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EXPORT-IMPORT BANK OF INDIA

OCCASIONAL PAPER NO. 119

**INDIAN PHARMACEUTICAL INDUSTRY :
SURGING GLOBALLY**

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EXECUTIVE SUMMARY

INTRODUCTION

Health is defined both as cause and effect of economic development. Therefore, the pharmaceutical industry is specifically recognized in the UN Millennium Development Goals as an actor that can contribute to economic development. In addition, the pharmaceutical industry provides significant socio-economic benefits to the society through creation of jobs, supply chains, and through community development. The industry also plays an important role in technological innovation, which may reduce costs of economic activity elsewhere in the economy.

Players in the pharmaceutical industry include: branded drug manufacturers, generic drug manufacturers, firms developing biopharmaceutical products, non-prescription drug manufacturers, firms undertaking contract research. In addition, there are also enablers of the industry such as universities, hospitals and research centers that play a role in R&D activities.

GLOBAL SCENARIO

Market Size

Global pharmaceutical market is highly dynamic and is characterised by greater levels of R&D expenditure and extensive regulation of its products. Global pharmaceutical sales are estimated to be US\$ 643 billion in 2006, a growth of 7% over the previous year. Sales have grown from US\$ 334 billion in 1999 to US\$ 643 billion in 2006, witnessing a CAGR of 10%. North America is the major pharmaceutical market accounting for around 48% of global pharmaceutical sales, followed by Europe (30%), Japan (9%). Leading therapy classes in world pharmaceutical market include lipid regulators (with a market share of 5.8%), oncologics (5.7%), respiratory agents (4%), acid pump inhibitors (4%), and anti-diabetics (3.5%).

Research and Development

Research and Development (R&D) is the backbone of the pharmaceutical industry all over the world. Globally, USA is the major hub for pharmaceutical R&D.

According to Pharmaceuticals Research and Manufacturers of America (PhRMA), USA, in the year 2005, has spent more than US\$ 50 billion in pharmaceutical R&D. R&D spending in US pharmaceutical industry accounted for over 17% of total sales. Europe, with R&D expenditure worth more than US\$ 25 billion, in 2005, stood at second position, followed by Japan (US\$ 8 billion).

Trade

Share of pharmaceutical products in world exports has grown over the years. From a level of 1.7% share in world exports in 2000, export of pharmaceutical products in world exports increased to 2.6% in 2005. In the year 2005, world export of pharmaceutical products amounted to US\$ 272 billion. European Union, as a bloc, is the largest exporter of pharmaceutical products accounting for 70% of total world exports in 2005. Of this, over 60% are traded intra-regionally. European Union, as a single bloc, is also largest importer of pharmaceutical products accounting for 57% in world pharmaceutical imports.

EMERGING TRENDS IN GLOBAL PHARMACEUTICAL INDUSTRY

Changing Demographic Trend

Developed countries have reached the era of demographic transition, where they are increasingly

confronting with the phenomenon of ageing population. This has resulted in increasing pressure on the countries' national healthcare system. Chronic diseases, particularly cardio-vascular diseases, have become more frequent cause of death in these countries. On the other hand, infectious diseases have remained more common cause of death in developing countries. In addition, lifestyle related diseases are going to be common among fast developing countries like China and India. All these factors would have major influence on the global pharmaceutical industry.

Patented Drugs Going Off-Patent

It has become a major concern for the large pharmaceutical firms that many of the blockbuster drugs will be going off-patent in the coming few years. It is estimated that in USA alone, blockbuster drugs going off-patent are valued at US\$ 27 billion in 2007, and US\$ 28 billion in 2008. These drugs are major sources of revenue for major pharmaceutical companies in the world. Production of generics in such products will put considerable pressure on the profit margin of these companies.

Lowering R&D Productivity

R&D in pharmaceutical industry is a very expensive and time-consuming process, as it involves a number of stages before a drug can

be introduced in the market. Moreover, at any stage, the process may have to be abandoned if it is not showing desired results both in terms of effectiveness and safety. In the world pharmaceutical industry, although the R&D expenditure by firms have shown significant increase, R&D productivity has come down. All these factors have led to added pressure on the profit margin of the leading players and thus there is a pressing need to cut down the costs.

Increasing Mergers and Acquisitions

Mergers and Acquisitions (M&A) have been dominating the global pharmaceutical industry. In the year 2005, M&A activities in the pharmaceutical industry amounted to US\$ 61 billion with the completion of nearly 700 deals. Major deals were in the generics segment. Drive to enhance the size and thereby attaining higher economies of scale has motivated such acquisitions. This trend is expected to continue with many firms from developing countries, particularly India, joining the race.

Outsourcing of Pharmaceutical R&D

Cost of bringing out new molecules is a very high and time-consuming process. As per industry estimates, on an average, out of 10,000 molecules developed in laboratories, only one or two successfully pass

all stages of drug development and goes for commercialization. Thus, many international pharmaceutical firms prefer to outsource their R&D activities to developing countries. Countries like India and China have become major beneficiaries of this trend due to cost advantages and availability of skilled manpower.

Bio-pharma Convergence

Biotechnology has emerged as one of the key technologies of this century. Biopharmaceuticals have been projected as potential drugs curing many diseases. Many research papers have opined that chemistry based medical innovations of the previous century are becoming to recede in importance, to be replaced by advances in biopharmaceutical research that will boost the growth of revenues and profits in the years to come. Given its potential, most of the global pharmaceutical companies are showing interest in the bio-pharmaceuticals sector. This trend is likely to continue, as these companies would try to reap the benefit of their sales and marketing capabilities along with technical expertise of biotechnology.

Licensing Activities

Another trend in global pharmaceutical industry is increasing licensing activities, both in-licensing and out-licensing. The current trend is more on out-licensing, with large pharmaceutical companies licensing



out their later stage R&D activities, particularly clinical trials. Licensing deals are increasingly being used to increase product portfolio, supplement research effort and strategically enter new markets.

Promises of Money Back Guarantee

Another recent trend in the global pharmaceutical industry is the introduction of new concept of 'money back guarantee' by some pharmaceutical companies, in the form of 'pay for performance'. This trend will prove to be a boon for the Governments, particularly from the developing countries, who are fighting to eradicate diseases like cancer and HIV, where the cost of treatment is significantly high.

Ethical Issues

The growth of pharmaceutical industry has given rise to few ethical issues also. With an increasing volume of clinical trials in the laboratories as well as outside the laboratories, use of animals and human beings for these trials at different stages pose ethical challenges. One such challenge is regarding genetic research and treating mental disorders. Availing the services of mentally disordered people to participate in clinical research remains an ethical issue.

Safety and Product Quality

Drug safety and product quality are other areas of concern. While

bringing out new drugs are challenging to the pharmaceutical firms, it has become a challenge for the regulatory authorities to ensure safety and quality. This calls for more intensive consultation between the drug manufacturers and the regulatory authorities before a drug is introduced.

Increasing Marketing Cost

As the competition amongst the pharmaceutical firms is aggravating, many firms have started to get into retail business. In this model, drugs will be sourced directly from the manufacturers providing proximity with the end users. Such a model would provide benefits both to producers (better supply chain management) and consumers (lower price).

Low Emphasis on Clinical Trials

With an increasing share of generics in total pharmaceutical sales, leading pharmaceutical firms are changing their strategies from traditional blockbuster model to niche market players in the areas such as diabetes, cancer and lipid disorders. Many large firms are adopting strategies with long term investment commitments, scientific advancements, and strategic positioning of their drugs as part of a more comprehensive approach to medical treatment.

Pricing Strategies

Pricing has never been a key issue in global pharmaceutical industry as it is today. Global pharmaceutical majors are increasingly adopting varied pricing strategies in each therapeutic and geographic market, with the objective of optimizing share, revenue and profit.

Increasing Patent Litigations

With a number of branded drugs going off-patent, the market share of the generic producers in the world pharmaceutical market shows an increasing trend. However, the growth path of the generic players is witnessing turbulence with increasing number of IPR related litigations. Legal cost associated with challenging of patent infringement cases turns out to be very high for many pharmaceutical companies. Another angle of such litigations is prohibition to manufacture such drugs till the time the cases are settled. This has emerged as a major challenge, of late, for the generics manufacturers.

EVOLUTION OF INDIAN PHARMACEUTICAL INDUSTRY

The Indian pharmaceutical industry has come a long way since the time of independence when multinational corporations dominated the industry. Over the years, under a favourable policy regime, the industry has grown phenomenally and has established itself as a major supplier

of not only generic products but also new formulations. The industry, in addition to meeting domestic demand, is in a position to export significant volume of pharmaceutical products to various destinations, including the developed markets of USA, EU and Japan.

Evolution of Indian pharmaceutical industry can be classified into the following three periods:

- ❖ *Pre-1970s*: During this period, the size of Indian pharmaceutical industry was small, both in terms of number of firms and volume of production. MNCs dominated the market, both in terms of volume of production and patent holdings, in India. The patent regime, based on Indian Patents and Designs Act, 1911, recognized both product and process patents. Due to monopoly status enjoyed by the MNCs, drug prices remained high during this period.
- ❖ *1970 – 1995*: Government of India introduced a new Patent Act, which came into effect in 1972, recognizing only process patent and not product patent. The Act enabled Indian firms to use ‘reverse engineering process’, to manufacture drugs, without paying royalty to the original patent holder. The Act, along with Drug Price Control

Order, provided little incentive for MNCs to introduce new pharmaceutical products in India. During this period, the number of domestic pharmaceutical firms increased considerably, from around 2000 units in 1970 to 24,000 units in 1995. Production of bulk drugs increased from Rs. 18 crores in 1965-66 to Rs. 1518 crores in 1995, while that of formulations increased from Rs. 150 crores to Rs. 7935 crores during this period. The increase in production was more pronounced in case of formulations due to large-scale production of generics by domestic firms. Low cost and high volume production has helped the Indian pharmaceutical industry in opening export channels to explore many developed and developing countries. Share of exports as a percentage of total production has shown significant increase from 3.22% in 1980-81 to 24% in 1994-95.

- ❖ *1995 onwards:* The year 1995 recorded another milestone for the Indian pharmaceutical industry. One of the Agreements under the World Trade Organisation was complying with the Trade Related Intellectual Property Rights (TRIPS) provisions. The TRIPS Agreement reintroduced product patent in India. Further, during

this period, tariff and non-tariff measures have come down. Such developments have worked in favour of Indian pharmaceutical industry to undertake activities such as clinical research and new drug development. Indigenous producers dominated the market accounting for more than 70% of the market share. Exports also continued to increase during this period, due to strong R&D process and low manufacturing cost.

PRESENT STATUS OF INDIAN PHARMACEUTICAL INDUSTRY

The annual turnover of the Indian pharmaceutical industry is over US\$ 11 billion. Globally it ranks 4th in terms of volume with a share of 8% in the world pharmaceutical market. In terms of value, it ranks 14th. Key therapeutic segments of Indian pharmaceutical industry include anti-infective, gastrointestinal and cardio-vascular. Acute therapies make up about 60% of the market. However, it is expected that with the changing lifestyle and aging population, sales of chronic therapies (i.e. diabetes, cardio-vascular) are growing rapidly.

The pharmaceutical industry is also showing good performance in terms of exports. It is one of the top export items from India accounting for more than 4% of India's total exports in 2006-07. Exports, which constitute around 50% of the

industry's total production, have grown at a CAGR of 14% in the last decade. Major export markets include highly regulated markets such as USA, Germany, UK and Canada. Europe is the biggest export destination for Indian pharmaceuticals accounting for more than 30% of the total exports, followed by the Americas region (25%).

Government policies, viz., Drugs and Cosmetics Act (1940), Drugs Policy (1986), Indian Patents Act (1970), Drug Price Control Order (1995), Pharmaceutical Policy (2002), Indian Patents (Amendment) Act (2005), have played a major role in the growth of Indian pharmaceutical industry. The Government has also formulated a Draft National Pharmaceutical Policy (2006), which will be finalized after consultation with the stakeholders. Besides, the Government has also facilitated the growth of the Indian pharmaceutical industry through institutional framework and encouraging investments in R&D.

SUCCESS STRATEGIES OF INDIAN PHARMACEUTICAL INDUSTRY

Indian pharmaceutical industry, utilizing the policy environment prevailing over the years, adopted various strategies to surge as a global player. These include:

Increasing R&D Activities

Since the formation of WTO and signing of TRIPS Agreement, Indian

pharmaceutical industry is increasingly becoming innovative rather than imitative. The players are changing their R&D strategy from 'reverse engineering' to 'patent driven'. R&D expenditure as a percentage of sales, which stood at around 2% in 1993-94, increased to around 5% in 2005-06.

Increasing Filings with USFDA

With an increase in R&D spending, Indian companies could file large number of Drug Master Files and Abbreviated New Drug Application (ANDA) with US-FDA. According to Organisation of Pharmaceutical Producers of India, India accounted for largest number of Drug Master Files with US-FDA.

Public-Private Partnership in R&D

Many Indian pharmaceutical firms, in addition to undertaking in-house R&D activities, are collaborating with research laboratories such as Central Drug Research Institute (CDRI), Lucknow; Indian Institute of Chemical Technology (IICT), Hyderabad; and Centre for Cellular and Molecular Biology (CCMB), Hyderabad.

Leveraging Biotechnology

Biotechnology is one of the areas that are showing promising future. Biotechnology drugs represent a significant part of the new innovative medicines launched worldwide. Bio-pharmaceuticals

account for more than 10% of global pharmaceutical sales. Many Indian pharmaceutical firms are leveraging the potential of biotechnology including manufacture of bi-generics.

Inorganic Growth Strategy

In tune with the M&A trends in global pharmaceutical industry, Indian pharmaceutical firms are also undertaking M&A activities in many parts of world. Though the trend of acquisitions by Indian pharmaceutical firms has started in 1995, they have been aggressively acquiring foreign firms since 2002. Most of the acquisitions by Indian pharmaceutical firms are in developed country markets such as USA and Europe. Buying out products from overseas companies to strategically enter the target markets is another inorganic growth strategy adopted by Indian firms. Some firms have also acquired proprietary drug development capabilities or facilities that only focus on one therapeutic segment.

Diversification of Markets

Over the years, Indian pharmaceutical firms have been successful in exporting pharmaceutical products to traditional as also new destinations. For example, in the early 1990s, Russia was the largest market accounting for 25% of India's total pharmaceutical exports. However,

over the years, concentration of India's exports to Russia has come down to a level of 5% in 2005-06. Nevertheless, Russia is still the third largest destination for pharmaceutical exports from India. Share of exports to USA, which is the largest pharmaceutical market in the world, has witnessed gradual increase from 10.8% in 1991-92 to more than 14% in 2005-06. China, Brazil, South Africa and Canada are some of the countries that have been targeted by Indian pharmaceutical firms in recent years. For many countries in Africa (Lesotho, Namibia, Guinea, Angola, Burundi, Eritrea, Malawi, Zambia, and Swaziland) and South Asia (Nepal, Maldives, Bhutan and Sri Lanka), India is one of the principal source countries for pharmaceutical imports.

Contract Research

Given the pressing need of global pharmaceutical industry to develop new drugs, major pharmaceutical producers across the globe are looking out for sourcing R&D activities. Indian companies are undertaking contract research (including drug discovery, pre-clinical and clinical research) for global pharmaceutical majors leveraging the prevailing advantages such as:

- ❖ Already well-developed pharmaceutical manufacturing base;

- ❖ Low R&D cost;
- ❖ Availability of highly qualified man-power;
- ❖ Large patient pool for clinical trials.

Contract Manufacturing

New start-up companies are increasingly getting international exposure through the contract manufacturing (of patented drugs, custom synthesis and scale-ups, specialized generics and old molecules) route. It is estimated that about 50% of global bulk drugs / API manufacturing and around 15% of formulations manufacturing are outsourced to low cost destinations. Global market for contract manufacturing in the pharmaceutical sector is valued at around US\$ 15 billion in 2005. India, with an estimated pharmaceutical contract manufacturing size of over US\$ 400 million per annum, accounts for about 3% of world contract manufacturing market.

Co-Marketing Alliances

Another growth strategy adopted by Indian firms is entering into co-marketing alliances with foreign firms to market their products. Co-marketing alliances are taking place not only between Indian and foreign producers, but also amongst Indian producers. Such alliances are proven to be beneficial to both the parties.

THE ROAD AHEAD

Strategies such as greater level of R&D activities, patent filings,

contract manufacturing, contract research, inorganic growth strategy through acquisitions, co-marketing and co-licensing arrangements have helped the Indian pharmaceutical industry to surge as a global player. However, challenges are also ahead for the Indian pharmaceutical industry with changes in global trends and TRIPS compliant patent regime in India.

Strengthening R&D

Increasing R&D activities has more relevance for India since new product patent regime has been introduced to comply with TRIPS regime. In the year 2005-06, Indian pharmaceutical industry has spent around 5% of total sales on R&D activities. Though this is well above the average R&D intensity in manufacturing sector (estimated to be 1%), compared to developed countries, such as USA, Germany, it is very low. Thus, it is important for Indian pharmaceutical industry to scale up their R&D intensity to strengthen their position in the global market place.

Market Penetration: Acquisitions in LDCs

Many Indian pharmaceutical firms have made a number of acquisitions in various countries. More than two-third of these acquisitions have been in the developed country markets of Europe and USA. However, there lies the scope for further penetration in other countries, especially least

developed countries. Under the TRIPS Agreement, such countries have been granted with longer transition period (upto 2016) to become TRIPS compliant. Indian generic producers can have a major role in these markets, through acquisitions and penetrate further in such markets.

Bio-pharma Convergence

India is being recognized as one of the important players in the biopharmaceuticals market. Many Indian pharmaceutical firms are going for convergence with biotech industry for development of new drugs. However, it is indeed very important to accelerate the level of convergence and the pace. Recently, USA has passed Food and Drug Administration (FDA) Revitalization Act to allow drug makers to sell generic version of biopharmaceuticals after 12 years of exclusive marketing rights by the innovator company. This will give ample opportunities for Indian pharmaceutical firms to tap this large bio-generics market.

Safety and Quality: Menace of Spurious drugs

Ensuring safety and quality of pharmaceutical products is another major concern, especially in the context of alleged prevalence of spurious drugs. It is alleged that a large percentage of the world's spurious drugs are produced in

India and these are allegedly sold mainly in rural markets of India. Re-usage of drugs past their expiry date is yet another menace faced by the pharmaceutical industry. This calls for stricter safety and product quality regulations for the industry.

More Thrust on Patent Filing

Indian pharmaceutical industry has comparative advantage in R&D due to its high intellectual base and low cost of R&D. However, number of patents filed by and approved for India is lower as compared to many developed as well as developing countries. According to WIPO's Report on Worldwide Patent Activities (2006), India scores very low in many patent filing intensity indicators as compared to many developed as well as developing countries. Thus, Indian companies need to intensify their patent filing efforts to remain globally competitive.

Pricing strategies

Pricing strategies for launching of pharmaceutical products have never been a key issue as it is right now. Business wisdom dictates that early assessment of a product's concept and its potential to generate acceptable investment returns is crucial when deciding allocation of funds for undertaking R&D activities. In addition, there are flexibilities provided under WTO to control prices through compulsory licensing

and parallel importation. Therefore it is crucial to consider optimal pricing strategies while determining the viability of launching a drug. The need for viable pricing strategies also increases in an era of rising R&D costs.

