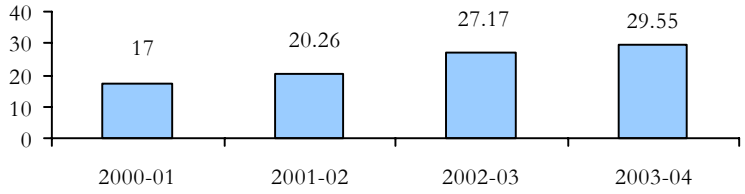
Source: ICRA

Indian exports are to more than 200 countries around the globe including highly regulate markets of US, Europe, Japan and Australia. More than 400 Bulk Drugs and about 60,000 Formulations (60 categories) are produced in India.

1.7 Import

Imports have registered a CAGR of only 2 per cent in the past 5 years. Import of bulk drugs have slowed down in the recent years.

Import of Pharmaceuticals (In Rs billion)



1.8 Growth Drivers

India's population is just over one billion at present and projected to rise to 1.6 billion by 2050 and India will become the world's most populous country. It is estimated that by 2025, 189 million Indians will be 60 or older up from about 63 million in year 2004. This projection shows the demand of pharmaceutical drugs will rise in coming years.

The government had promised to increase public expenditure on healthcare from 0.9 per cent of GDP in 1999 to 2 per cent of GDP by 2010.

India manufactures more than 96 generic group drugs.

Indian government has framed a favorable policy to boost foreign investment in the pharmaceutical sector. Tax holidays are offered to industrial operations established in specified Special Economic Zone or under developed areas, deduction of profits earned from exports, liberal depreciation allowances, deduction of capital R & D expenditure; and relief on all contributions to approved domestic research institutions are some examples.

Foreign Direct Investment up to 100 per cent is permitted through the automatic route and Automatic approval for Foreign Technology Agreements also is available in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those restricted by the Government of India.

India has excellent skilled and educated manpower. There are 115,000 scientists with their master's degrees and 12,000 with Ph.D. in chemistry alone pass out every year.

Clinical trials account for over 40 per cent of the costs of developing a new drug, and Rabo India Finance (a subsidiary of the Netherlands based Rabo Bank) estimates that a standard drug could be tested in India for as little as $ 90 million – 60 per cent of the sum it would cost to test in the US.

Maximum US FDA approvals outside USA are with Indian Companies – approx. 197.Largest No. of US Drug Master File's (DMF) – 213 (38 per cent of DMFs filed in First half of 2005 are from India)

1.9 Vision 2020

Responsibilities and Resources would make an important beginning in the transition of efficient and effective use of pharmaceutical in building a prosperous and healthy India. In doing so, following issues have been identified for realizing the Pharma Vision 2020.

- The Indian pharmaceutical industry shall ensure that essential drugs at affordable prices are available to the vast population of this sub-continent and also continue providing employment for millions.

- India shall implement all the rules and regulations, which guide, monitor and control the activities of the providers of the healthcare system in the country and shall

examine the way to bring them up to international standards. The government should implement the recommendations of Mashelkar committee and constitute the Central Drug Authority at the earliest.

- The basic course of education should be designed to ensure that the newly qualified pharmacist has the necessary knowledge and skills to commence practicing competently in a variety of settings including community and hospital pharmacy and the pharmaceutical industry. Continuing professional development must then be a lifelong commitment for every practicing pharmacist. Concept of National schools of pharmacy should be established to develop and introduce model curriculum.

- Pharmacists should become knowledgeable to participate in medication management and outcome monitoring. Pharmacy profession should orient concept of pharmacy practice at community and hospital pharmacies through appropriate training and compensation.

- The pharmacy profession will make the clinical trial industry in India to grow to over a billion dollars in the next five years and position itself as a destination of choice for CRO services by way of strict implementation of patent laws, single window clearance of clinical trial protocols by regulatory clearances and shall accord industry status to this sector.

- India will emerge as a major global player in the field of pharmaceuticals exports and as a provider of quality medicines at low costs. It shall also emerge as a major player in the generic drugs market in USA and Europe.

- India shall attain new heights in herbal drugs research in shaping Indian Systems of Medicine into a popular system of medicine of the future for holistic health care and ensuring health care for all - especially for the welfare of the poor.