Regulatory / Policy Reforms

Policies that influence Indian pharmaceutical industry can be broadly categorized into healthcare policy, industrial policy and health safety policy. Some of the concerns of the industry, regulators and end users are addressed through such policy framework. These include: accessibility and affordability of medicine by common man, ensuring quality and efficacy of medicines, strengthening the growth of generic medicines, promoting R&D, technology transfer, strengthening industry-institutional linkages and capacity development.

At present, both central and state Governments regulate Indian pharmaceutical industry. While the state regulatory authorities are responsible for regulating manufacturing, sales and distribution of drugs, the national regulator approves new drugs and clinical trials, controls import of drugs and also coordinates among the state bodies. A Task Force, headed by Dr. Pronab Sen, set up the Government of India has recommended that in the long run functions of drug regulation and price control should be with the same

agency, so that an integrated regulatory system exists in the economy. Strengthening of regulatory system is also required in the context of new patent regime. There is a need to simplify procedures and shorten the timeline for various approvals. Strengthening of regulatory system with respect to data protection is also crucial. Such measures will help in attracting R&D outsourcing to India. With India emerging as a major hub for contract research, particularly clinical trials, it is important to ensure good clinical practices in the country. Most of these issues are addressed in Draft Pharmaceutical Policy also.

Skill Development

Pharmaceutical industry is highly R&D intensive. In order to remain globally competitive the industry requires pool of highly skilled man-power. India has already made its mark in scientific research in the world with large pool of scientific man-power. The education system in India with wide network of universities providing quality science education has helped immensely in this regard. However, with the changing composition of economic growth there is an emerging trend of students not preferring science stream for career opportunities. In addition, the problem of skilled professionals migrating to developed countries is also prevalent in India. Thus, it is important to devise

policies that would attract more students to the science stream. Establishing strong industry-academia linkages will also play a significant role in this regard.

Tackling Patent Infringement Cases

The growth path of the generic players is witnessing turbulence with increasing number of IPR related litigations. Legal cost associated with challenging of patent infringement cases turns out to be very high for many pharmaceutical companies. Problems associated with increasing number of patent infringement cases should be tackled by the Indian firms through proper understanding of the patent laws and move towards greater compliance. Another approach, which has already been adopted by many pharmaceutical companies is 'out of the court settlement', which may prove to be

much cheaper and faster to resolve patent related disputes.

SUM-UP

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

1. INTRODUCTION

Health is defined both as cause and effect of economic development. Therefore, the pharmaceutical industry is specifically recognized in the UN Millennium Development Goals, as an actor that can contribute to economic development. In addition, the pharmaceutical industry provides significant socio-economic benefits to the society through creation of jobs, supply chains, and through community development. The industry also plays an important role in technological innovation, which may reduce costs of economic activity elsewhere in the economy. There are expectations, however, by some stakeholders that pharmaceutical industry should contribute more to economic development, through their own activities and indirectly, through improvements in healthcare infrastructure and capacity. This reflects the complex role of companies in healthcare, as well as the special obligation inherent in a sector whose products and services are needed by people when they are most vulnerable.

Players in the pharmaceutical industry include: branded drug

manufacturers, generic drug manufacturers, firms developing biopharmaceutical products, non-prescription drug manufacturers, firms undertaking contract research. In addition, there are also enablers of the industry such as universities, hospitals and research centers that play a role in R&D activities.

Indian pharmaceutical industry is one of the high performing knowledge based segments of the manufacturing sector. The industry has achieved a global status through firm level strategies, industry initiatives and also with appropriate policy support. At present, Indian pharmaceutical industry meets around 95% of the country's domestic demand for medicines. In addition to catering to the needs of the domestic demand, the pharmaceutical industry is also engaged in contract manufacturing, contract research, clinical trials, contract R&D, and direct exports to developed and developing country markets.

Various policies of the Government of India have helped the Indian pharmaceutical industry to consolidate their position in a



competitive environment. The soft patent regime, prior to 2005, provided opportunities for this industry to witness significant growth, particularly in generics production and exports. During this time, the industry prepared itself to surge ahead in the global competitive environment by adopting strategies such as increasing R&D activities, patent filings, inorganic growth strategy, contract manufacturing, contract research, co-marketing and co-licensing arrangements, and diversification of markets.

Indian pharmaceutical industry is entering an era in which it is not only going to play a pivotal role in providing generics medicine to the world but also in the process of becoming a global hub for R&D activities, which may be in the area of new drug discovery or different stages of clinical trails. The industry is gaining momentum to face the challenges of new patent regime and increasing competition from low cost manufacturing and R&D destinations

like China. Such challenges are helping the industry to modify the business strategies and thereby to retain its competitive position.

Many Indian pharmaceutical companies have adopted the strategy of inorganic growth through mergers and acquisitions (M&As). Such M&As are being concluded with the objective of complimenting the strengths of two entities to get market access, new technologies as also new products. Indian pharmaceutical industry has also been increasing the R&D expenditure significantly in the recent years. Another noticeable trend in the Indian pharmaceutical industry is that, it has emerged as an attractive destination for sourcing contract research, particularly clinical trials, as also contract manufacturing by many large firms from the developed countries. A well-developed manufacturing base, low cost R&D, large pool of skilled man-power are some of the factors for success of Indian pharmaceutical industry in these segments of business.

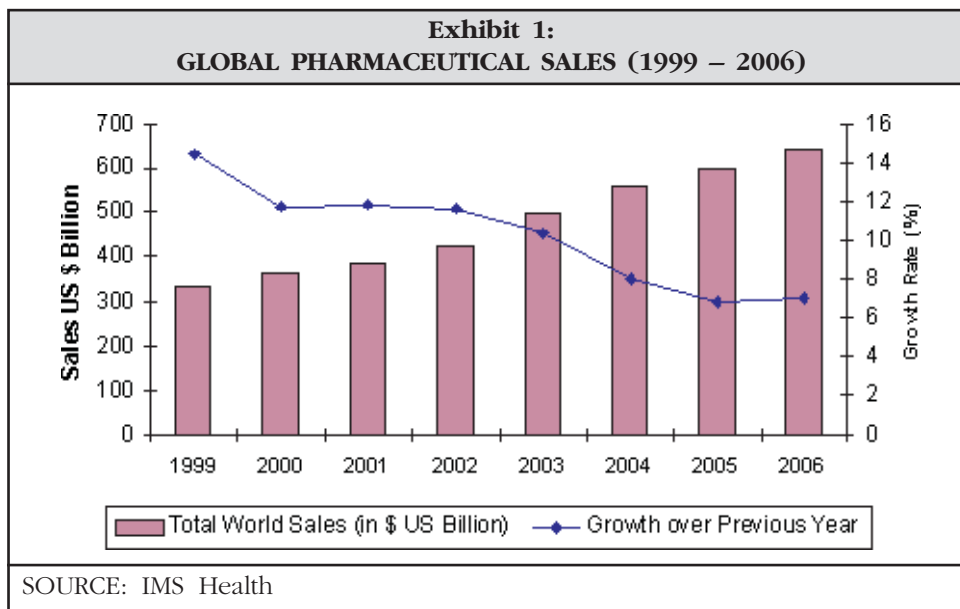


2. GLOBAL SCENARIO

MARKET SIZE

The global pharmaceutical market is highly dynamic and is characterized by greater levels of R&D expenditure and extensive regulation of its products. Increasing R&D expenditure, longevity of population, strong economies are driving the global pharmaceutical market. Though the developed countries dominate the global pharmaceutical market, the share of developing countries, like India, China, Mexico, is increasing in

recent years. The global pharmaceutical sales are estimated to be US\$ 643 billion in 2006¹, a growth of 7% over the previous year. Global pharmaceutical sales have grown from US\$ 334 billion in 1999 to US\$ 643 billion in 2006, with a CAGR of 10%. However, it may be noted that though the global pharmaceutical sales are increasing in absolute terms, the rate of growth has been receding over the years (Exhibit -1). The growth rate of global pharmaceutical sales was



¹ IMS Health, 2006

14.5% for the year 1999 which has come down to 7% in 2006.

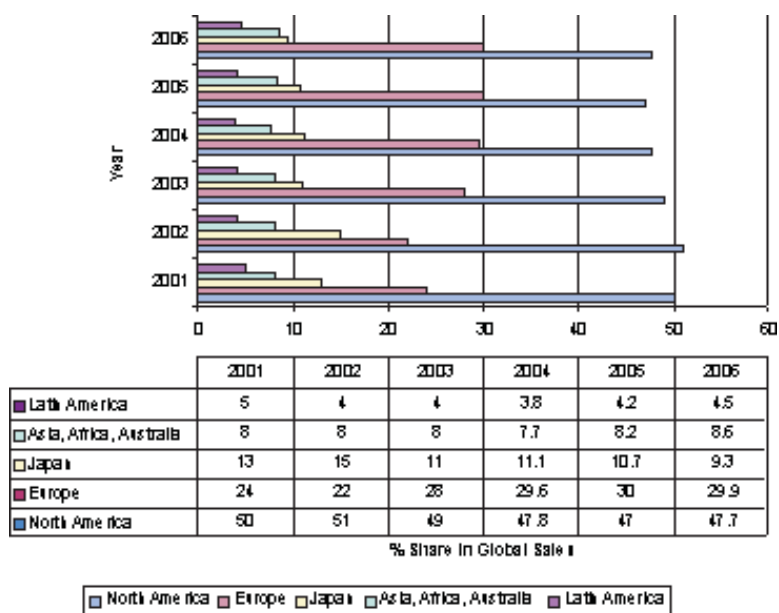
At regional level, North America is the major pharmaceutical market accounting for around 48% of global pharmaceutical sales, followed by Europe (30%). It may be noted that the trend in sales shows a decline in market share of USA and Japan and growth in market share of Europe during the period 2001-2006.

The strong growth in the North American market has been attributed to the impact of Medicare Part D benefit in USA and the resulting increase in prescription volume, as

well as 7.6% sales growth in Canada². Europe is the next largest market accounting for 29.9% of the global sales. Japan which stands at third position, accounting for 9.3% of global sales, has been experiencing negative growth. Japan's share in global sales has been falling from 13% in 2001 to 9.3% in 2006. It is reported that Japanese Government's biennial price cut has been cited as one of the reasons for its declining share in global pharmaceutical sales.

Nevertheless, in absolute terms, the US pharmaceutical market has more than doubled in the past one

**Exhibit 2:
REGIONAL DISTRIBUTION OF GLOBAL PHARMACEUTICAL SALES
(% SHARE 2001- 2006)**



SOURCE: IMS Health

² IMS Health

decade³. Amongst European countries, sales increases in Spain and UK were larger than that of Germany during this period.

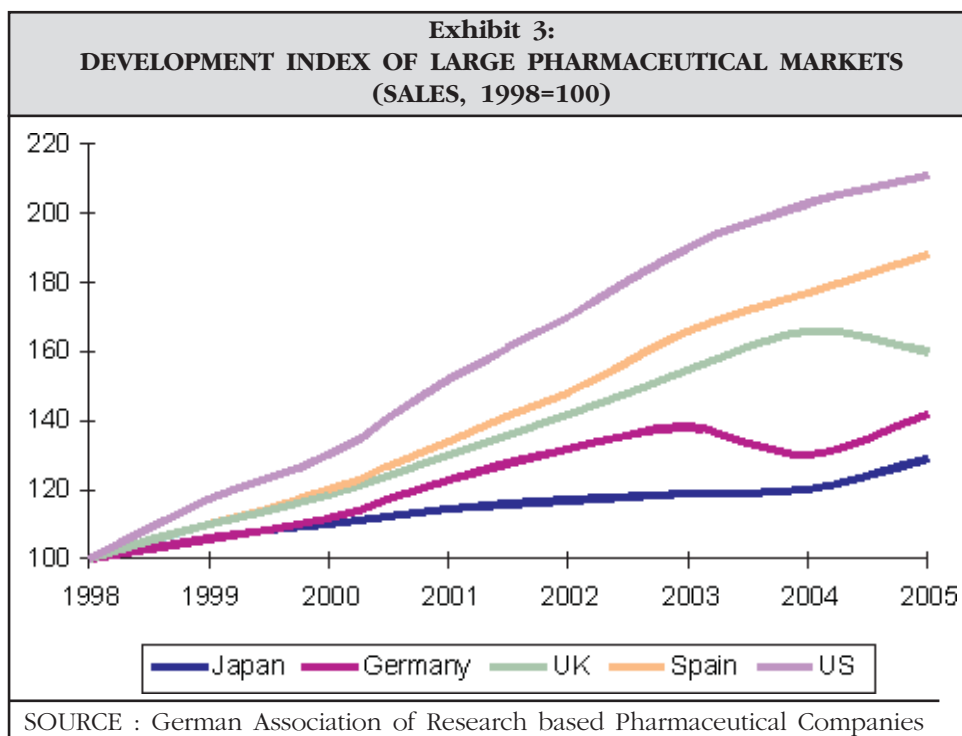
IMS Health estimates that the leading therapy classes in terms of sales in 2006 include: Lipid regulators (with a market share of 5.8%), Oncologics (5.7%), Respiratory agents (4%), Acid pump inhibitors (4%) and Antidiabetics (3.5%).

Major pharmaceutical companies in the world, such as Pfizer, GlaxoSmithkline, Johnson & Johnson, are either mostly USA or Europe based. Pfizer sells 25 major pharmaceutical products, most of which are blockbuster drugs. Its

revenue for 2006 was around US\$ 48 billion and R&D spending for the same year was US\$ 7.6 billion. UK based firm GlaxoSmithkline is the second largest pharmaceutical company in the world with a turnover of over US\$ 40 billion in 2006. Top ten pharmaceutical companies account for more than 58% of global market share.

RESEARCH AND DEVELOPMENT

Research and Development (R&D) is the backbone of the pharmaceutical industry all over the world. Countries are increasingly looking at innovation and R&D as key drivers of competitive growth



³ German Association of Research Based Pharmaceutical Companies.

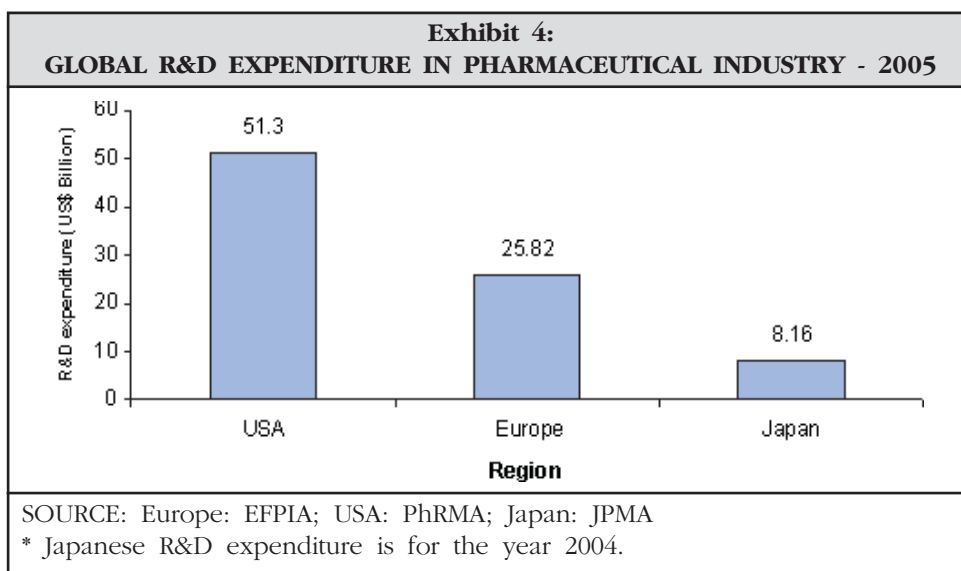


Table 1: TOP TEN PHARMACEUTICAL COMPANIES OF THE WORLD			
Sl. No.	Company	Market Share (%)	Location
1	Pfizer	12.5	USA
2	GlaxoSmithkline	7.9	UK
3	Johnson & Johnson	6.9	USA
4	Merck & Co	6.1	USA
5	AstraZeneca	5.0	UK
6	Novartis	4.4	Switzerland
7	Sanofi-Aventis	4.3	France
8	Amgen	4.3	France
9	Bristol-Myers Squibb	3.7	Switzerland
10	Wyeth	3.5	USA

SOURCE: CRIS INFAC, 2005

in the pharmaceutical sector. Globally, USA is the biggest hub for pharmaceuticals R&D. According to Pharmaceuticals Research and Manufacturers of America (PhRMA), USA, in the year 2005, has spent more than US\$ 50 billion in

pharmaceutical R&D. R&D spending in US pharmaceutical industry accounted for over 17% of total sales. Europe, with R&D expenditure worth more than US\$ 25 billion,⁴ in 2005, stood at second position, followed by Japan (US\$ 8 billion).



⁴ European Federation of Pharmaceutical Industries and Associations, The Pharmaceutical Industry Figures - 2006



EXPORTS

The share of pharmaceutical products in world exports has grown over the years. From a share of 1.7% in world exports in 2000, share of pharmaceuticals in world exports has increased to 2.6% in 2005. However, there has been a marginal decline in share, since 2003, which is depicted in Exhibit - 5.

In the year 2005, world export of pharmaceutical products amounted to US\$ 272 billion. European Union, as a bloc, is the largest exporter of pharmaceutical products accounting for 70% of total world exports in 2005; majority of which are traded within the EU member nations. USA accounts for a share of 9.5% in world pharmaceutical exports. China is the fourth largest exporter of pharmaceutical products (US\$ 3.78 billion) accounting for 1.4% of total world exports. India occupies 8th position exporting pharmaceutical products worth US\$ 2.81 billion. Exports from India have shown a growth rate of 18% during the period 2000-05. The top 15 countries account for almost

98% of the total world pharmaceutical exports.

Annexures 1 & 2 depict share of pharmaceutical exports in total merchandise exports, and share in global pharmaceutical exports of select countries, respectively.

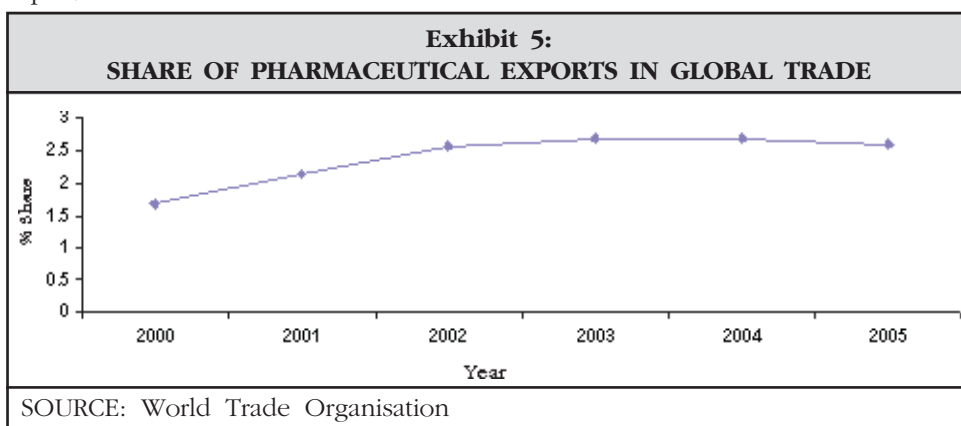
IMPORTS

European Union, as a single bloc, is also largest importer of pharmaceutical products. In 2005, the region imported over 57% of world pharmaceutical imports. USA accounts for 14% of total world imports, followed by Switzerland (4.8%), Japan and Canada (3% each).