- India's Patents Act should ensure that it does not exceed the requirements of TRIPS, and that prioritizes access to medicines and public health, while retaining the right to participate in the compulsory license scenario. India should lead a movement of developing nations and create a TRIPS south and G-20 alliance is a step in that direction.

The Government should take immediate steps to remove the anomalies in the Indian Pharmacopoeia Commission created by it, and give necessary teeth to truly function as an independent and autonomous scientific body.

2. COMPETITION OVERVIEW

2.1 Major Players in the Pharmaceuticals Industry

Competition is mainly from the domestic manufacturers and imports from China because of the low manufacturing cost. With the new patent regulations the industry expects to see a major structural shift with the entry of foreign pharmaceutical manufacturers.

There are five government-owned companies the Indian public sector. These companies are the Indian Drugs and Pharmaceuticals, Hindustan Antibiotics Limited, Bengal Chemicals and Pharmaceuticals Limited, Bengal Immunity Limited and Smith Stanistreet Pharmaceuticals Limited. Some of the major Indian private companies are Alembic Chemicals, Aurobindo Pharma, Ambalal Sharabhai Limited, Cadila Healthcare, Cipla, Dr. Reddy's, IPCA Laboratories, Jagsonpal Pharma, J.B. Chemicals, Kopran, Lupin Labs, Lyka Labs, Nicholas Piramal, Ranbaxy Labs, Matrix Laboratories, Orchid Chemical and Pharmaceuticals, Sun Pharmaceuticals, Ranbaxy Laboratories, Torrent Pharma, TTK Healthcare, Unichem Labs, and Wockhardt.

The foreign companies in India include Abott India, Astra Zeneca India, Aventis Pharma India, Burrough-Wellcome, Glaxo SmithKline, Merck India, Novartis, Pfizer Limited, and Wyeth Ledele India.

India also exports pharmaceuticals to numerous countries around the world, including to the U.S., Germany, France, Russia and UK.

Name	Ranbaxy
Year of Establishment	The company was incorporated in 1961 and went public in 1973.
Company Profile	Ranbaxy is among the top 100 pharmaceuticals in the world and that it is the 15th fastest growing company. It is consolidating its position to become the top 5 generics producer in the World, with the purchase of French firm RGP Aventis in 2003. It keeps a dedicated research facility staffed with over 1100 scientists. They currently have two molecules in Phase II trials and 3-5 in pre-clinical testing. The Company is aggressively pursing its internationalization strategy it has also gained market leadership in India, leveraging its strong brand building skills.
Sales/Revenues/Turnover	For the year ended Dec 31, 2006, the Company's Global Sales were at USD 1,340 Million. Overseas markets accounted for around 80% of global sales. The Company's largest market, USA with the sales of USD 380 Million, while Europe and BRICS (Brazil, Russia, India, China, South Africa) countries

	contributed USD 194 Million and USD 477 Million to global sales.
Global Presence/ Marketing Network	Ranbaxy has an expanding international portfolio of affiliates, joint ventures and representative offices across the globe with a presence in 23 of the Top 25 pharma markets of the world. It has robust operations in USA, UK, France, Germany, Russia, India, Romania and South Africa, and is strengthening its business in Japan, Italy, Spain and several other markets in the Asia Pacific.
Acquisitions/Divestment	The Company has successfully concluded 15 acquisitions since 2004, including 8 in 2006 (4 in Europe, 1 in the US, 2 in India and 1 in South Africa). Ranbaxy will continue to look at target acquisitions in US, Europe, India and emerging markets based on value and synergies that can be unlocked from such transactions.
Future Prospects	By 2012, Ranbaxy hopes to be one of the top 5 generics producers in the world. The Company will focus on increasing its momentum in the generics business in its key markets of US, Europe, BRICS and Japan through organic and inorganic routes.