PROFILE OF PHARMACEUTICAL INDUSTRY IN SELECT COUNTRIES

USA

With an estimated share of around 40% of the world pharmaceutical output, the US is currently the major manufacturing hub for pharmaceuticals in the world. USA



**Table 2:
MAJOR EXPORTERS OF PHARMACEUTICAL PRODUCTS
IN THE WORLD (2005)**

Sl. No	Exporters	Value (in US\$ billion)	Share
1	European Union (25)	190.90	70.2
	<i>Extra-EU (25) exports</i>	<i>73.04</i>	<i>26.9</i>
2	United States	25.95	9.5
3	Switzerland	25.13	9.2
4	China	3.78	1.4
5	Canada	3.48	1.3
6	Japan	3.33	1.2
7	Singapore	2.94	1.1
	Domestic exports	2.32	0.9
	Re-exports	0.62	0.2
8	India	2.81	1.0
9	Australia	2.46	0.9
10	Israel	1.97	0.7
11	Mexico	1.40	0.5
12	Hong Kong, China	0.68	-
	Domestic exports	0.18	0.1
	Re-exports	0.50	-
13	Norway	0.53	0.2
14	Brazil	0.51	0.2
15	Korea, Republic of	0.51	0.2
	Total Above	265.88	97.8
Grand Total		272.00	100.00
SOURCE: World Trade Organisation			

is the origin of major pharmaceutical companies, who are into development of new chemical and biological entities. USA is the origin of 21 top pharmaceutical companies of the world in 2004. USA is also the origin for 16 top R&D spenders in the world pharmaceutical industry, out of 40 top R&D companies in the world. Between the period 2001 and 2005, pharmaceutical firms from USA have launched 61 new chemical and

biological entities, out of 149 that have been launched by the world pharmaceutical industry (a share of 41%).

Total sales of prescription pharmaceuticals in the US market have increased from US\$ 195.1 billion in 2002 to US\$ 274.8 billion in 2006. While the value of sales of branded pharmaceuticals amounted to US\$ 220.6 billion, sale of generics amounted to US\$ 54.1 billion in 2006.

**Table 3:
MAJOR IMPORTERS OF PHARMACEUTICAL PRODUCTS
IN THE WORLD (2005)**

Importers	Value (in US\$ billion)	Share
European Union (25)	155.92	57.2
<i>Extra-EU (25) imports</i>	<i>38.06</i>	<i>14.0</i>
United States	39.32	14.4
Switzerland	12.98	4.8
Japan	8.20	3.0
Canada	7.81	2.9
Australia	5.46	2.0
Russian Federation	3.89	1.4
Turkey	3.18	1.2
Mexico	2.83	1.0
Brazil	2.47	0.9
China	2.31	0.8
Saudi Arabia	2.03	0.7
Korea, Republic of	1.97	0.7
Singapore	1.58	0.6
Retained imports	0.96	0.4
Taipei, Chinese	1.38	0.5
Total Above	251.32	92.2
Grand Total	272.00	100.0
SOURCE: World Trade Organisation		

However, in terms of number of prescriptions, generics accounted for nearly two-third of prescriptions dispensed in USA. In 2006, top 10 generic drugs, by prescriptions

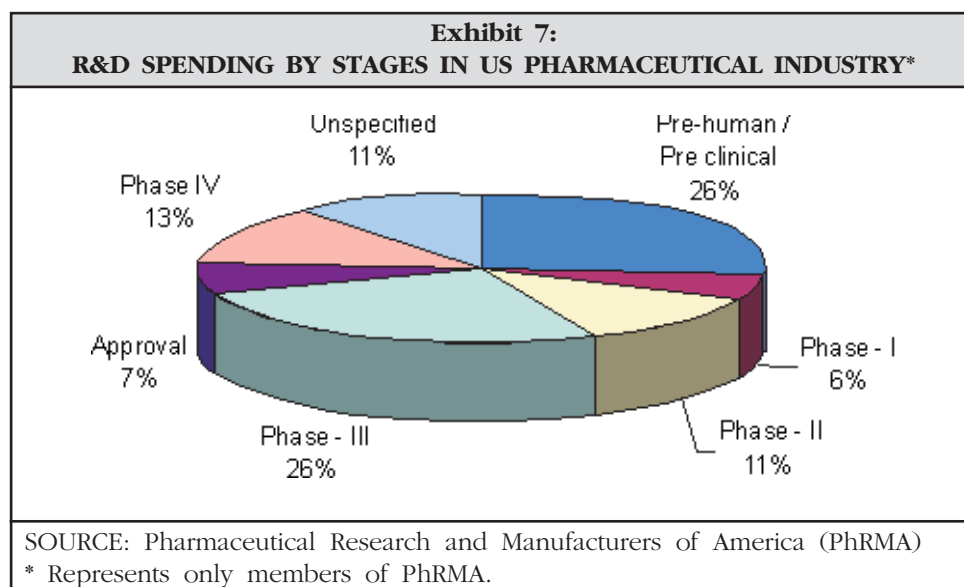
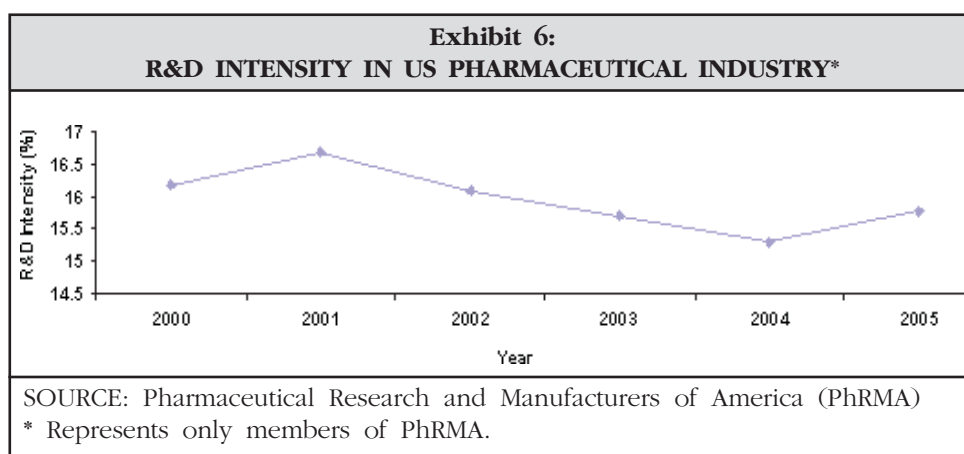
dispensed in the United States, were Acetaminophen, Hydrocodone, Hydrochlorothiazide, Lisinopril, Amoxicillin, Metformin, Levothyroxine, Atenolol, Albuterol, and Furosemide.

**Table 4:
PHARMACEUTICAL SALES IN USA**

Year	Sales (US\$ Billion)
2002	195.1
2003	219.5
2004	239.8
2005	253.7
2006	274.8
SOURCE: IMS Health	

The growth of sales in generic drugs has increased significantly in USA. In the year 2006, the US market for unbranded generics grew by 22.3% in 2006. Since many of the branded drugs are going off-patent, the generic market in US is expected to expand further. List of medicines that are going off-patent in the next couple of years is given at Annexure-3.

US based firms are spending large amount in R&D activities. In the year 2006, pharmaceutical firms in USA have spent over US\$ 55 billion on R&D, a growth of 6.5% over the previous year⁵. In terms of R&D intensity (share of R&D spending in total sales), the pharmaceutical industry average in USA is estimated to be around 15% in 2005. R&D



⁵ Pharmaceutical Research and Manufacturers of America, Industry Profile 2007.

spending by US firms (company financed) are mostly in Pre-clinical and Phase – III of clinical stages (about 26% share each in total R&D spending).

As regards trade, the pharmaceutical industry in USA exported goods worth US\$ 25 billion, a share of 9.5% in global export of pharmaceutical products, and imported pharmaceuticals worth US\$ 39.3 billion, a share of 14.4% in global imports, in 2005. USA’s pharmaceutical exports amounted to 2.9% of its total merchandise exports, in 2006, an increase from a share of 1.7% in 2000.

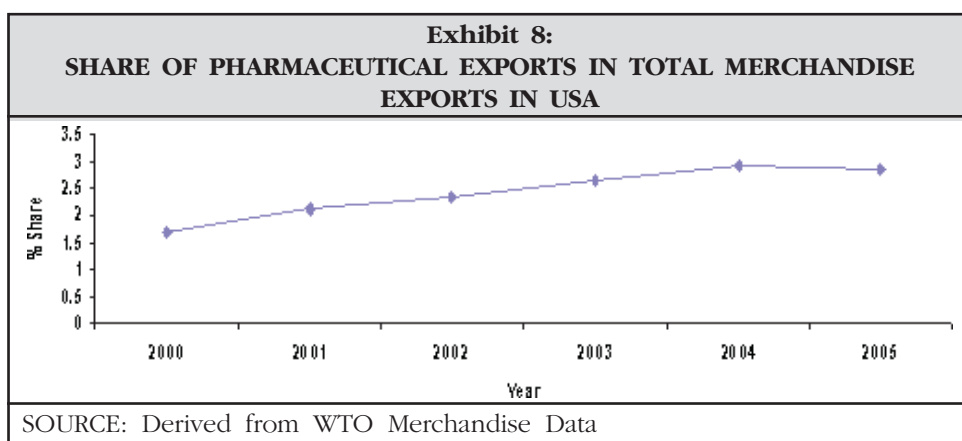
Europe

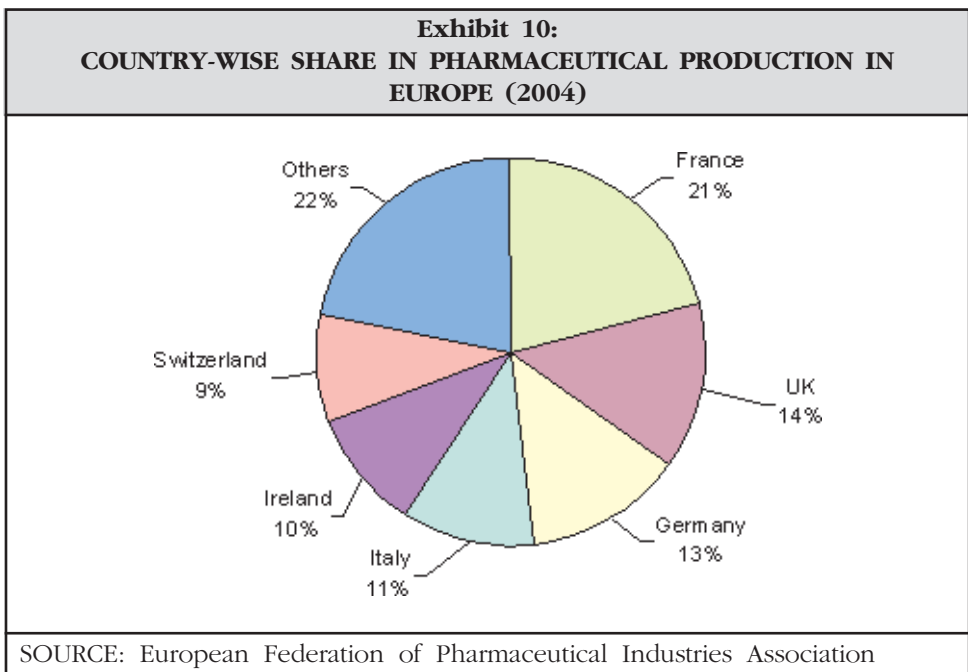
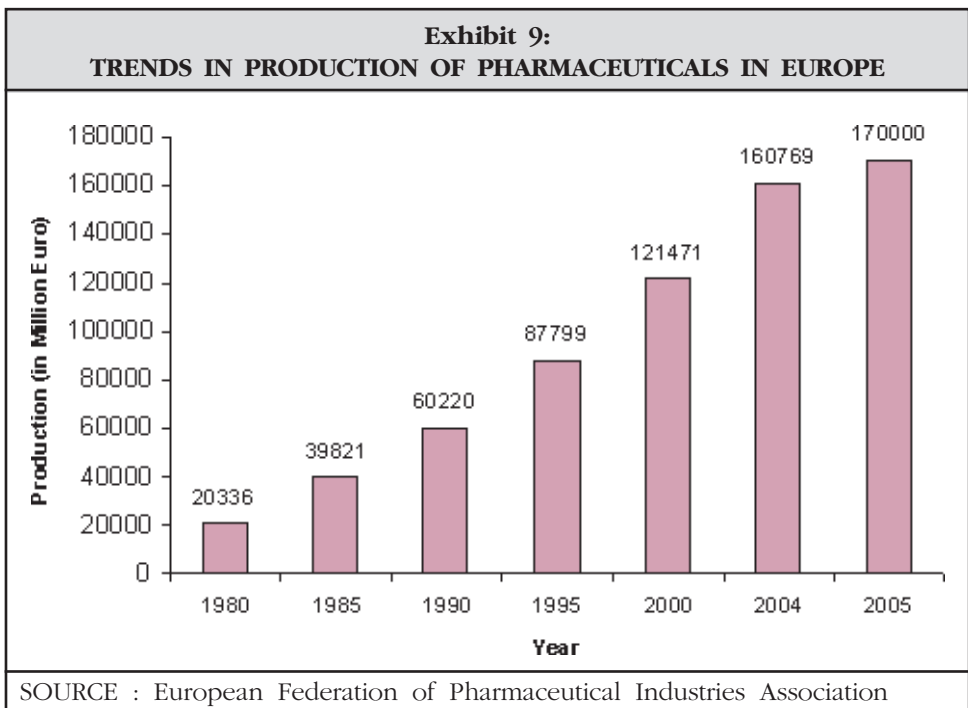
Europe is the second largest pharmaceutical market, next to USA, with a production level of over US\$ 200 billion in 2005. The European pharmaceuticals industry has grown at little over 7% during the period 1990 to 2005. The industry, with over 2000 entities, employed around

615,000 persons, of which R&D employment alone was estimated to be over 103,000 persons. Europe is a home for around 8 out of top 20 pharmaceutical companies in terms of sales; 12 out of top 40 pharmaceutical companies in terms of R&D investment; 8 out of top 30 medicines by worldwide sales, in 2005. These statistics are indicative of the size of the pharmaceutical market in Europe.

Some of the major European countries producing pharmaceutical products include France (21%), UK (14%), Germany (13%), Italy (11%), Ireland (10%), and Switzerland (9%). These six countries together have produced over three-fourth of total pharmaceutical production in Europe.

Research based pharmaceutical industry is one of the leading industries in Europe. European pharmaceutical firms have spent over US\$ 26 billion in R&D in 2005. R&D spending by European pharmaceutical industry accounts for





18% of total R&D budget by the manufacturing industry. In terms of R&D intensity (R&D spending as percentage of sales), it was little over 15% in 2004.

Given the increasing need for R&D expenditure, the European companies have also expanded the size of R&D budget substantially. In 2005, the R&D expenditure for the industry as whole was • 21.7 billion, i.e. 18% of all industrial research and development in Europe. In the last five years more than 50 chemical and biological entities have been launched in Europe. Some of the EU countries spending large amount on R&D are UK, France, Germany, Switzerland, Belgium and Italy. UK accounts for more than 22% of total R&D expenditure in Europe, followed by France with almost 19%.

In terms of allocation, pharmaceutical firms in Europe have spent around 43% of their R&D budget on clinical trials (Phases 1 to 3) required for approval of medicine followed by pre-clinical functions (synthesis and extraction, biological screening and pharmacological testing, toxicology and safety testing, pharmaceutical dosage/formulation and stability) 26%. While around 13% of R&D budget were spent on additional trials (pharmacovigilance), around 9% were allocated to approval process.

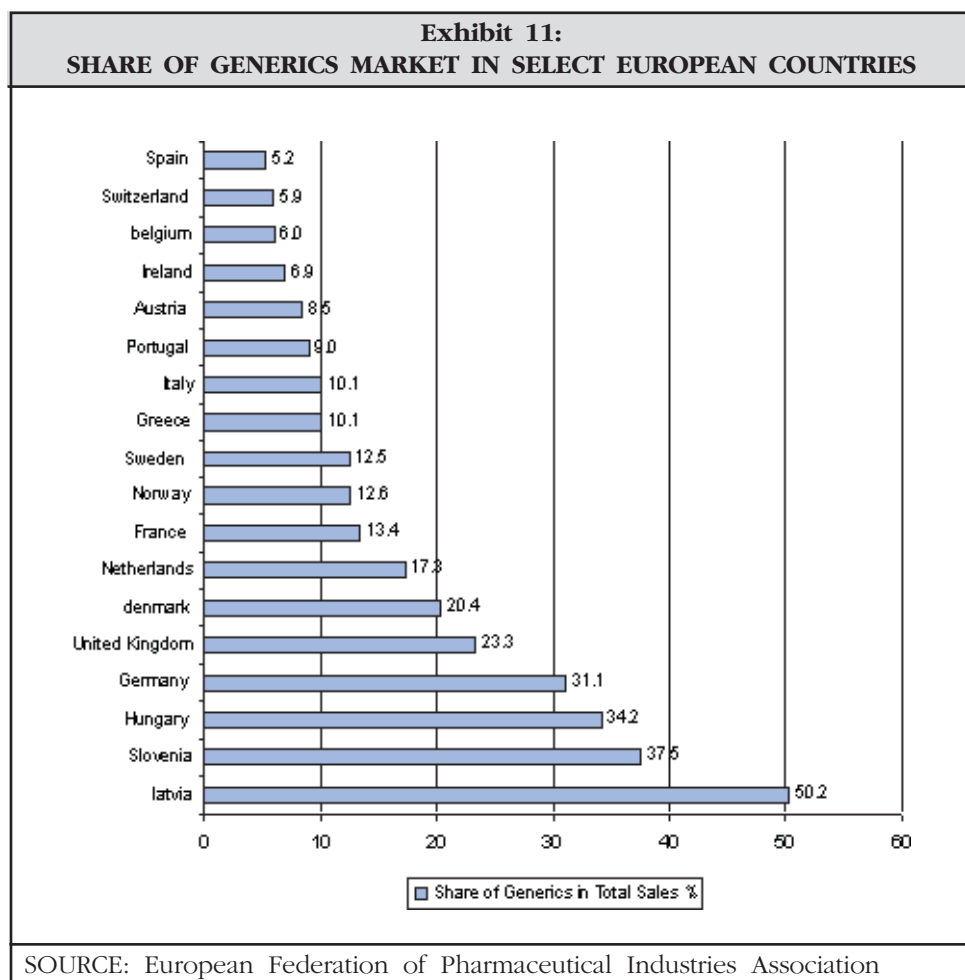
Generic medicine market in Europe account for around 50 percent of all prescriptions and it is expected that the share would reach 75 percent by 2007. Patent expiry for most of the healthcare products and EU enlargement are possible reasons for growth and expansion of generic medicine market in Europe.