Name	Dr. Reddy's Laboratories
Year of Establishment	The company was Founded in 1984 with USD 160,000
Sales/Revenues/Turnover	Dr. Reddy's is a vertically integrated, global pharmaceutical company with proven research capabilities and presence across the pharmaceutical value chain. They manufacture Active Pharmaceutical Ingredients (API) and Finished Dosage forms. In addition, the drug discovery arm of the company conducts basic research in the areas of diabetes, cardiovascular, inflammation and bacterial infection. Dr. Reddy's was the first Asia-Pacific pharmaceutical outside of Japan and the sixth Indian company to be listed on the New York Stock Exchange. 58 per cent of Dr. Reddy's revenues come from generic drugs. Dr. Reddy's has long been a research-oriented firm. It had set up a New Drug Development Research (NDDR) in 1993 and out-licensed its first compound just four years later. Dr. Reddy's has since outlicensed two more molecules and currently has three others in

	clinical trials.
Sales/Revenues/Turnover	Revenues for fiscal 2007 were USD 1.51 billion.
Global Presence/ Marketing Network	They market their products globally, with a focus on United States, Europe, India and Russia.
Acquisitions/Divestment	– Acquires Benzex Laboratories Pvt. Limited in 1988 to expand its Bulk Actives business. – Acquisition of American Remedies Limited, a pharmaceutical company based in India. in 1999 – Dr. Reddy's Laboratories becomes India's third largest pharmaceutical company with the merger of Cheminor Drugs Limited, a group company in 2001 – Conducts its first overseas acquisition – BMS Laboratories Limited and Meridian Healthcare in UK in 2002 – Acquires Roche's API Business with a total investment of USD 59 million in 2005. – Acquires betapharm- the fourth-largest generics company in Germany for a total enterprise value of € 480 million in 2006.
Future Prospects	Future Prospects – Dr Reddy's Laboratory Licensing deal with Novo Nordisk Open to brand acquisitions Bulk prices haven't bottomed out as yet

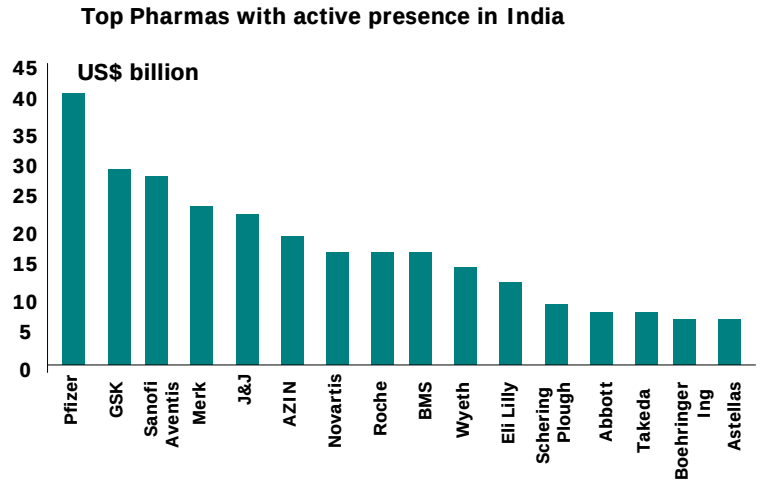
Name	Nicholas Piramal
Year of Establishment	Established in 1988
Company Profile	Nicholas Piramal started its existence with the 1988 acquisition of Nicholas Laboratories and grew through a series of mergers, acquisitions and alliances. The company has formed a name for itself in the field of custom manufacturing. It cites its 1700-person global sales force as another core strength. It is well-poised for the challenge of surviving in the aftermath of product patent protection. The company has respected intellectual property rights since its inception.
Sales/Revenues/Turnover	The company grossing USD 350 million per year
Global Presence/ Marketing Network	Nicholas Piramal gained a sales and marketing network spanning 90 countries.
Acquisitions/Divestment	The company started its existence with the 1988 acquisition of Nicholas Laboratories and grew through a series of mergers, acquisitions and alliances. It has recently acquired Rhodia's

	inhalation anaesthetics business.
Future Prospects	Nicholas Piramal is well-poised for the challenge of surviving in the aftermath of product patent protection. It decided to make its own intellectual property and opened a research facility in Mumbai with hopes of launching its first drug in 2010 at a cost of USD 100,000.

Name	Cipla
Year of Establishment	In 1935, The Chemical, Industrial & Pharmaceutical Laboratories was set up, which came to be popularly known as Cipla. It was officially opened on September 22, 1937 when the first products were ready for the market.
Company Profile	Today they have 31 world-class manufacturing facilities spread across the country, with dedicated plants for Oncology products, Hormones, Inhalers, Carbapenems, and Cephlosporins, among others. They more than meet the stringent international standards, such as that of US FDA, MHRA-UK, TGA Australia, Bfarm-Germany MCC-South Africa, WHO, TPD-Canada. Cipla produces one of the widest range of products and dosage forms in the world today, everything from metered-dose inhalers, pre-filled syringes, trans-dermal spray patches, lyophilized injections, nasal sprays, medical devices, and thermolabile foams. Whether it is constantly extending our product range or consistently introducing innovations, the mission is always to make the life of the patient better.
Sales/Revenues/Turnover	Revenue in 2004 totaled USD 552 million (using Rs 43.472 = USD1) about 75 per cent of which was derived in India.
Global Presence/ Marketing Network	Cipla has been building a strong global presence, and it now distributes its 800-odd products in over 170 countries.
Acquisitions/Divestment	Mainly focused on the domestic market, Cipla has largely refrained from big-ticket acquisitions overseas, new molecules research and patent challenges.
Future Prospects	Cipla started with a vision to build a healthy India. And along the way realised, that in their own small way, they could contribute to making the world a healthier place. They will continue to

	bring a smile on as many faces as they can to heal the world as much as they can.

Name	Biocon
Year of Establishment	Biocon India is incorporated as a joint venture between Biocon Biochemicals Ltd. of Ireland and an Indian entrepreneur, Kiran Mazumdar-Shaw in 1978.
Company Profile	Biocon is India's premier biotechnology company. Headquartered in Bangalore Biocon has evolved from an enzyme company to a fully integrated biopharmaceutical enterprise, focused on healthcare. Biocon strategically focuses its activities on its bio-pharma business verticals that include APIs, biologicals and proprietary molecules. Biocon Limited and its two subsidiary companies, Syngene International Limited and Clinigene International Limited form a fully integrated biotechnology enterprise specializing in biopharmaceuticals, custom research and clinical research.
Sales/Revenues/Turnover	Total Revenues is Rs 9.9 billion for the year-ended 31st March, 2007.
Global Presence/ Marketing Network	Biocon's integrated business approach has enabled the company to establish a significant presence in the global biopharmaceutical market via its product offerings and customised, high value solutions at any stage in the lifecycle of a drug-from discovery to market.
Acquisitions/Divestment	In 2007, Biocon made a strategic decision to divest its historic enzymes business to Novozymes A/S of Denmark.
Future Prospects	Consistent with their long-term growth strategy, Biocon remains committed to building biotherapeutics franchise through their own R&D efforts. To further enhance their IP and technology platforms, they have made an investment of Rs. 764 million in R&D, which is a 76% increase over the previous fiscal.


Top Pharmas with active presence in India
US$ billion
45
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Pfizer
GSK
Sanofi Aventis
Merk
J&J
AZIN
Novartis
Roche
BMS
Wyeth
Eli Lilly
Schering Plough
Abbott
Takeda
Boehringer Ing
Astellas

3. REGULATORY FRAMEWORKS

The Indian pharmaceutical industry is highly regulated. The Government controls prices of a large number of bulk drugs and formulations. Profit margins of players vary widely in both domestic and export sales due to many factors.

The Export Promotion Cell in the Pharmaceutical Division acts as a nodal agency in the matters related to export of pharmaceuticals. In order to give adequate attention to day-to-day problems faced by the exporters, the Cell interacts with various Ministries/Departments and our Missions abroad. The Cell also collects statistical data on export and import of pharmaceuticals in the country and provides commercially useful information on developing and increasing drugs and pharmaceutical exports. The Cell has been entrusted with organization of seminars and workshops on standards, quality control requirements etc. of important countries so as to prepare domestic companies for exporting their products.

It communicates with 131 Missions abroad to collect information related to pharmaceutical industry in these countries such as, status of the pharmaceutical industry, details of documentation, guidelines for licensing of pharmaceutical companies as well as registration for medicines, details of pharmaceutical market with information on local production, demographic data, details of health care system, health indicators and prevalent disease pattern, details of imports of pharmaceuticals of these countries, details of joint venture units for pharmaceuticals operating in these countries etc. It provides commercially useful information to the industry/exporters for boosting pharmaceutical exports.

3.1 FDI Regulation

The current Foreign Direct Investment Policy of the Government of India allows

- FDI up to 74 per cent in the case of bulk drugs, their intermediates and formulations (except those produced by the use of recombinant DNA technology) would be covered under automatic route.
- FDI above 75 per cent for manufacturing of bulk drugs will be considered by the Government on case to case basis for manufacture of bulk drugs from basic stages and their intermediates and bulk drugs produced by the use of recombinant DNA technology as well as the specific cell/tissue targeted formulations provided it involves manufacturing from basic stage.