Table 5: SHARE OF COUNTRIES IN TOTAL PHARMAEUTICAL R&D EXPENDITURE IN EUROPE	
Country	% Share in total R&D
United Kingdom	22.65
France	18.72
Germany	18.49
Switzerland	11.77
Belgium	7.24
Italy	4.76
Sweden	3.81
Denmark	3.43
Spain	3.24
Netherlands	2.16
SOURCE: European Federation of Pharmaceutical Industries Association	

Some countries such as Hungary, Germany, UK, the Netherlands have greater level of generic medicine market than countries such as Spain, Switzerland and Belgium. In general, there is a link between low levels of generic penetration and poor pricing conditions for innovative medicines in Europe. This means that the market share of generics is significantly lower in price-controlled environments than in unrestricted ones.

Japan

Japan is a major pharmaceutical market in Asia. The total pharmaceutical sales in Japanese market in the year 2006 were estimated at around US\$ 57 billion, thus accounting for over 9 percent of global sales. However, the pharmaceutical sales in Japan experienced a negative growth (-0.7%) in 2006, over the previous year. Though the Japanese economy

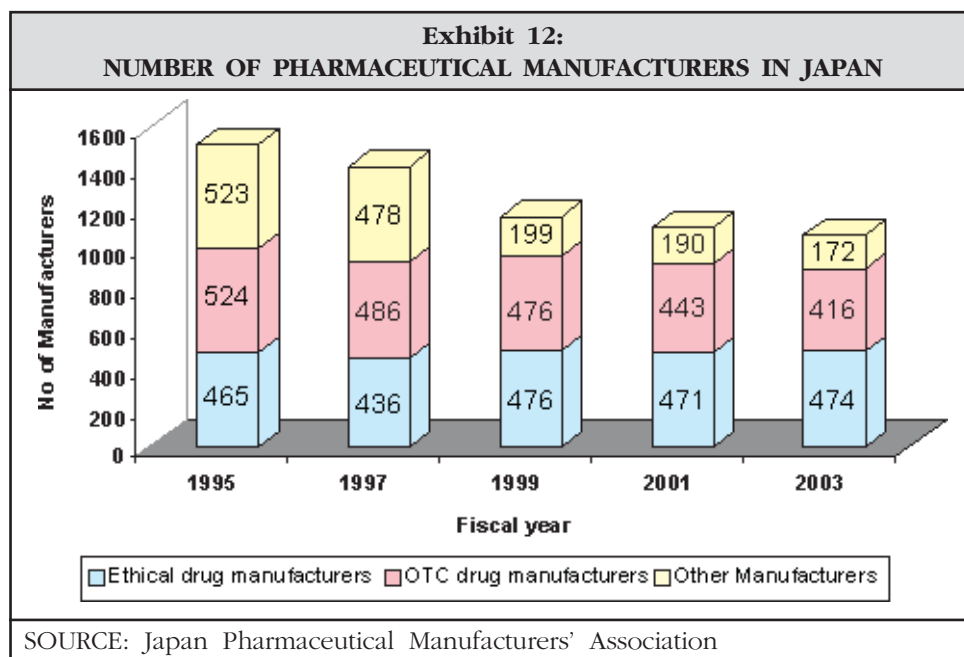


is in the path of recovery, it is believed that it may take some more time for the domestic demand to attain a sustainable level.

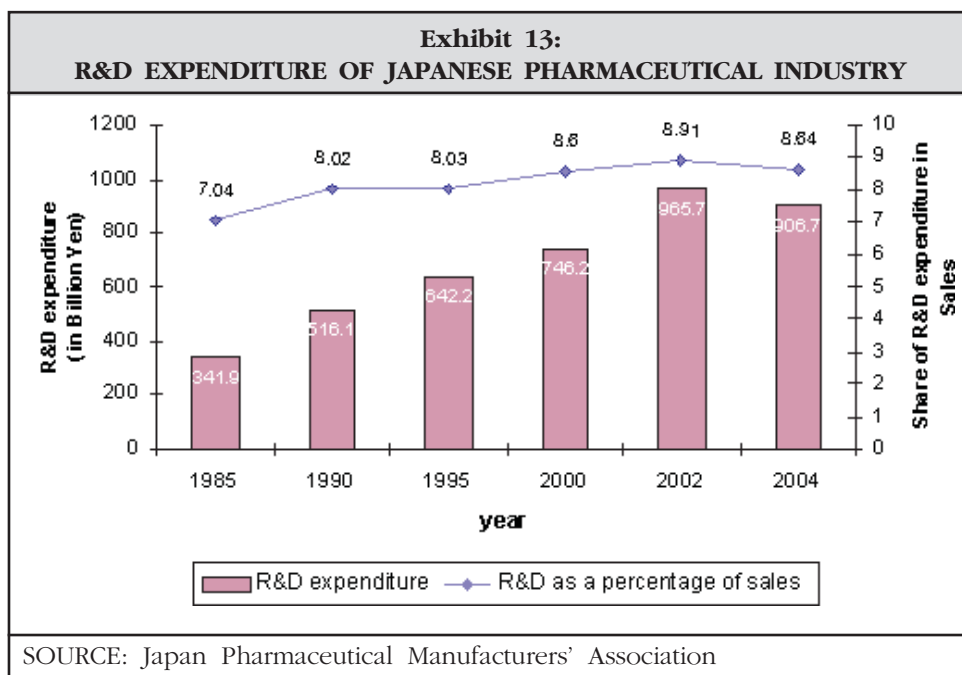
In 2003, the Japanese pharmaceutical industry had about 1060 firms, a reduction from over 1500 units engaged in manufacture of pharmaceuticals in 1995. Cardiovascular drugs are the largest therapeutic segment produced in the country accounting for 22% of total drug production of the country. Other major pharmaceuticals produced in Japan by therapeutic category include central nervous system related drugs (8.4%), antibiotics (6.2%), blood/humoral products (5.4%), biologicals (4.5%), and dermatological drugs (4.1%).

As regards international trade, Japan is experiencing a negative balance in pharmaceuticals trade. In the year 2005, Japan imported pharmaceutical products worth US\$ 8.2 billion, while its exports amounted to US\$ 3.3 billion.

Japanese pharmaceutical industry has realized the need for increasing R&D in order to remain globally competitive. R&D expenditure in Japan has shown a steady growth since 1995 reaching ¥ 906.7 billion by the end of 2004. This accounts for 8.64 percent of pharmaceutical sales in the same year⁶. R&D as a percentage of sales has remained around 8% during the last decade.



⁶ Report on the Survey on Research and Development, Government of Japan.



China

China's pharmaceutical market, excluding traditional Chinese medicine market, was valued at US\$ 19 billion in 2005. The pharmaceutical industry in China has been witnessing an average growth of 20 percent in the last five years, and is expected to position the country to achieve the rank of being the fifth largest pharmaceutical market by 2010. It is expected that the pharmaceutical industry in China would reach a size of US\$ 47 billion in 2010. The Chinese pharmaceutical industry is a fragmented one, with approximately 7000 companies. However, the industry is still largely represented by small-scale units, with around 15 percent of them

complying with Good Manufacturing Practices (GMP).

China still uses largely Traditional Chinese Medicines with only 25 percent share in overall healthcare spending oriented to synthetic pharmaceuticals. It is estimated that over 90 percent of the synthetic pharmaceuticals produced in China are generic products. The popularity of generics is greater in China in view of low per capita annual spending on healthcare in China (US\$ 15 per person).

Over the Counter (OTC) market in China, at present, accounts for little lower than 20 percent (US\$ 4.2 billion) of country's pharmaceutical market – positioning China as the fourth largest

market, and fastest growing market in the world. TCM account for more than 50 percent of OTC drugs in China, with cough and cold drugs accounting for another 10%.

Chinese pharmaceutical industry has been increasingly focussing on R&D. In addition, the world pharmaceutical industry is looking at China as destination for R&D outsourcing as the country offers unique advantages in pharmaceutical research. Since 2002, world pharmaceutical giants such as AstraZeneca, Novo Nordisk, Eli Lilly, GlaxoSmithKline, Johnson & Johnson and Roche have set up R&D centers in China. In addition, domestic industry, as also the Government has undertaken significant R&D investment in biotechnology, generics, and stem cell research.

Export of pharmaceutical products from China has been experiencing growth in the last five years. Exports have increased at a CAGR of 18 percent, from US\$ 1.98 billion in 2001 to US\$ 3.78 billion in 2005. USA is the biggest export destination for China, accounting for 23 percent of its total exports, followed by Japan (10%).

EMERGING TRENDS IN GLOBAL PHARMACEUTICAL INDUSTRY

Changes in Global Demographic Trend

The developed countries have reached the period of demographic transition where they are increasingly confronting with the



phenomenon of aging population. This has resulted in increasing pressure on the countries' national health care system. OECD countries have spent, on an average, 8.8% of their GDP on healthcare in 2003. The expenditure is highest in USA with 15% share in national GDP. The demographic transition has also resulted in changes in the disease pattern in these countries. Chronic illness, particularly cardiovascular (CVS) problems have become more frequent cause of death in these countries. On the other hand, infectious diseases have remained more common cause of death in developing countries. Economic progress in some of the developing countries such as India and China, led to increasing healthcare demand in these countries. The demand is expected to increase further as lifestyle related diseases are going to be more common in these countries.

Blockbuster Drugs Going Off-patent

It has become a major concern for the large pharmaceutical firms that many of the blockbuster drugs will be going off patent in the coming few years. It is estimated that in US alone, block-buster products going off-patent are valued at US\$ 27 billion in 2007, and US\$ 28 billion in 2008⁷. Drugs like Lotrel (Novartis), Norvoasc (Pfizer) have

already gone off-patent and many more such drugs will go off-patent in the next couple of years. These drugs were major source of revenue for these pharmaceutical companies, which enabled them to devote large percentage of their revenue for R&D activities. Once these drugs go off-patent, the market will get flooded with their generics version. This will put considerable pressure on the profit margin of these MNCs.

Lowering R&D productivity

In the world pharmaceutical industry, although the R&D expenditure by the firms have shown significant increase, R&D productivity has come down. It may be noted that R&D in pharmaceutical industry is a very expensive and time-consuming process, as it involves a number of stages before a drug can be introduced in the market. Moreover, at any stage, the process may have to be abandoned if it is not showing desired results both in terms of effectiveness and safety. For example, on December 02, 2006, Pfizer, one of the largest pharmaceutical companies, informed the US FDA that it is suspending Phase-3 clinical trial of its developmental drug Torcetrapib. Such developments add pressure on the profit margin of the research based firms and thus there is a pressing need to cut costs.

⁷ Generic Pharmaceutical Association, USA.

Increasing Mergers & Acquisitions

Mergers and Acquisitions (M&A) have been dominating the global pharmaceutical industry. The year 2005 experienced M&A activity in the pharmaceutical and healthcare sector worth US\$ 152 billion with the completion of over 2,000 deals. Out of these nearly 700 are pharmaceutical deals worth US\$ 61 billion.

The biggest deals were in the generics segment. Acquisition, by Israel's Teva Pharmaceutical Industries, of IVAX Corporation in the US alongside Novartis' acquisitions of Eon Labs in the US and Hexal in Germany are the major deals in the generics segment. The drive to

enhance the size and thereby attaining higher economies of scale has motivated such acquisitions. Consolidating their position in the global market has also remained a motivation for many companies to adopt merger and acquisition path. This trend is expected to continue with many companies from developing countries, particularly India joining the race.

Outsourcing of Pharmaceutical R&D Activities to Developing Countries

Cost of bringing out new molecules is a very high and time-consuming process. Moreover, as per the industry estimates⁸, on an average, out of 10,000 molecules developed

**Table 6:
TOP TEN PHARMACEUTICAL M & A DEALS IN THE WORLD (2005)**

Rank	Value (\$ Million)	Target/Merger Partner	Country	Bidder/Merger Partner	Country
1	7555	Daiichi pharmaceutical	Japan	Sankyo	Japan
2	7366	IVAX	US	Teva	Israel
3	5685	Hexal	Germany	Novartis	Switzerland
4	5555	Chiron	US	Novartis	Switzerland
5	3427	Boots healthcare International	UK	Reckitt Benckiser	UK
6	2633	Eon labs	US	Novartis	Switzerland
7	2127	Abgenix	US	Amgen	US
8	2079	Fournier Pharmaceutical	France	Sovay	Belgium
9	1916	Vicuron Pharmaceuticals	US	Pfizer	US
10	1383	Transkaryotic Therapies	Shire pharmaceutical		UK

SOURCE: Insights: Pharmaceutical Sector, *PricewaterhouseCoopers*

⁸ European Federation of Pharmaceutical Industries and Associations

in laboratories, only one or two successfully pass all stages of drug development and go for commercialisation. Therefore, most of international pharmaceutical companies prefer to outsource R&D, clinical trial activities to low cost destinations rather than continuing in the high cost home countries. Developing countries like India and China have become major beneficiary of this trend due to their cost advantage and also availability of skilled manpower. These countries are also trying to attract international pharmaceutical players by offering grants, incentives and infrastructure support. These outsourcing activities in developing countries amount to 20% to 30% per cent of total global clinical trials. The pharmaceutical companies of developing countries are increasingly adhering to cGMP and other regulatory requirements imposed by the developed countries and thereby encourage such outsourcing.

Biopharma Convergence

Biotechnology has emerged as a key technology of this century. Biopharmaceuticals have been projected as potential drugs, curing many diseases. The size of world biopharmaceuticals industry has been estimated at over US\$ 60 billion in 2005 with sales of more than 200 drugs. R&D expenditure in world biopharmaceuticals sector

has been showing continuous increase reaching US\$ 23.20 billion. Top biopharmaceutical companies in the world include Amgen, Genentech, Genzyme, Serono SA, BiogenIdec, Chiron Corporation.

According to a white paper prepared by Economist Intelligence Unit and Deloitte Group, the chemistry based medical innovations of the last century are becoming to recede its importance, and would be replaced by advances in biopharmaceutical research that will boost the growth of revenues and profits in the years to come. Given its potential, most of the global pharmaceutical companies are showing increasing interest in the biopharmaceuticals sector. This has led to growing mergers and acquisitions in this sector. Chiron Corporation, one of the oldest biotech companies in the world was acquired by Novartis in 2005. Two other major deals in the top ten M&A in biopharmaceuticals sector in 2005 involved vaccines companies. GlaxoSmithKline acquired the Canadian vaccine company ID Biomedical for US\$ 1.4 bn. ID Biomedical is a leading manufacturer of vaccines for flu and is developing a number of vaccines for other illnesses such as pneumonia. This trend is likely to continue, as these companies would try to reap the benefit of their sales and marketing capabilities along with technical expertise of biotechnology.



Licensing Activities

Another emerging trend in the global pharmaceutical industry is the increasing licensing activities, both in-licensing and out-licensing activities. Under in-licensing, the company acquires the rights to a product from a third party. On the other hand, under out-licensing the company sells the right to a product or a technology to a third party. In recent times, increasingly licensing deals are being used by pharmaceutical firms to enhance product portfolio, supplement research efforts and enter into new markets. Increasing financial pressure on the big pharmaceutical companies has further accelerated this trend. These companies are increasingly recognizing the potential of licensing. In fact, for the top 20 companies, an average of 19.5% (US\$ 63 billion) of their ethical sales is being derived from licensed products in 2004 compared to 17.5% (US\$ 48 billion) in 2002⁹. Merck and GlaxoSmithKline were the most active licensing deal-makers during this period.

A study by Datamonitor¹⁰ on the licensing activities of the top 20 pharmaceutical companies predicts that such licensing activities of the companies will further increase. The study forecasts that these companies will derive over 26% of their ethical sales from licensed products by 2010.

⁹ Pharmaceutical Field Magazine

¹⁰ 'Licensing Strategies: Trends in the Top Pharmaceutical Companies' Activity' : Datamonitor

Acquiring licensing deals have become increasingly competitive. Successful licensing deals require enabling factors such as marketing expertise, licensing history, and good alliance management. At present, the focus is more on out licensing, with large pharmaceutical companies licensing out their later stage R&D activities, particularly clinical trials. However, there is potential for early stage in-licensing particularly for the smaller firms when the competition is relatively less.

Promises of Money Back Guarantee

A very recent trend in the global pharmaceutical industry is the introduction of new concept of 'money back guarantee' by some pharmaceutical companies. Such guarantee is offered to Governments and would be valid if their expensive drugs do not work on patients. Many pharmaceutical companies in the US and the UK have adopted this innovative model of 'pay for performance'. For example, recently Janssen – Cilag, a UK –based division of Johnson and Johnson offered to give the UK Government their 'money back guarantee' if its expensive new bone-cancer medicines do not work on patients. This will prove to be a boon for the patients, particularly from the developing countries, who

are suffering from diseases like cancer and HIV, where the cost of treatment is significantly high.

Ethical Issues

The growth of pharmaceutical industry has given rise to few ethical issues also. With an increasing volume of clinical trials in the laboratories as well as outside the laboratories, use of animals and human beings for these trials at different stages pose ethical challenges. One such challenge is regarding genetic research and treating mental disorders. Availing the services of mentally disordered people to participate in clinical research remains an ethical issue. Another issue involves animal to human transplantation. Recent scientific developments may mean that the problem of rejection of tissue transplanted between species can be overcome. However, there still remains complex ethical and safety issues. Therefore, there is need for rigorous regulation in this regard. With the increasing volume of clinical trials in the laboratory as well as outside the laboratory, use of animal for these trails and also human beings at different stages pose additional ethical challenges.

Safety and Product Quality

Drug safety and product quality are other areas of concern. While bringing out new drugs are challenging to the pharmaceutical

firms, it has become a challenge for the regulatory authorities to ensure safety and quality. This calls for more intensive consultation between the drug manufacturers and the regulatory authorities before a drug is introduced. Many consumer groups and scientists have already questioned the safety level of some FDA approved drugs like Vioxx (a pain killer produced by US based manufacturer Merck) and more recently diabetes pill Avandia produced by GlaxoSmithKline.

Increasing Marketing Cost

As the competition amongst the pharmaceutical firms is aggravating, many firms have started to get into retail business. In this model drugs will be sourced directly from the manufacturers providing proximity with the end users. Such a model would provide benefits to both producers (better supply chain management) and consumers (lower price). This will reduce the number of intermediaries, which will help the pharmaceutical companies to become more price competitive.

Low Emphasis on Clinical Trials

With an increasing share of generics in total pharmaceutical sales, leading pharmaceutical firms are changing their strategies from traditional blockbuster model to niche market players in the areas such as diabetes, cancer and lipid disorders.

Many large firms are adopting strategies with long term investment commitments, scientific advancements, and strategic positioning of their drugs as part of a more comprehensive approach to medical treatment.

Pricing Strategies

Pricing has never been a key issue in global pharmaceutical industry as it is today. Global pharmaceutical majors are increasingly adopting varied pricing strategies in each therapeutic and geographic market, with the objective of optimizing share, revenue and profit.

Increasing Patent Litigations

With a number of branded drugs going off-patent, the market share of the generic producers in the world pharmaceutical market shows an increasing trend. However, the growth path of the generic players is witnessing turbulence with increasing number of IPR related litigations. Legal cost associated with challenging of patent infringement cases turn out to be very high for many pharmaceutical companies. Another angle of such litigations is prohibition to manufacture such drugs till the time the cases are settled. This has emerged as a major challenge, of late, for the generics manufacturers.

3. EVOLUTION OF INDIAN PHARMACEUTICAL INDUSTRY

BACKGROUND

The pharmaceutical industry in India has come a long way since the time of independence when the industry was dominated by MNCs. Over the years, under a favourable policy regime, the industry has grown phenomenally and has established itself as a major supplier of not only generics but also new formulations. The industry, in addition to meeting the domestic demand, is in a position to export significant volume of pharmaceutical products to various destinations, including the developed markets of USA, EU and Japan. Thus, the industry is emerging as a player in the global pharmaceutical industry.

Since the formation of WTO, the sector is facing some new challenges. The most important one is the introduction of product patent regime complying with TRIPS requirements. Besides, the industry is also facing increasing competition from low cost manufacturing destinations like China. Such challenges have enabled the industry to modify their business strategies to remain globally competitive. Many Indian

pharmaceutical companies have adopted the strategy of inorganic growth through M&As. Such M&As are being concluded with the objective of complementing the strengths of two entities to get market access, new technologies as also new products. Indian pharmaceutical industry has also been increasing the R&D expenditure significantly in the recent years. Another noticeable trend in the Indian pharmaceutical industry is that, it has emerged as an attractive destination for outsourcing contract research, particularly clinical trials, as also contract manufacturing by many large firms from the developed countries. A well-developed manufacturing base, low cost R&D, large pool of skilled man-power are some of the factors for success of Indian pharmaceutical industry.

EVOLUTION OF INDIAN PHARMACEUTICAL INDUSTRY

Evolution of Indian pharmaceutical industry can be classified into the following three periods. The first period is prior to 1970s, the second one being from 1970 to 1995; and

then the third period is since 1995 onwards.

Till 1970:

Till 1970, the size of the Indian pharmaceutical industry was very small in terms of number of firms as well as production capacities. Bengal Chemicals and Pharmaceutical Works in Kolkata and Alembic Chemicals in Baroda, set up around 1910 were the first two Indian firms to start pharmaceutical production. The market was dominated mainly by multinational companies (MNCs) through their subsidiaries, who imported bulk drugs into India from the country of their origin, which were later processed into formulations. During this period, the patent regime, based on The Indian Patents and Designs Act, 1911, recognized both product and process patents. This acted as major entry barrier for Indian firms to enter pharmaceutical manufacturing. Between 1947-57, 99% of the drugs and pharmaceutical patents in India were held by foreign MNCs. During this period, due to the monopoly status enjoyed by the foreign companies, the drug prices in India were at very high level. Given the high drug prices and low technical base of the domestic companies, the Government decided to directly intervene in the drug production. A major Government initiative in this regard was to set up two public

sector drug companies, viz., a) Hindustan Antibiotic Ltd. (HAL) established in 1954, with the help of WHO and UNICEF; and b) The Indian Drugs and Pharmaceutical Limited (IDPL), in 1961. The Government received technical support from countries like Russia to set up and start pharmaceutical manufacturing. These two companies played an important role in producing critical drugs for domestic market including penicillin. The Government has also encouraged MNCs to set up manufacturing base in India. However, during this period, FDI in drugs and pharmaceuticals industry was minimal and the country was totally dependent on imported bulk drugs.

1970 to 1995:

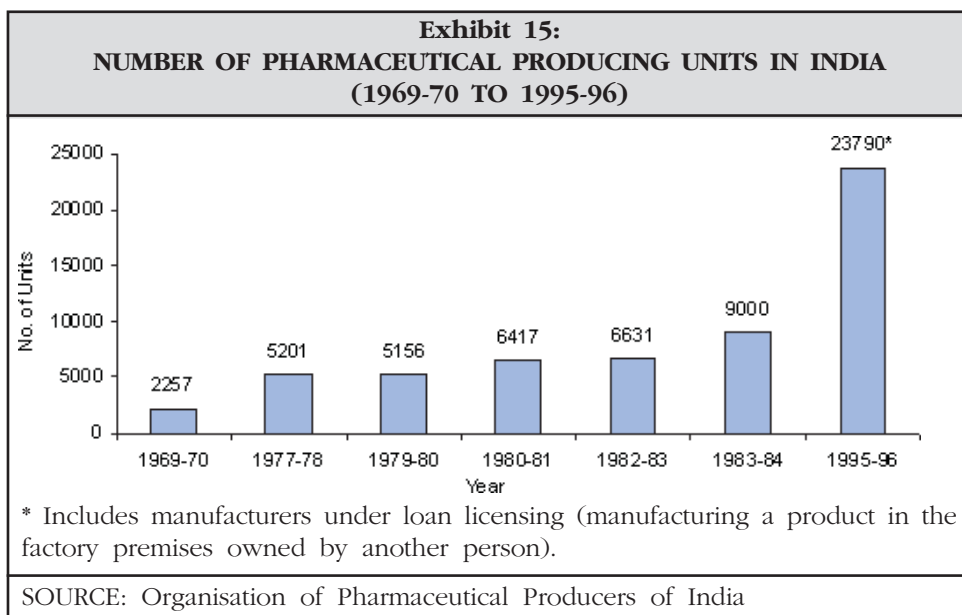
The decade of 1970's was a turning point for the Indian pharmaceutical Industry. In 1970, the Government of India had introduced a new Patent Act, which became effective from 1972. This Act recognized only process patent and not product patent. Thus, as per this Act, drugs patented in other countries could be analyzed and manufactured in India using a different process, popularly called as 'reverse engineering', without paying royalty to the original patent holder. Moreover, the statutory term of a patent was shortened to five years from its being granted or seven years from

application, whichever is shorter. With the introduction of this Act along with price control under Drug Price Control Order (DPCO), there was very little incentive for the MNCs to introduce new products in India. The MNCs, therefore had confined their focus on vitamins, cough preparations and painkillers. The Act had contributed to significant reduction of share by MNCs in the total formulation production in the country.

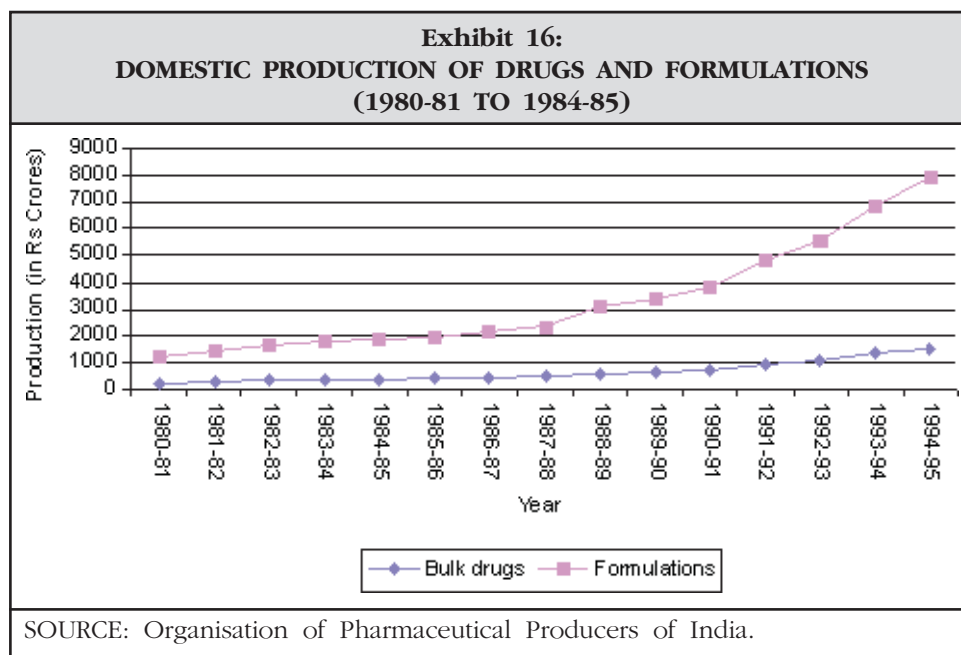
On the other hand, the Act was instrumental to the growth of indigenous pharmaceutical production. The number of domestic firms engaged into pharmaceutical production increased considerably since then as is evident from Exhibit - 15. From over 2200 units in 1969-70, the size of Indian pharmaceutical

industry has increased to nearly 24000¹¹ in 1995-96. Many of them were small-scale units and were receiving number of incentives from the Government, including reservation of drugs for exclusive production. Many of them have commenced their operations specializing in generics production.

Production by indigenous units has also increased during this period. Production of bulk drugs, which was at Rs. 18 crores in 1965-66 has increased to Rs. 1518 crores by the end of 1994-95. Production of formulations, during this period has increased from Rs. 150 crores to Rs. 7935 crores. The increasing trend in domestic production of bulk drugs as well as formulations is evident from Exhibit - 16.



¹¹ Includes manufacturers under loan licensing (manufacturing a product in the factory premises owned by another person)



The increase in production was more pronounced in case of formulations due to large-scale production of generics by domestic firms. Technologies for the production of several bulk drugs including antibiotics like Ampicillin, Amoxicilin, Erythromycin; anti TB drugs; anti cancer drugs were indigenously developed. This approach has helped the country to attain self-sufficiency in case of drugs production, and enabled the country to make available essential drugs at affordable prices. Many drugs like Chloramphenicol, Metronidazole, Ibuprofen were available in India at less than half of the then prevailing prices in neighbouring countries like Pakistan, Bangladesh, and Sri Lanka. By 1991, domestic firms accounted for

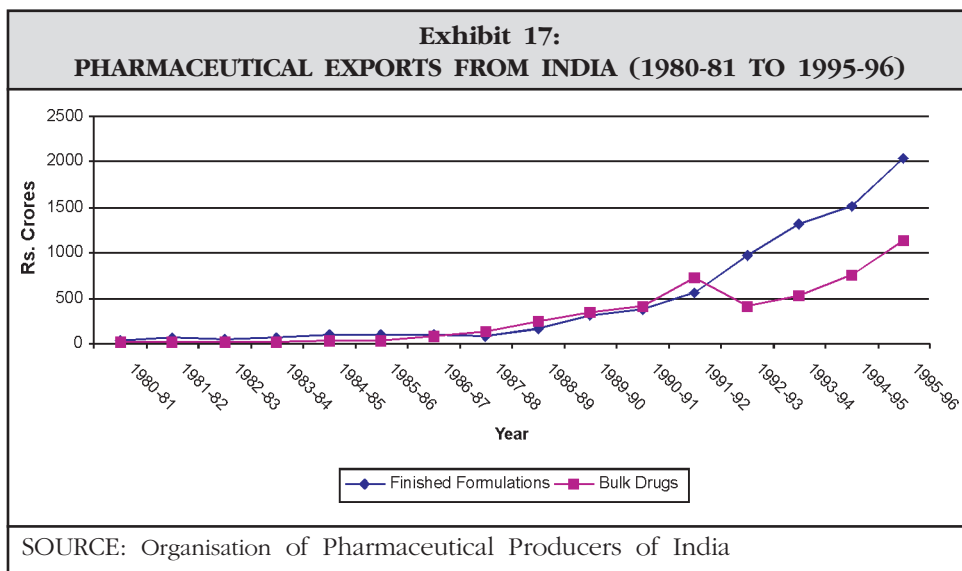
70% of bulk drugs and 80% of formulations produced in the country.

Low cost and high volume production has helped the Indian drugs manufacturers in opening export channels to explore many developed as well as developing countries. Exports showed substantial growth, especially for formulations from the beginning of 1990. Since then, India has been maintaining a positive trade balance in pharmaceutical trade. Pharmaceutical exports, which constituted 2.0% of India's total exports in 1984-85, increased to more than 3% by 1995-96. The low priced generic exports from India is playing a critical role in the fight against AIDS in sub-Saharan Africa, South America and Southern and Southeast Asia.



Table 7: COMPARATIVE PRICES OF SELECT DRUGS IN 1992						
Name of the Drug	Unit	India	Pakistan	Bangladesh	Sri Lanka	Indonesia
Chloramphenicol (anti biotic)	250 mg/ 10caps	9.95	16.87	21.74	31.86	44.76
Metronidazole (anti-diarrhoeal)	200 mg/ 10 tabs	3.65	15.65	4.89	19.30	99.15
Ferrous-supphate (anti-anaemic)	150 mg/ 15 caps	8.65	20.84	6.52	45.04	48.51
Ibuprofen (analgesic)	200 mg/ 10 tabs	3.71	6.78	6.44	8.87	9.52
Propranolol Hcl (anti- hypertensive)	10 mg/ 10 tabs	3.70	10.06	1.79	5.71	NA
Salbutamol (anti -asthmatic)	2 mg/ 10 tabs	1.98	NA	1.94	6.82	NA
Nifedipine (cardiac drug)	10 mg/ 10 caps	5.78	37.18	2.48	10.64	61.28
Cimetidine (anti ulcer)	200 mg/ 10tabs	8.75	45.92	11.26	94.52	106.72

SOURCE: Organisation of Pharmaceutical Producers of India.



The Indian pharmaceutical industry has gradually started becoming more and more export oriented. Share of exports as percentage of total production has shown substantial increase from a mere 3.22% in 1980-81 to 23.97% by 1994-95.

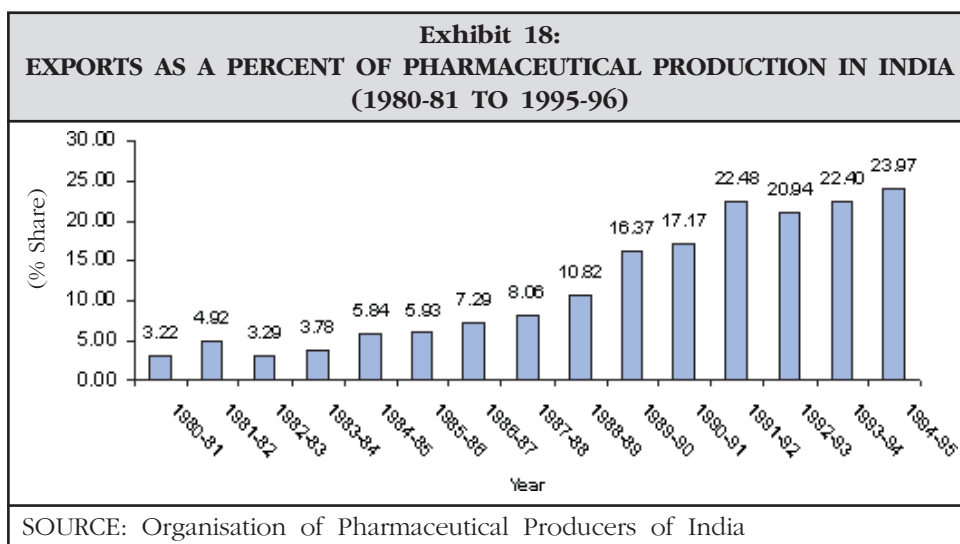
1995 onwards:

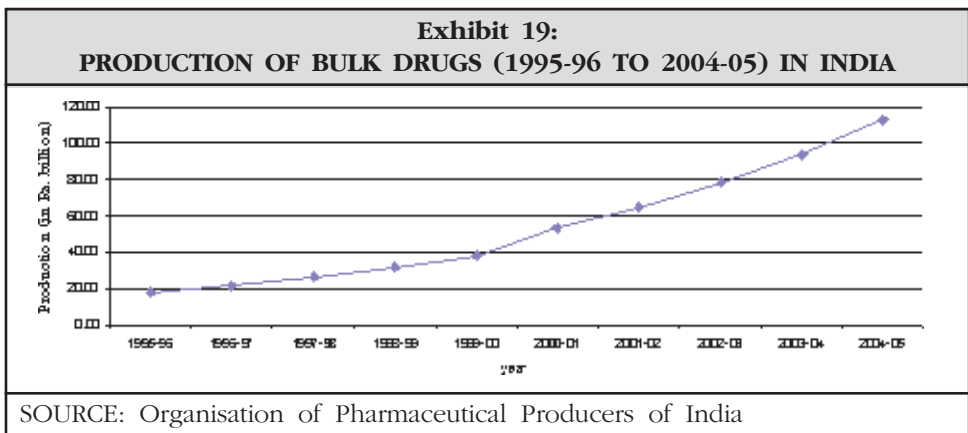
The year 1995 recorded another milestone for the Indian pharmaceutical sector. The World Trade Organisation (WTO) came into effect in 1995. One of the Agreements negotiated under WTO was for the Trade Related Intellectual Property Rights (TRIPS). Since India is a founder member of WTO, India automatically became a signatory of the TRIPS agreement.

The TRIPS agreement opened up the prospects of re-introduction of product patent in many countries.

However developing countries like India were given ten years (till end 2004) of transition period to make their patent policies TRIPS compliant. Further, during this period, due to WTO initiatives, tariff and non-tariff measures, affecting the world trade, were coming down. Such developments have worked in favour of Indian pharmaceutical industry to undertake activities such as clinical research, new drug development and helped them to plough-back most of their profit in generic business for R&D.

Such timely steps taken by the industry during the transition period have helped the sector to continue its resilience beyond 1995 also. By the end of 2005, production of bulk drugs reached a level of Rs.113 billion. Over 400 bulk drugs (Active Pharmaceutical Ingredients) and over 60,000 formulations in 60 different therapeutic categories were produced.

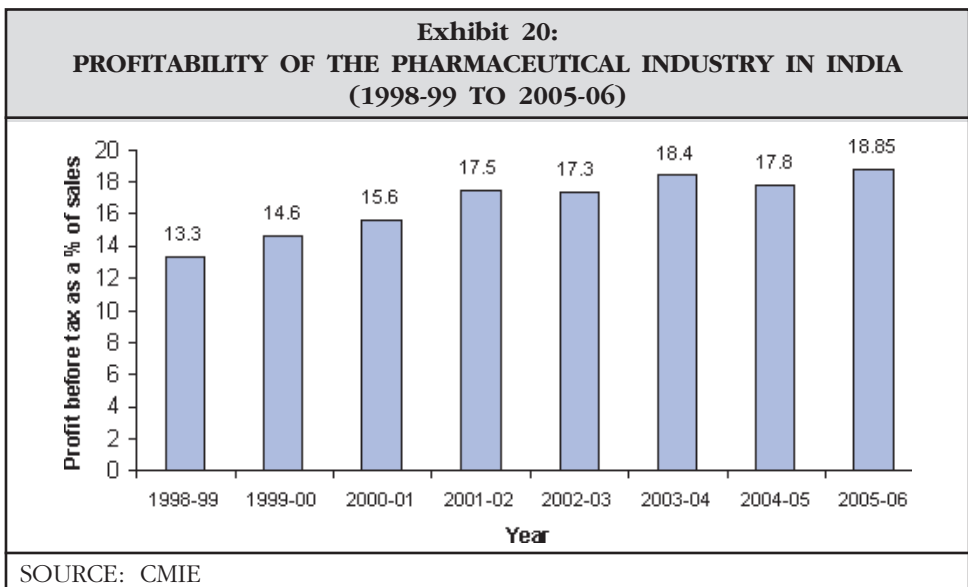




The size of pharmaceutical industry in 2005 reached the level of 10,000 units, of which around 300 units were in the large and the medium sectors. Not only the number of units increased substantially during this period, the profitability of the sector also showed steady rise. Industry estimates showed that the profit (before tax) for the industry increased from 2% of sales in

1990-91 to 19% of sales by 2005-06. This trend of increasing profitability acted as an incentive for increasing their investment in R&D activities. In 2001, the level of investment in the sector was Rs. 34 billion, which has increased to Rs. 60 billion by the end of 2005¹².