3.2 Pharmaceutical Intellectual Property Right

The importance of intellectual property in India is well established at all levels- statutory, administrative and judicial. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) came into force from 01 January 1995. It lays down minimum standards for protection and enforcement of intellectual property rights in member countries, which are required to promote effective and adequate protection of intellectual property with a view to reducing distortions and impediments to international trade.

India, as a developing country, had a transition period of five years (with effect from 01 January, 1995), i.e., till 01 January 2000 to apply the provisions of the Agreement.

Keeping in view the changes in trade and commercial practices, globalization of trade, need for simplification and harmonization of trade marks registration systems etc., a comprehensive review of the Trade and Merchandise Marks Act, 1958 was made and a Bill to repeal and replace the 1958 Act has since been passed by Parliament and notified in the Gazette on 30.12.1999. This Act not only makes Trade Marks Law, TRIPS compatibility but also harmonizes it with international systems and practices.

3.3 Some Key Features of the Indian Patents Act of 2005

- Re-introduction of product patents for drugs, medicines and foods, including products of chemical reactions
- Patent term made 20 years from the date of submission of the complete specification
- Statutory publication of patent applications after 18 months of the priority date.
- Provisions made for early publication on request
- Creation of an appellate board for appeals
- New definitions of some terms relevant to the pharmaceutical industry, including 'inventive step, new invention and pharmaceutical substances
- Reduction in number of drugs under price control to 28 as against 74
- 100 per cent foreign investment automatically permitted
- Abolishment of industrial licensing for bulk drugs, intermediates and formulations
- Automatic approval for Foreign Technology Agreements

3.4 Policy Initiatives

- The patent (Third amendment) Act, 2005
- Revision of schedule Y to permit conduct of phase II-IV clinical trials in India
- Amendment of schedule M to make industry compliance to Good Manufacturing Practices
- Stringent measures for makers of spurious drugs
- Creation of pharma R&D fund with a total corpus of US$ 33.3 million
- Concessional Industrial Package for pharmaceutical manufacturers in certain hilly states
- Constitution of India Pharmacopoeia Commission
- Creation of Export Promotion Council "Pharmexcil"
- Tax exemptions at par with IT
- Reduction in peak custom duties from 30 per cent to 25 per cent
- Increase on rate of depreciation on life saving equipment from 25 per cent to 40 per cent
- Tax holiday for R&D companies

3.5 Key Features of the Union Budget 2005 – 2006

- 22 per cent increase in allocation under the National Rural Health Mission
- Formation of a SME Growth Fund to provide equity support to small & medium units in the pharmaceutical & biotechnology sectors
- Import duty on select equipments used in pharmaceutical & biotech research reduced from 20 per cent to 5 per cent
- 150 per cent weighted deduction on R&D expenditure

4. CHALLENGES AND OPPORTUNITIES

4.1 Challenges

4.1.1 Underdeveloped new molecule discovery program

The main weakness of the industry is an underdeveloped new molecule discovery program. Even after the increased investment, market leaders such as Ranbaxy and Dr. Reddy's Laboratories spent only 5-10 per cent of their revenues on R&D, lagging behind Western pharmaceuticals like Pfizer, whose research budget last year was greater than the combined revenues of the entire Indian pharmaceutical industry. This disparity is too great to be explained by cost diffentials, and it comes when advances in genomics have made research equipment more expensive than ever.

The drug discovery process is further hindered by a dearth of qualified molecular biologists. Due to the disconnect between curriculum and industry, pharmas in India also lack the academic collaboration that is crucial to drug development in the West

4.1.2 Hue & cry against exploitation

In clinical testing persons from developing countries will be used to generate data about possible effects of a drug. A feeling of unrest among them or some section of society might develop that we are being used as guinea pigs. It might lead to demonstrations or legislations which will hamper the growth of industry.

4.1.3 Back lash against outsourcing

Similar to BPO there might be unrest in developed nations that outsourcing of clinical trials will lead to job loss culminating into legislation banning the whole procedure.

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4.1.4 IP leakage

IP leakage is one of the major concerns by companies outsourcing research work to India. So any major incident of IP leakage by Indian company can taint the image of whole industry.

4.1.5 Restricted items

There are a lot of items that are restricted under the EXIM policy from free trading. These items are given under annexure 1. These restrictions are a weakness for the industry and hence pose to be a threat for its development.

4.1.6 Reservation for small scale industries

Some drugs are reserved for exclusive manufacture by the small scale units. These are Niacinamide, Paracetamol, Glycero Phosphates, Nicotinic Acid.

The present investment limit for units to qualify as a small scale unit is Rs. 30 million.

4.1.7 No brand value

India has a low beep on the radar screen of MNC drug companies as no potential clinical testing has been ever outsourced to India. So we have a low brand value in global arena.

4.1.8 Safety concerns

With recent high profile product withdrawals, there are also concerns that regulatory agencies will tighten up safety and efficacy testing requirements. A particular focus will be on the application of pharmacogenomic techniques to improve safety profile, but the advent of such techniques in the long run will improve industry productivity as more pharmacogenomic data is collated.

4.1.9 Generic competition

Generic substitution is a policy for healthcare cost containment. National reimbursement and insurance bodies are providing physicians and pharmacists with incentives for prescribing cheaper generic drugs. There is increased pressure on revenues for pharmaceutical companies, which have to concentrate on lifecycle management. The pharmaceutical industry will experience a significant reduction in the revenues associated with their blockbuster products as generic competition captures market share. As a result, given that R&D productivity is low and the cost of developing new drugs at an all time high, the pharmaceutical industry faces considerable hurdles with respect to maintaining revenue and earnings growth in the future.

4.2 Opportunities

The Indian pharmaceutical industry has a lot of strengths and hence ample of opportunities. A few important strengths are mentioned below.

4.2.1 Competent workforce

India has a pool of personnel with high managerial and technical competence as skilled workforce. It has the largest English speaking population in the world. Professional services are easily available.

4.2.2 Cost-effective Chemical Synthesis

Its track record of development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules is excellent. It provides a wide variety of bulk drugs and exports sophisticated bulk drugs.

4.2.3 Legal & Financial Framework

India has a 53 year old democracy and hence has a solid legal framework and strong financial markets. There is already an established international industry and business community.

4.2.4 Information & Technology

It has a good network of world-class educational institutions and established strengths in Information Technology.

4.2.5 Globalization

The country is committed to a free market economy and globalization. It has a 70 million middle class market, which is continuously growing.

4.2.6 Consolidation

The international pharmaceutical industry is finding great opportunities in India as the process of consolidation has started taking place in India.

4.2.7 Low priced products

The industry has thrived so far on reverse engineering skills exploiting the lack of process patent in the country. This has resulted in the Indian pharmaceutical players offering their products at some of the lowest prices in the world.

4.2.8 Quality assurance

The quality of the products is reflected in the fact that India has the highest number of manufacturing plants approved by US FDA (61 plants), which is next only to that in the US.

4.2.9 Dominance in the market

Multinational companies have traditionally dominated the industry, which is another trend seeing a reversal. Currently, it is the Indian companies which are dominating the marketplace with the local players dominating a number of key therapeutic segments.

4.2.10 Self-reliance

Displayed by the production of 70 per cent of bulk drugs and almost the entire requirement of formulations within the country.

4.2.11 Other Strengths

Low cost of production, Low R&D costs, Innovative Scientific manpower and Increasing balance of trade in Pharma sector are also significant strengths of the Indian pharmaceutical industry.

4.2.12 R&D

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

- Primary Research Facility Mumbai

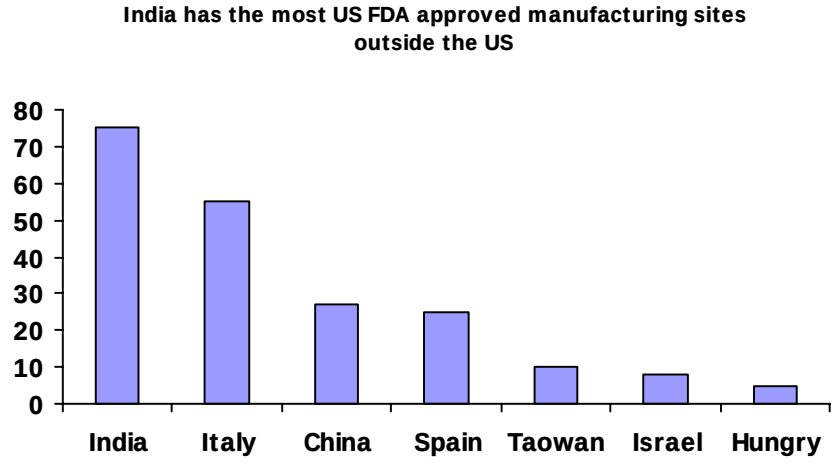
  It gets technical and financial assistance from NIH, USA. It is established on 25 acres of land with an Investment of US$ 16.7 million and has a facility to house 7500 breeding stocks. The center has received US$ 3mn grant from US and US$ 4 million from ICMR.