The local producers dominated the Indian market and accounted for

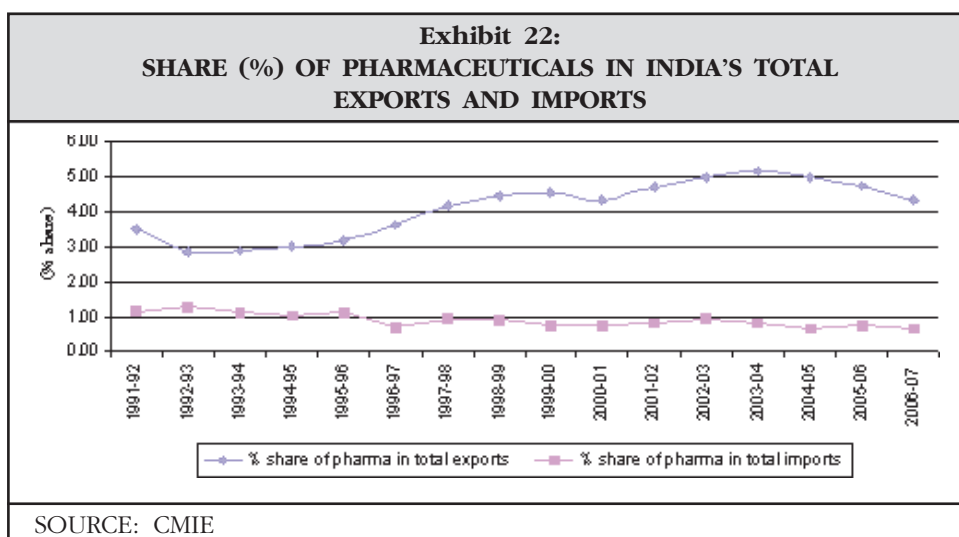
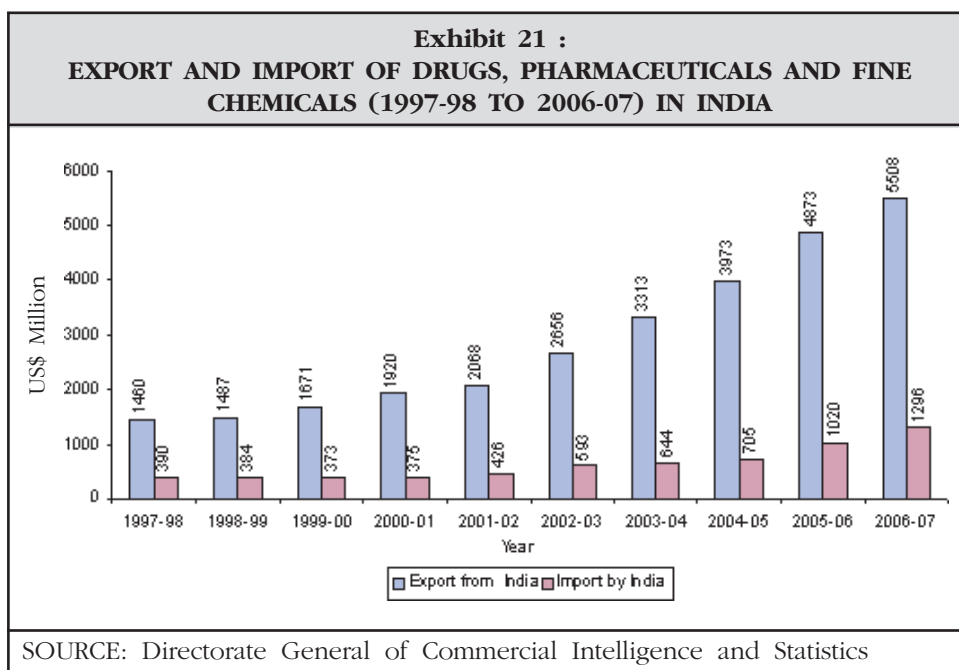


¹² OPPI and CMIE



more than 70% of the market size. Exports also continued to increase at a high rate. Strong process R&D and low manufacturing cost helped the Indian companies to further penetrate into the export markets. Between 2001 and 2005, formulation exports

from India posted a compounded annual growth rate of 20%. At the end of 2006-07, total exports of drugs, pharmaceuticals and fine chemicals, from India were around US\$ 5.5 billion, targeted to over 65 countries across the world.



Due to Government's commitment to recognize product patent in drugs after 2005, MNCs have started showing renewed interest in Indian market. Lower production cost in India is another reason for growing attention by the MNCs. Parent companies of a number of MNCs have increased the equity stake in their India operations. Foreign Direct Investment (FDI) inflows in pharmaceutical sector have crossed a level of US\$ 1.2 billion between August 1991 and March 2007. Top MNC pharmaceutical companies like Pfizer, GSK, Aventis, Novartis have active presence in India. These companies are expected to launch 200-250 new drugs over next 8-10 years¹³.

PRESENT STATUS

Indian pharmaceutical industry is one of the fastest growing segments of Indian manufacturing sector. The pharmaceutical industry has experienced a growth rate of 12%, with the annual turnover of the sector crossing US\$ 11 billion, in 2005-06¹⁴. Globally, Indian pharmaceutical industry ranks 4th in terms of volume with a share of 8% in the world pharmaceuticals market. In terms of value, Indian pharmaceuticals industry ranks 14th. In the Asia-Pacific pharmaceuticals

market, India holds a share of 6.6%. Japan is the biggest player in the Asia-Pacific region accounting for 67% of the total market value¹⁵. The sector has attained self-reliance in the production of formulations and produces almost 70% bulk drug requirements of the country.

The key therapeutic segments include anti-infective, gastrointestinal, cardiovascular segments. In India, acute therapies make up about 60% of the pharmaceutical market. However, it is expected that with the changing lifestyle and aging population, sales of medicines for chronic therapies (such as diabetes, cardiovascular) is growing rapidly. A study has estimated that by the year 2010, the Central Nervous System and Cardiovascular segment would have a market share of 33%¹⁶.

The industry is fragmented with more than 10,000 registered units, of which 300 units are large and medium scale units. In terms of value, however, top 20 players control more than 50 per cent of total market. Some of the top players are Ranbaxy, Cipla, Dr Reddy's Laboratories, Lupin, GlaxoSmithKline, Aurobindo Pharma, Sun Pharmaceuticals, Cadila Healthcare, Wockhardt, and Nicolas Piramal. In the organized sector, Ranbaxy, one of the largest Indian

¹³ 'Pharmaceuticals' *A Report by Ernst & Young for IBEF*

¹⁴ CMIE.

¹⁵ Datamonitor, 2005

¹⁶ 'Health Quotient' (2006) Ernst & Young report.

Sl. No	Category	Value (Rs. Billion)	Market Share (%)
1	Anti-infective	32.8	16.4
2	Gastrointestinal	21.8	10.9
3	Cardiac	20.7	10.3
4	Respiratory	20.4	10.2
5	Vitamins/ Minerals/ Nutrients	19.3	9.6
6	Pain/analgesics	19.1	9.5
7	Dermatologicals	10.8	5.4
8	Gynaecology	10.7	5.3
9	Neuro psychiatry	10.6	5.3
10	Antidiabetics	8.8	4.4
11	Ophthalmicals	3.5	1.7

SOURCE: 'Pharmaceuticals' A Report by Ernst & Young for IBEF

pharmaceutical companies, holds nearly 9% of the market size, followed by Cipla (6%). It may be noted that these companies have increased their market share over the years. Besides

Indian companies, MNCs such as Glaxosmithkline (market share is 3.24%), Pfizer (1.17%) have strong presence in the Indian market.

			<i>(Percent)</i>
Firm	2000-01	2005-06	
1 Ranbaxy Laboratories	5.87	8.73	
2 Cipla	3.25	6.51	
3 Dr.Reddy's Laboratories	3.04	4.70	
4 Lupin	2.76	3.54	
5 GlaxoSmithKline	2.91	3.24	
6 Aurobindo Pharmaceuticals	3.01	3.16	
7 Sun Pharmaceutical Inds	1.91	2.93	
8 Cadila Healthcare	1.50	2.77	
9 Wockhardt	1.70	2.01	
10 Nicholas Piramal India	1.22	1.88	

SOURCE: Industry Size and Market Share, CMIE

The production of therapeutic segments belonging to the bulk category, for select pharmaceutical companies is given in Table - 10.

India's Exports

Export performance of the Indian pharmaceutical sector is also impressive. The sector is one of the top export items from India accounting for more than 4% of India's total exports in 2006-07.

Exports, which constitute around 50% of the industry's total production, have grown at a CAGR of 14% in the last decade. Major export markets include highly regulated markets such as USA, Germany, United Kingdom and Canada. Top 10 destination countries for India's pharmaceutical exports amounted to over 40 percent of India's total pharmaceutical exports.

Table 10:
DATA ON PRODUCTION OF SELECT BULK DRUGS BY SELECT COMPANIES IN ORGANISED SECTOR (IN MT)

Therapeutic Groups	2002-03	2003-04	2004-05
Anaesthetics	41.00	52.08	59.79
Analgesics & antipyretic	3886.83	3972.22	4476.30
Anti Asthmatics	316.34	310.6	438.96
Antibiotics	3009.82	2928.47	2492.36
Pencillins [^]	9157.17	8282.11	3649.20
Anti Diabetics	123.13	102.76	47.427
Anti Dysentery drugs	1875.34	1762.00	2770.44
Anti Helmentics	45.13	52.17	52.52
Anti Histamins	52.99	39.83	51.67
Anti TBdrugs	925.68	1072.08	1147.36
Cardiovascular drugs	13.12	8.10	4.86
CNS stimulants	75.34	58.21	14.51
Corticosteroids	6.72	5.96	5.071
Diuretics	69.19	79.66	23.34
Gastro intestinal	713.98	661.13	695.52
Other anti Bacterials	449.17	433.30	376.91
Sulpha drugs	4.79	0.00	0.00
Tranquilizers & Sedatives	12.18	15.32	15.15
Vitamins	1259.97	1552.89	1375.78

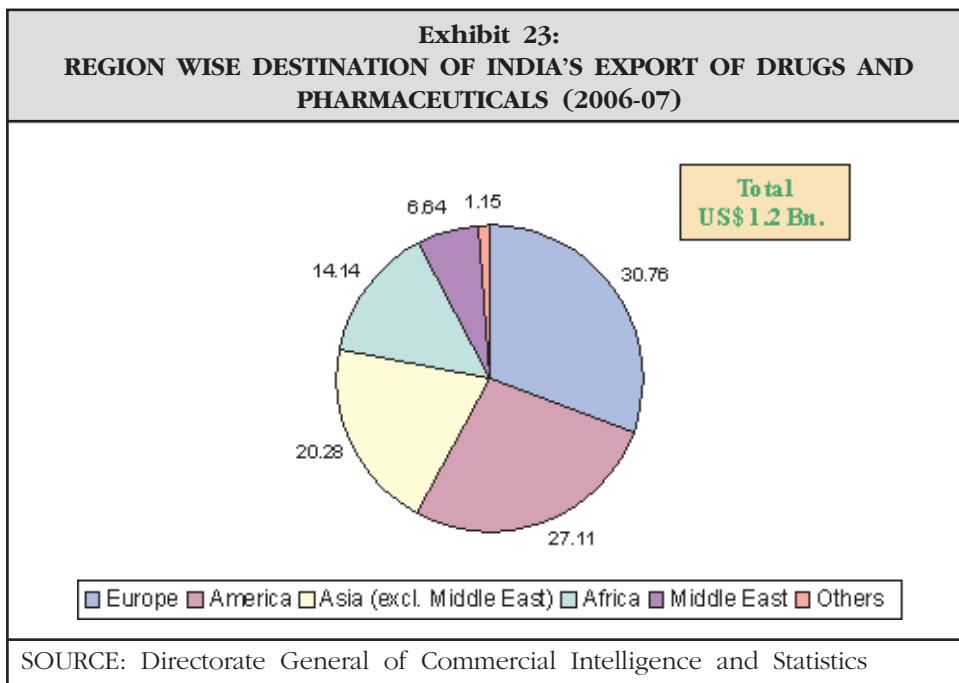
SOURCE: Annual Report – 2005-06; Ministry of Chemicals and Fertilizers, Government of India.

[^] The unit is MMU (Millimass Units)



Table 11: MAJOR DESTINATIONS OF INDIA'S EXPORTS OF DRUGS AND PHARMACEUTICALS (2006-07)			
Sl No	Importing Country	Value (US\$ million)	% Share
1	USA	887.07	16.10
2	Germany	277.93	5.05
3	Russia	270.90	4.92
4	UK	182.57	3.31
5	Brazil	164.60	2.99
6	China	144.03	2.61
7	Nigeria	130.48	2.37
8	Canada	117.48	2.13
9	Israel	115.23	2.09
10	Ukraine	105.67	1.92
	Total Above	2395.96	43.50
	World	5508.41	100.00

SOURCE: Directorate General of Commercial Intelligence and Statistics.



Europe, as a region, is the major export destination for Indian pharmaceuticals accounting for more than 30% of total pharmaceutical exports. The Americas¹⁷ come as next major region with a share of 25%. USA, as an individual country, alone accounts for 14% of India's total pharmaceutical exports. Among South American countries Brazil and Mexico are important destinations for Indian pharmaceuticals. A share of 21% goes to Asian countries excluding Middle East.

India's Position in Select Pharmaceutical Markets

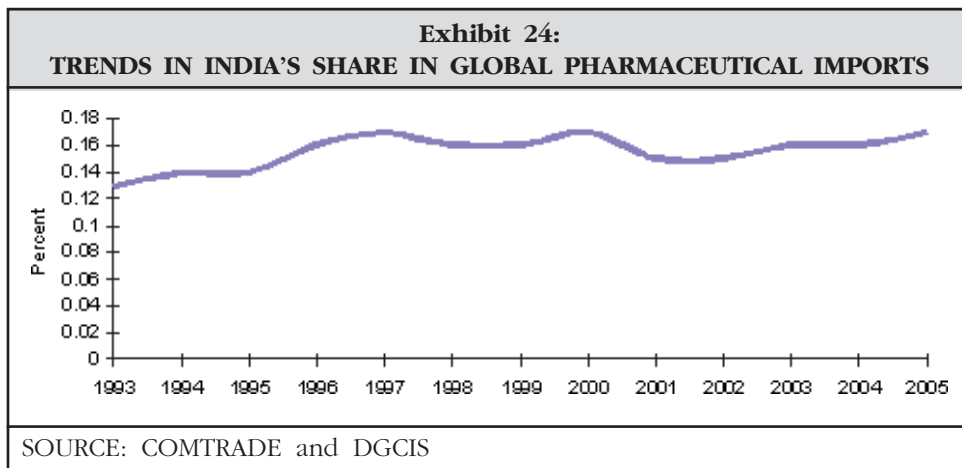
USA

USA is the largest pharmaceutical market in the world. In the year 2005, USA imported pharmaceutical products worth US\$ 39 billion. Major source countries for USA include

Belgium, which accounts for 18% of total imports, followed by UK (11%) and Germany (10%). India's export of pharmaceutical products to the USA accounted for only 0.84% of the USA's total pharmaceutical imports. China's share is slightly higher at 0.94%.

Belgium

Belgium, which is second largest importer of pharmaceutical products in the world, imported pharmaceutical products worth US\$ 27 billion. Major source countries for pharmaceutical imports by Belgium include Germany (41%), Ireland (30%), and France (8%). India is ranked at 25th position as source country for import of pharmaceutical products by Belgium. India exported pharmaceutical products accounted for 0.03% share in pharmaceutical imports by Belgium, in 2005.



¹⁷ Includes both North and South American countries.

**Table 12:
SOURCES OF PHARMACEUTICAL IMPORTS BY USA (2005)**

Rank	Sources of Export	Share
1	Belgium	18.05
2	UK	10.86
3	Germany	10.35
4	Ireland	7.99
5	France	7.99
6	Switzerland	7.71
7	Canada	7.27
8	Sweden	4.28
9	Israel	4.23
10	Japan	3.70
18	China	0.94
19	India	0.84

SOURCE: COMTRADE

Germany

European Union as a bloc is the largest pharmaceutical market accounting for 57% of the global pharmaceutical imports. Among the European countries, Germany is one of the major importers. Germany imported pharmaceutical products

worth US\$ 25 billion in 2005. Germany sources its pharmaceutical requirements from within the EU region. Belgium is the major source country for Germany's import requirements of pharmaceutical products accounting for 41%, followed by Switzerland (10%), UK

**Table 13:
SOURCES OF PHARMACEUTICAL IMPORTS BY BELGIUM (2005)**

Rank	Sources of Export	Share
1	Germany	40.83
2	Ireland	29.68
3	France	7.91
4	USA	5.75
5	Italy	5.11
6	UK	2.54
7	Netherlands	2.25
8	Switzerland	1.90
19	China	0.10
25	India	0.03

SOURCE: COMTRADE

Table 14: SOURCES OF PHARMACEUTICAL IMPORTS BY GERMANY (2005)		
Rank	Sources of Export	Share
1	Belgium	41.03
2	Switzerland	10.33
3	UK	9.07
4	France	7.89
5	Italy	5.34
6	Netherlands	4.39
7	Sweden	4.28
8	Ireland	3.46
9	USA	3.20
10	Spain	2.92
16	China	0.26
17	India	0.24
SOURCE: COMTRADE		

(9%) and France (8%). USA accounts for 3.20% of the total pharmaceutical imports of Germany.

India's export of pharmaceutical products to Germany during 2005, accounted for a share of 0.24%. China's exports in 2005 amounted to US\$ 66.06 million, a share of 0.26% in Germany's total pharmaceutical imports in the same year.

France

France imported pharmaceutical products worth around US\$ 15 billion in 2005. Major source countries for pharmaceutical imports by France include Belgium and UK (16% each), Switzerland (13%) and Germany (10%). India's export of pharmaceutical products in 2005 had a share of 0.11 %.

Table 15: SOURCES OF PHARMACEUTICAL IMPORTS BY FRANCE (2005)		
Rank	Sources of Export	Share
1	Belgium	16.20
2	UK	15.72
3	Switzerland	13.52
4	Germany	10.35
5	USA	8.11
6	Italy	7.55
7	Netherlands	7.37
8	Sweden	5.42
9	Ireland	4.41
10	Spain	3.16
18	China	0.22
20	India	0.11
SOURCE: COMTRADE		

Rank	Sources of Export	Share
1	USA	18.89
2	Belgium	14.29
3	France	11.03
4	Germany	11.01
5	Switzerland	8.16
6	Italy	6.81
7	Ireland	6.00
8	Netherlands	5.74
9	Spain	5.34
10	Sweden	2.09
16	India	0.83
22	China	0.16

SOURCE: COMTRADE

United Kingdom

United Kingdom imported pharmaceutical products worth around US\$ 15 billion in 2005. Major source country for pharmaceutical imports by United Kingdom is USA with a share of 19%. Other major pharmaceutical suppliers are however other European nations, like Belgium (14%), France (11%), Germany (11%). In UK market, India is ranked at 16th position with a share of 0.83 %. India is relatively better positioned than China (0.16%) in UK market.

Japan

Japan is another major pharmaceutical market in the world. Japan imported pharmaceutical products valued at US\$ 8.2 billion

in 2005 and accounted for 3% of world pharmaceutical imports. Major source countries for pharmaceutical imports by Japan include USA (19%), UK (15%), Switzerland (14%), and Germany (14%). India accounted for 0.15% of Japan's total pharmaceutical imports.

China

China imported pharmaceutical products worth US\$ 2.31 billion in 2005. Hong Kong is the major source country for China's imports of pharmaceutical products, with a share of almost 19%, followed by Switzerland (12%) and USA (10%). India's exports of pharmaceutical products accounted for 1.21% of China's total pharmaceutical imports.

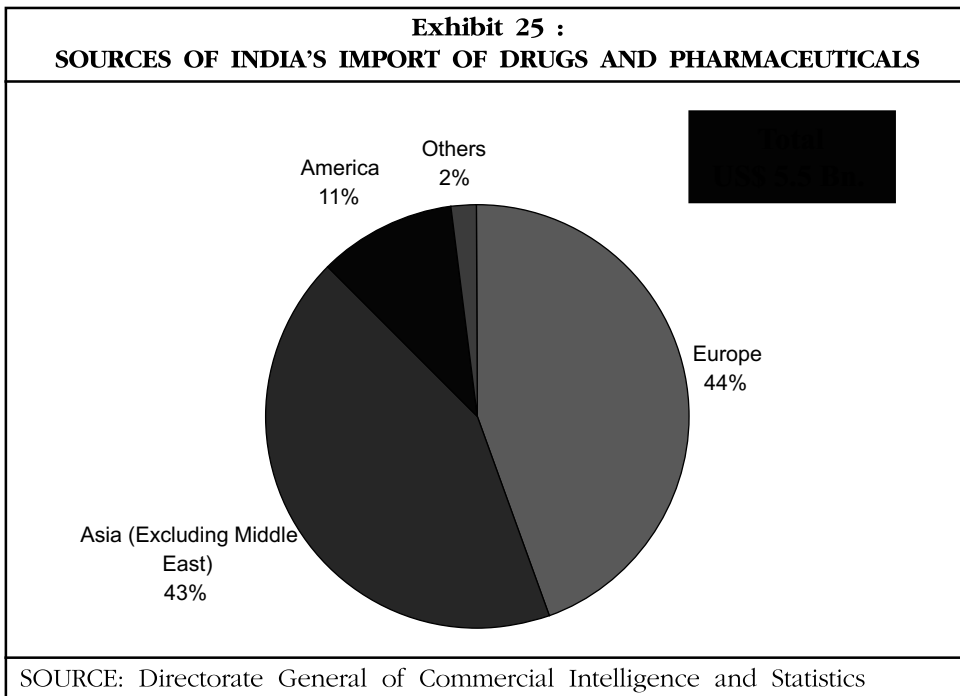
Table 17: SOURCES OF PHARMACEUTICAL IMPORTS BY JAPAN (2005)		
Rank	Sources of Export	Share
1	USA	19.43
2	UK	15.32
3	Switzerland	14.34
4	Germany	14.01
5	France	8.62
6	Belgium	5.95
7	Italy	5.70
8	Ireland	3.36
9	China	2.25
10	Sweden	2.05
23	India	0.15
SOURCE: COMTRADE		

Table 18: SOURCES OF PHARMACEUTICAL IMPORTS BY CHINA (2005)		
Rank	Sources of Export	Share
1	Hong Kong	18.57
2	Switzerland	11.87
3	USA	9.98
4	France	8.32
5	UK	7.84
6	Germany	6.68
7	Japan	5.94
8	Belgium	5.73
9	Australia	3.52
10	Ireland	3.28
18	India	1.21
SOURCE: COMTRADE		

der

(1995), Pharmaceutical Policy (2002), Indian Patents (Amendment) Act (2005), and the Draft National Pharmaceutical Policy (2006), have not only helped in improving the healthcare scenario in India but also facilitated the growth of drugs and pharmaceuticals industry.

Improvement in public health has remained as one of the foremost policy objectives for the Government of India. Availability of essential and life saving drugs of proven quality at affordable price is one of the important pre-requisite for achieving this goal. In order to achieve this goal, Indian Government has been playing



a pro-active role in promoting the pharmaceuticals sector. The basic objectives of Government's policy relating to drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. The objectives include:

1. Ensuring abundant availability, at reasonable prices, of essential and life saving medicines of good quality for mass consumption;
2. Strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;
3. Creating an environment conducive to channelising new investment into the pharmaceutical industry to encourage cost-effective production with economic sizes and to introduce new technologies and new drugs; and,
4. Strengthening the indigenous capability for production of drugs.

Thus, the policy recognized the need for expansion of the domestic pharmaceutical industry inviting more investment. At the same time, the policy ensured that the prices of drugs are maintained at an affordable level. Two forms of legislations have been used to achieve this end. They are: 1) Patent Act, and 2) Drug Price Control Order. Besides, Drug and

Cosmetic Act was put in place to ensure quality in drugs manufacturing.

Patent Act (1970)

A patent is a monopoly right granted to a person or a company who has invented a new and useful article or an improvement of an existing article or a new process of making an article. It allows the inventor to exclusively manufacture and market the patented product for specified period of time. Granting of patents was introduced mainly to encourage inventions and also to act as an incentive for inventors to disclose information that would become a substantive database for technical information, which might otherwise have remained secret.

In India, the first act related to patent came into force in 1856 (Act VI, 1856). The Act granted certain exclusive privileges to inventors of new manufacturers for a period of 14 years. This law was based on British patent law. It was modified several times and finally replaced by The Indian Patents and Designs Act, 1911. This law recognized product as well as process patent and was applicable in India till 1970. During this period MNCs dominated the Indian market as most of the patents were held by these firms. Drug prices remained at high level during this period.

In order to develop an indigenous pharmaceutical sector and also to

bring down the drug prices in the country, a major change was brought about in the patent regime with the introduction of Patent Act, 1970. The Act became effective from 1972 onwards. Main features of this act are:

- There will be no more product patent for pharmaceuticals, food and chemical based products. These industrial sectors were covered by process patent only;
- The term of the patent was 7 years from the date of application or 5 years from the date of sealing of patent whichever was less;
- Automatic licenses of right could be issued three years after the granting of the patent;
- For licenses of right, the royalty ceiling was stipulated at 4%.

The Act relaxed the patent regime in the country to a great extent and gave a major boost to pharmaceutical industry in India. In the absence of product patent, Indian pharmaceutical firms started producing generics through 'reverse engineering process' and were developing alternative processes for the patented drugs. Moreover, as a result of the automatic license of right, firms interested in exploiting the patent process involving a drug could do so after obtaining the concurrence of the patentee. Such policy measures increased the production, particularly in the formulations segment, by Indian firms significantly.

Patents Act, 2005

In 1995, WTO came into effect, and India became a member of WTO, as also a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS Agreement attempts to narrow down the gaps in the way these rights are protected around the world, and to bring them under common international rules. TRIPS Agreement establishes minimum levels of protection that each Government has to give to the intellectual property of fellow WTO members. TRIPS Agreement puts product patent back into practice in member countries, including India. The main features of this agreement are:

- Product patent will be allowed for all products including drugs, food and agro chemicals.
- Patent term for all existing and future patents are twenty years.
- Patentee can import the patented drug and has no obligation to produce it locally.
- In case of process patent the burden of proof lies with alleged infringer.

Under the new Patent Act, 2005, the 'right to licensing' provision was removed and the flexibility of granting compulsory licensing was also greatly reduced. Thus, the new Patent Act, 2005, marked the beginning of a new chapter for the Indian pharmaceutical

industry. Adoption of new Patent Act is expected to have significant impact on the domestic drugs manufacturers, particularly the generics manufacturers who benefited greatly from the erstwhile patent regime (Patent Act, 1970). The new Patent Act (2005) prevents them from producing generics of patented drugs using different process. One comforting fact in this regard is that many branded drugs are going to be off-patent soon. Nevertheless, under the new patent regime, it will be highly imperative for the Indian firms to invest more in R& D and come up with new drugs.

Drug Price Control Order (1970)

The second objective of the Government of India is to ensure abundant availability of essential and life saving medicines of good quality at reasonable price. Drug Price Control Order (DPCO), which regulates the drug prices in the country was introduced to achieve this goal. DPCO controls the prices of major bulk drugs and their formulations. The Order provides a list of price-controlled drugs, procedures for fixation of prices for drugs, method of implementation of prices fixed by Government and also penalties for contravention of provisions, among other things.

Drug Price Control Order was first introduced in 1970, which has been

modified in 1979, 1987 and 1995, subsequently. During the introductory period, DPCO was more of a control on the profitability of a pharmaceutical business, and thus indirectly sought to control the prices of pharmaceuticals. In its 1979-revised version, DPCO stipulated ceiling prices for controlled categories of bulk drugs and formulations.

Drug Price Control Order (1995)

The basic structure of DPCO, 1995 has remained the same as its previous revisions, but the number of drugs under its control has come down significantly. At present 74 bulk drugs and their formulations, which cover approximately 40% of the total market, are covered under DPCO, 1995.

Other steps initiated in strengthening the manufacturing capabilities of Indian pharmaceutical industry include:

- Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs provided by the use for recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations.
- The reservation of 5 drugs for manufacture by the public sector had also been removed in 1999.

Box 1:
SAFEGUARDS AND FLEXIBILITIES IN TRIPS AGREEMENT

TRIPS Agreement contains flexibility, to a limited extent, as well as some safeguards, which are mainly provided with the objective of mitigating the anticipated negative impact on drug prices and on access to drugs, especially in developing countries. The most important safeguards are:

- ❖ Compulsory License - is a license to use an invention, which has been granted without the permission of the patent holder. A compulsory license can be used to allow the production and sale of generics before expiry of the patent - thereby, increasing opportunities for competition. The basic rationale for a compulsory license is that since a patent is a privilege granted by the Government, the Government retains the right to limit that privilege, if necessary. Many countries, including developed countries, have provisions for compulsory licenses in their national laws, and compulsory licenses are allowed under TRIPS.
- ❖ Parallel Importation - refers to importation, without the consent of the patent holder, of a patented product that is marketed in another country. Parallel importation allows one to 'shop around' for a good price. The TRIPS Agreement states that parallel importation cannot be challenged under the WTO dispute settlement mechanism, thus, *de facto*, leaving countries the freedom to choose whether or not to allow parallel importation.
- ❖ The "Bolar Provision" - allows testing and regulatory approval of generic versions of a drug before its patent expires; thus, it allows generic producers to get ready, so that they can start the production and sale of a generic drug as soon as its patent expires. In this way, a Bolar Provision facilitates generic competition.

- Foreign investment through automatic route was raised from 51% to 74% in March 2000.

'National Pharmaceutical Pricing Authority' (NPPA) has been entrusted with the responsibility of implementing the provisions of DPCO. As per the provisions of DPCO, NPPA fixes two types of prices viz. 'ceiling prices' and 'non-ceiling prices' for medicines in the controlled

category. Ceiling price refers to a single maximum selling price fixed for the bulk drugs that is applicable throughout the country. Non-ceiling prices are specific to a particular pack size of scheduled formulation of a particular company. Thus, they are drug specific and company specific. The prices fixed for non-ceiling packs are communicated to the respective firms by issuing office orders.

Box 2:
TIMELINE OF INDIAN PATENT SYSTEM

Year	Developments in Indian Patent System
1856	The Act VI of 1856 on Protection of Inventions Based on The British Patent Law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.
1859	The Act Modified As Act XV; Patent Monopolies Called Exclusive Privileges (Making, selling and using inventions in India and authorizing others to do so for 14 years from date of filing specification).
1872	The Patents & Designs Protection Act.
1883	The Protection of Inventions Act.
1888	Consolidated as The Inventions & Designs Act.
1911	The Indian Patents & Designs Act.
1972	The Patents Act (Act 39 Of 1970) Came into force on 20th April 1972.
1999	On March 26, 1999 Patents (Amendment) Act, (1999) came into force from 01-01-1995.
2002	The Patents (Amendment) Act 2002 came into force from 20th May 2003
2005	The Patents (Amendment) Act 2005

SOURCE: Controller General of Patents, Designs and Trademarks, Department of Industrial Policy and Promotion, Government of India.

Box 3:
FUNCTIONS OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY

1. To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it;
2. To deal with all legal matters arising out of the decisions of the Authority;
3. To monitor the availability of drugs, identify shortages, if any, and to take remedial steps;
4. To collect / maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations;
5. To undertake and / or sponsor relevant studies in respect of pricing of drugs / pharmaceuticals;
6. To recruit / appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government;
7. To render advice to the Central Government on changes / revisions in the drug policy;
8. To render assistance to the Central Government in the parliamentary matters relating to the drug pricing.

Drug and Cosmetics Act (1940)

Another important objective of the Government is to ensure quality of the drugs available in the country. This is being ensured by the Drugs and Cosmetics Act (1940) and the related Drugs and Cosmetics Rules (II Amendment 2005). The Drugs and Cosmetics Act provides the central legislation, which regulates import, manufacture, distribution and sale of drugs in the country. The main objective of the Act is to ensure that the drugs available to the people are safe and efficacious. Central Drug Control Organization and number of State Drug Control Organizations have been set up to administer various regulatory measures related to quality.

The main functions of the Central Drug Standard Control Organization (CDSCO) include control of the quality of drugs imported into the country, co-ordination of the activities of the State/UT Drug Control Authorities, approval of new drugs proposed to be imported or manufactured in the country, laying down of regulatory measures and standards of drugs and acting as the Central Licensing Approving Authority in respect of whole human blood, blood products, large volume parenterals, sera and vaccines. The State Drug Control Authorities are responsible for regulation of manufacture, sale and distribution of drugs.

Pharmaceutical Policy - 2002

In the context of opening up of the economy and strong trend towards globalization of regulatory and scientific requirement pertaining to safety and quality, it has become imperative to benchmark the regulatory standards against the international standards. Accordingly, changes were brought into the Pharmaceutical Policy in the year 2002. The reasons for undertaking such changes include:

- ❖ Scope of industrial licensing was reduced and tariff and non-tariff barriers were brought down under the liberalization policies, thus making import of medicines much easier and cheaper;
- ❖ Commitment under WTO for implementation of TRIPS compliant Patent Law;

In such scenario, the Government has felt that the pharmaceutical industry needs to re-orient itself to face these challenges and become internationally competitive. It may be mentioned in this context that the pharmaceutical industry has been recognized as one of the most important knowledge-based industries in which India has a comparative advantage given its already existing strong manufacturing base and highly qualified human resources. Keeping all these in view, the Pharmaceutical Policy, 2002 was introduced. The policy mainly

Box 4:	
DRUGS CONTROL ADMINISTRATION IN INDIA	
Central Government	State Governments
Statutory Functions	
Laying down standards of drugs, cosmetics, diagnostics and devices;	Licensing of drug manufacturing and sales establishments;
Laying down regulatory measures, amendments to Acts and Rules;	Licensing of drug testing laboratories;
To regulate market authorization of new drugs;	Approval of drug formulations for manufacture;
To regulate clinical research in India;	Monitoring of quality of Drugs & Cosmetics, manufactured by respective state units and those marketed in the state;
To approve licenses to manufacture certain categories of drugs as Central Licence Approving Authority i.e. for Blood Banks, Large Volume Parenterals and Vaccines & Sera;	Investigation and prosecution in respect of contravention of legal provisions;
To regulate the standards of imported drugs;	Administrative actions;
Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC);	Pre- and post- licensing inspection;
Testing of drugs by Central Drugs Labs;	Recall of sub-standard drugs;
Publication of Indian Pharmacopoeia;	
Other Functions	
Coordinating the activities of the State Drugs Control Organizations to achieve uniform administration of the Act; and policy guidance;	
Guidance on technical matters;	
Participation in the WHO GMP certification scheme;	
Monitoring adverse drug reactions (ADR);	
Conducting training programmes for regulatory officials & Govt. analysts;	
Distribution of quotas of narcotic drugs for use in medicinal formulations;	
Screening of drug formulations available in Indian market;	
Evaluation/Screening of applications for granting No Objection Certificates for export of unapproved/banned drugs.	
SOURCE: Central Drugs Standards Control Organisation, Government of India	

addressed two issues, which have arisen on account of globalization and implementation of India's obligation under TRIPS. These are:

- ❖ Reintroduction of product patent regime made it essential to increase the incentives for R&D in the Indian pharmaceutical industry to achieve sustainable growth;
- ❖ Secondly, there was need for reducing the rigours of price control in view of the ongoing liberalization process;

Thus, in order to make the Indian pharmaceutical sector globally competitive the Pharmaceutical Policy (2002) emphasized on:

- ❖ Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector;
- ❖ Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals;
- ❖ Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by

creating an environment conducive to channelising a higher level of investment into R&D in pharmaceuticals in India;

- ❖ Creating an incentive framework for the pharmaceutical industry, which promotes new investment and encourages the introduction of new technologies and new drugs.

Increasing R&D activities by attracting more investment into pharmaceutical sector has been a focal point of the Pharmaceutical Policy 2002. A Pharmaceutical Research and Development Committee (PRDC) was set up in 1999 by the Department of Chemicals and Petrochemicals, Government of India, to identify the support required by Indian companies to undertake domestic R&D. The Committee has recommended setting up of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research & Development Support Fund (PRDSF) to promote R&D activities in the Indian pharmaceutical industry.

Draft Pharmaceutical Policy, 2006

The Government has announced a Draft Pharmaceutical Policy (2006) with the principal objectives of (among others): ensuring availability of medicines at reasonable prices; facilitating higher investment for increased production of quality

medicines; promoting greater research and development in the pharmaceuticals sector by providing suitable incentives; enabling domestic pharmaceutical companies to compete internationally by implementing Current Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and other established international guidelines; and developing India as a preferred global destination for pharmaceutical R&D and manufacturing. The policy also proposes to strengthen the drug regulatory system, patent office infrastructure, human resources development, and focus on provision of incentives for R&D process development, drug discovery, drug development and clinical trials, in the form of higher Maximum Allowable Post-Manufacturing Expenses (MAPE).

Small Scale Sector

Small-scale units constitute a significant part of the Indian pharmaceutical industry. In order to promote this section, Government of India has reserved few drugs and pharmaceutical products for exclusive production by small-scale sector. These include: Pyrazolones, Potassium Citrate (industrial grade), Diethyl Phthalate, Dioctyl Phthalate, Niacinamide, Chlorinated Paraffin Wax, and Lanolin Anhydrous.

Other policy measures supporting the small-scale units

include exemption from the Drug Price Control Order and drug policy parameters, preferential procurement under Government health programmes.