- International Animal Research Facility Hyderabad

  Government of Andhra Pradesh has allotted 100 acres of land at the Biotech Park in Genome Valley for International animal research facility. Department of Biotechnology has also provided US$ 4.4 million for the same. The facility will be of international standards with animal testing facilities, hi-tech equipment, a strong technical board and ethical committee.

4.2.13 Clinical Research- India, Most Significant Emerging Geography

Indian clinical research industry is estimated at over US$ 100 million. It complies with ICH-GCP protocols. It is a growing body of trained and experienced investigators. India is expected to capture about 10 per cent of the global clinical research market by 2010.



Source: US Food and Drug Administration

Big Pharma organizations are contributing patients from India for multicentric global trials for FDA/EMEA submissions. Seven of the top 10 global CROs have a presence in India.

The above mentioned advantages arer an asset and have strengthened the Indian pharmaceutical industry, thus generating a great deal of opportunities for the sector to flourish. The major opportunities that the industry enjoys today are as under.

4.2.14 Labor force

With one of the largest and most genetically diverse populations in any single country, India can recruit for clinical trials more quickly and perform them more cheaply than countries in the West.

4.2.15 The Indian Generics market

The Indian generics market is witnessing rapid growth opening up immense opportunities for firms. This is further triggered by the fact that generics worth over $40 billion are going off patent in the coming few years which is close to 15 per cent of the total prescription market of the US. The Indian pharmaceutical companies have been doing extremely well in developed markets such as US and Europe, notable among these being Ranbaxy, Dr. Reddy's Labs, Wockhardt, Cipla, Nicholas Piramal and Lupin. The companies have their strategies in place to leverage opportunities and appropriate values existing in formulations, bulk drugs, generics, Novel Drug Delivery Systems, New Chemical Entities, Biotechnology etc.

4.2.16 Smaller bio tech firms

With pharmaceutical companies struggling to maintain R&D productivity, biotechnology companies present opportunities to enhance product pipelines. Increasing convergence of the pharmaceutical and biotechnology sectors was observed during 2004. The demand for biopharmaceuticals is encouraging pharmaceutical companies to invest in smaller biotech firms.

4.2.17 Ageing and obese population

Healthcare needs will increase and drugs will be used for longer. For instance, an ageing global population is poised to drive pharmaceutical drugs for indications such as Alzheimer's disease. Drugs that address rising multifactorial disorders such as cancer as well as lifestyle disorders such as obesity are also likely to experience strong revenue growth.

4.3 Future Outlook

Indian companies are climbing the value chain by moving to developed markets and from bulk drugs to formulation exports. As a result, Indian companies are expected to produce six of the top 10 drugs that are scheduled to lose patent protection over the next five years. Indian companies are targeting opportunities rising in the regulated and unregulated markets.

Research focus of large companies has shifted towards discovery of New Chemical Entities keeping in view the product patent era commenced from 1st Jan., 2005.

The big players will speed up the launch of new products and will look at brand acquisition from other relatively smaller players. The latter will either close down or be taken over by larger players. Hence the currently fragmented industry may consolidate further.

The Indian Pharma sector is growing exponentially. Its value in 2004 was US$ 6 billion and US$ 10 billion by the end of year 2006. According to the Mc Kinsey study Indian Pharma industry is poised to grow to US$ 25 billion with market capitalization of almost us$ 150 billion from the current $US 6 billion generic based drug industry.

With the global players extending their bid to tap India's manufacturing prowess, contract manufacturing is estimated to generate US$ 1 billion in revenue in 2010. The growth is likely to be driven by increasing outsourcing of late-stage and off-patent molecules by big-pharmaceutical organisations.

On-patent molecules in highly competitive therapies e.g., proton pump inhibitors (PPI) also being outsourced.