INSTITUTIONAL SUPPORT

Another important reason for success of Indian pharmaceutical industry is the institutional support provided by the Government. These include setting up of public sector manufacturing units as also industry support institutions. To name a few, in 1961, when Indian pharmaceutical industry was dominated by the multinational companies, Government of India has set up the first public sector pharmaceutical company, Hindustan Antibiotic Ltd. (HAL), in Pimpri, Pune. It was established with the help of WHO and UNICEF. Then in 1961, the second public sector drug company, the Indian Drugs and Pharmaceuticals Limited (IDPL) came up. Government has received technical support from countries like Russia to set up and start manufacturing process in these pharmaceutical firms. These two companies played an important role in producing critical drugs, for the domestic market, such as penicillin.

Of late, Government has been playing a facilitator role by setting up of institutions that would strengthen the quality aspects, R&D activities and exports. Setting up of Central Drugs Laboratory, Central Indian Pharmacopoeia Laboratory, National

Institute of Pharmaceutical Education and Research (NIPER), Pharmaceutical Export Promotion Council (Pharmexil) are some of the positive steps taken in these directions.

Central Drugs Laboratory, Kolkata

The Central Drugs Laboratory (CDL), Kolkata is the national statutory laboratory of the Government of India for quality control of drug and cosmetics. CDL has been established under the Indian Drug & Cosmetics Act, 1940, and has been functioning under the administrative control of the Director-General of Health Services in the Ministry of Health and Family Welfare, Government of India. Statutory functions of CDL include analytical quality control of drugs available in Indian market, including imported drug, and acting as Appellate authority in matters of disputes relating to quality of drug. In addition, CDL actively collaborates with the World Health Organisation in the preparation of International Standards and Specifications for International Pharmacopoeia. CDL also undertakes collaborative study on behalf of the Indian Pharmacopoeia Committee.

Pharmaceutical Export Promotion Council

Pharmaceutical Export Promotion Council (Pharmexil) has been set up in 2004, by the Government of

India, to focus exclusively on the promotion of pharmaceutical exports from India. Skilled and specialised services such as contract manufacturing, contract research, clinical research and other resources like traditional knowledge, herbal science, biotechnology, genetic diversity, intellectual property are some of the focus areas of Pharmexil in order to make the Indian pharmaceutical industry competitive, both domestically and globally. Pharmexil works closely with the Department of Commerce, and the Export Promotion Cell of Department of Chemicals and Petrochemicals, Government of India to undertake various activities, including promotion of exports.

National Institute of Pharmaceutical Education and Research

National Institute of Pharmaceutical Education and Research (NIPER) is an autonomous body set up, under the aegis of Ministry of Chemicals and Fertilizers, Government of India, in 1998. The Government of India has declared NIPER as an 'Institute of National Importance'. The Institute is conceived to provide leadership in pharmaceutical sciences and related areas not only within the country, but also to the countries in South East Asia, South Asia and Africa. NIPER is a member of Association of Indian Universities and Association of Commonwealth Universities. The institute conducts

Box 5 :**EXIM BANK'S SUPPORT TO INDIAN PHARMACEUTICAL INDUSTRY**

Exim Bank has been closely associated with the evolution of Indian pharmaceutical industry. The Bank has been providing integrated financing for R&D activities of the pharmaceutical and bio-pharmaceutical companies. The financing will be in the form of either term loan / equity participation or hybrid product, and would facilitate R&D expenditure and approvals in regulated markets. This facility is primarily extended to pharmaceutical and bio-pharmaceutical companies. The eligible R&D activities under this financing programme include:

- Development and commercialisation of new product / process / application;
- Significant improvements in existing product / process / application/ design;
- Development of technology or design to satisfy domestic or international environment, technical requirements/ standards, specifications;
- Setting up, expansion of pilot plants;
- Research studies necessary for obtaining regulatory approvals, product registrations, cost of filing and maintaining international patents;
- R&D centers.

The eligible R&D expenditures under this financing programme include:

- Acquisition of technology at the 'proof of concept' or design stage which will be used to develop new product/ process;
- Land and building, civil works for housing eligible R&D activities;
- Dies, tools, laboratory and other R&D equipment, mould, computer hardware, software, miscellaneous fixed assets;
- Salaries of R&D personnel, support staff during the R&D project phase including training costs;
- Cost of regulatory approvals, filing and maintenance of patent registration;
- Expenditure on external consultants for outsourcing a component of R&D project;
- Product documentation and allied costs during the R&D project phase;
- Costs of materials, surveys, technology demonstration studies, field trials.

The Bank has supported many pharmaceutical companies to invest in or acquire overseas ventures for manufacturing and marketing, under its Overseas Investment Finance Programmes. The bank has also provided loans to number of SME pharmaceutical exporters to expand and upgrade production facilities to effectively compete in the global market.

The Bank, in association with the Centre for Promotion of Imports from Developing Countries, The Netherlands, facilitated participation of Indian pharmaceutical firms in the Export Promotion Programme (EPP) in Europe. EPP provides combination of elements such as assistance on adhering to EU regulations and standards, marketing, organization of production and operational management and training in export marketing.

research in various areas such as medical chemistry, pharmaceuticals, natural products, pharmacology and toxicology, biotechnology, and pharmaceutical management.

INCENTIVE FRAMEWORK

Given the crucial role of R&D in pharmaceutical sector, the Government of India has taken a number of initiatives to promote R&D activities in this sector. Such measures include:

- ❖ Weighted tax deduction of 125% to the sponsor of sponsored research programmes in universities, approved technological institutions and national laboratories;
- ❖ Weighted tax deduction of 150% on R&D expenditure incurred in the in-house R&D centers (approved by Department of

Scientific and Industrial Research, Government of India) of companies engaged in biotechnology, production of drugs and pharmaceuticals;

- ❖ Income tax holiday of ten consecutive assessment years for commercial R&D companies;

In the Union Budget (2007-08), few other measures have been announced with the objective of further boosting R&D activities in this sector. These include:

- ❖ Reduction in customs duty from 7.5% to 5% on 15 specified machinery for pharmaceutical and biotechnology sector;
- ❖ Pass-through status to be granted to venture capital funds in respect of investments in venture capital undertakings in biotechnology.

4. SUCCESS STRATEGIES OF INDIAN PHARMACEUTICAL INDUSTRY

The Indian pharmaceutical industry witnessed significant growth due to favourable policy environment, institutional set-up as also the industry initiatives to meet up the changing business environment. However, post WTO era is expected to pose some new challenges to the industry. One of the challenges being faced by the industry is the re-introduction of product patent to meet the TRIPS obligations. With such change in patent regime, Indian pharmaceutical firms can no longer resort to reverse engineering process, which was one of the reasons for the growth of the industry in the past. Besides, the liberalization process has reduced the tariffs and other trade barriers to a great extent, thus making the imports cheaper in many countries. This has made it necessary for Indian firms to become more innovative and also to explore overseas markets, in order to remain globally competitive. Accordingly, the industry has been adopting new business strategies to cope up with the changing scenario. Many Indian pharmaceutical firms could foresee the changes as also challenges in the business environment at much earlier stage and adopted number strategies to deal with them. These strategies are discussed in this chapter.

INCREASING R&D ACTIVITIES

Pharmaceutical industry is knowledge intensive and R&D investment plays a crucial role in the growth of the industry. R&D in pharmaceutical industry include directional search for solutions to existing medical problems and unmet medical requirements. In addition, pharmaceutical R&D may also be aimed at improving the existing solutions to improve the efficiency or safety of medicines. Thus, the pharmaceutical R&D may be concentrated in New Chemical Entities (NCEs), Novel Drug Delivery Systems (NDDS) or in generic products.

Historically, research in Indian pharmaceutical firms was concentrated mainly on process engineering of bulk drugs and development of NDDS for formulations. Though research in the area of discovery of NCE has taken place, due to heavy investment required in the clinical trial phase, many companies have either licensed the molecules to players abroad or collaborated with the overseas players to conduct clinical research. However, the post –WTO patent regime introduced new challenges for the Indian pharmaceutical industry. Now

the pharmaceutical companies are increasingly becoming innovative rather than imitative. The industry is changing their R&D strategy from 'reverse engineering' to 'patent driven' research.

Though the product patent was introduced from 2005, many pharmaceutical companies realized the need of increasing their R&D efforts much earlier. R&D expenditure of the Indian pharmaceutical sector,

which was Rs. 50 Crores during 1986-87, has more than doubled (to Rs. 125 crores) by 1993-94. This constituted around 1.8% of sales. In the later years, R&D expenditure of the industry increased further to reach a level of Rs. 1220 crores by the end of 2004-05. This accounts for 5% of total sales of the industry, though few research-based companies are in fact spending more than 10% of their sales on R&D.

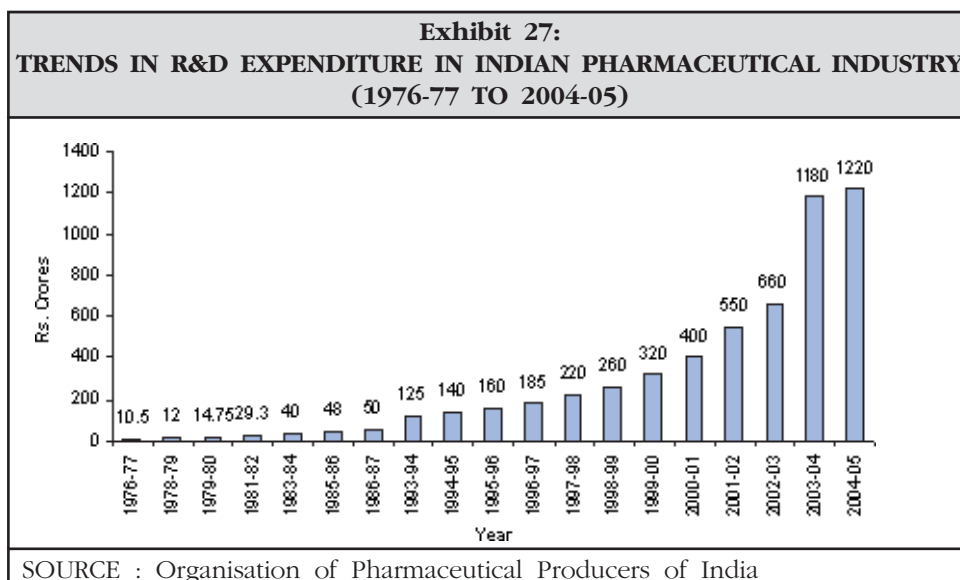
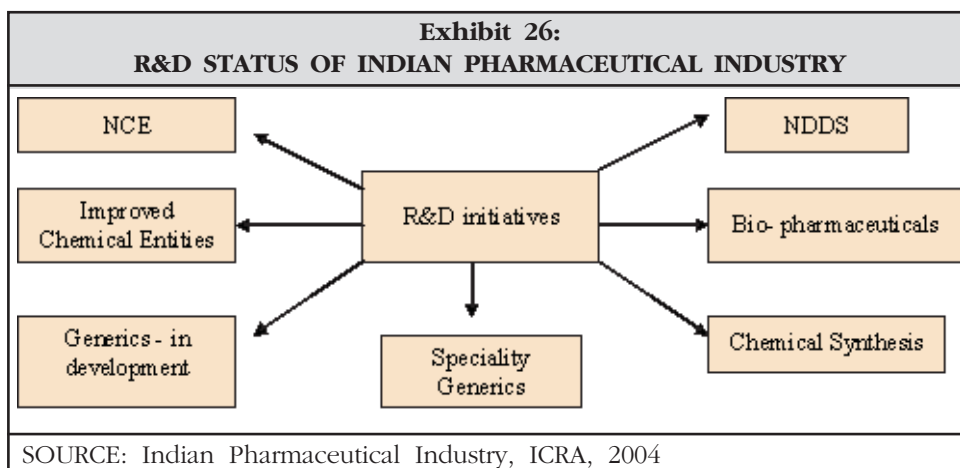


Table 19: R&D EXPENDITURE OF SELECT INDIAN PHARMACEUTICAL COMPANIES				
Company Name	R&D Expenditure (in Rs Crore)		% Share of R&D Expenses to Sales	
	1999-00	2005-06	1999-00	2005-06
Ranbaxy Laboratories Ltd.	55.39	639.33	2.93	17.21
Dr. Reddy's Laboratories Ltd.	13.27	253.95	2.69	10.85
Sun Pharmaceutical Inds. Ltd.	18.80	161.49	3.92	11.93
Cipla Ltd.	30.02	155.40	3.89	5.01
Cadila Healthcare Ltd.	21.27	118.70	4.45	8.87
Nicholas Piramal India Ltd.	9.26	91.15	1.89	6.04
Torrent Pharmaceuticals Ltd.		87.36		
Wockhardt Ltd.	36.34	81.08	4.17	8.73
Aurobindo Pharma Ltd.	14.34	77.01	1.92	5.22
Orchid Chemicals & Pharmaceuticals Ltd.	4.54	61.36	1.26	6.95
Panacea Biotec Ltd.	12.59	49.02	6.48	8.87
Glenmark Pharmaceuticals Ltd.	5.20	46.69	3.58	7.52
Jubilant Organosys Ltd.	3.24	39.38	0.53	2.61
Ipca Laboratories Ltd.	6.44	37.86	1.75	4.61
SOURCE: CMIE, Prowess				

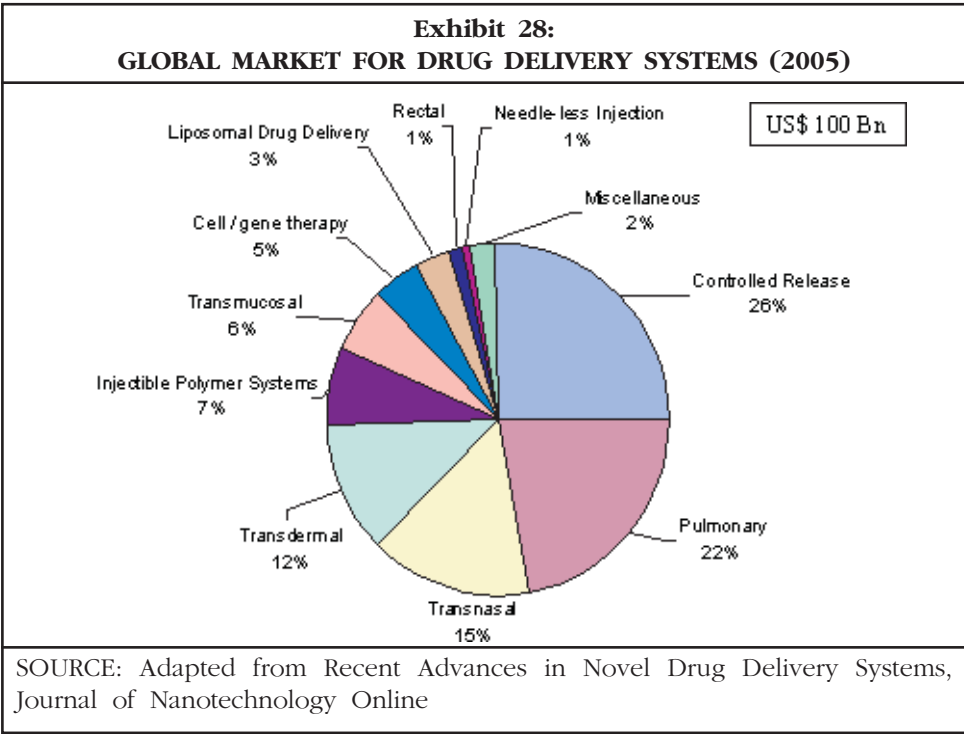
Large Indian pharmaceutical companies such as Ranbaxy, Cipla, Dr. Reddy's Laboratories have increased their R&D spending significantly over the years. Ranbaxy spends over 17% of sales in R&D. Its R&D expenditure is directed towards both drug discovery and development. Ranbaxy has a total of three modern state-of-the-art multi-disciplinary research facilities, out of which two centres focus on the development of generics and NDDS research; the third one is dedicated to New Drug Discovery Research. Another major pharmaceutical

producer, Dr.Reddy's Laboratories focuses on discovery and development of therapeutically useful NCEs. The current research programs at discovery research of the company are focused towards developing promising drug candidates in key therapeutic areas such as metabolic disorder and cardiovascular indications. Other companies like Nicholas Piramal, Wockhardt, Sun Pharmaceuticals, IPCA Laboratories have also set up fully dedicated R&D centers at different places to meet the new R&D challenges.



Box 6:
NOVEL DRUG DELIVERY SYSTEM (NDDS)

Historically the most common form of drug administration was oral administration. However, it has been found to be not very effective in some therapeutic areas. Moreover, drug development has become increasingly complex, time consuming and expensive. As a result there is an increased focus on making clinically established drugs to perform better, therapeutically, in terms of efficacy, safety and improved patient compliance by designing novel and patentable technologies or delivery systems. This initiated research to find out other effective ways of delivering drugs to the body. Besides focusing on mode of administration, NDDS also focuses on finding new dosage forms, so that the effectiveness of the drug is enhanced. Research on NDDS has become very attractive among the pharmaceutical producers, of late, because if a patented molecule is combined with NDDS, it qualifies for fresh patent filing. Further, since many patented drugs are going off-patent in the next few years, the pharmaceutical companies have the possibility of extending the exclusivity of marketing those products.

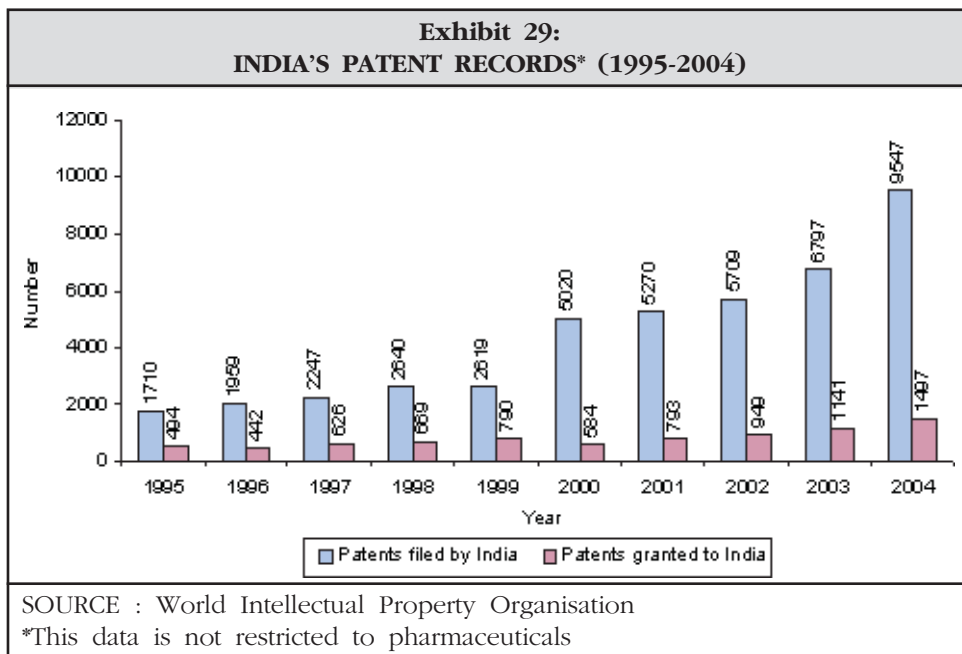


INCREASING PATENT FILINGS

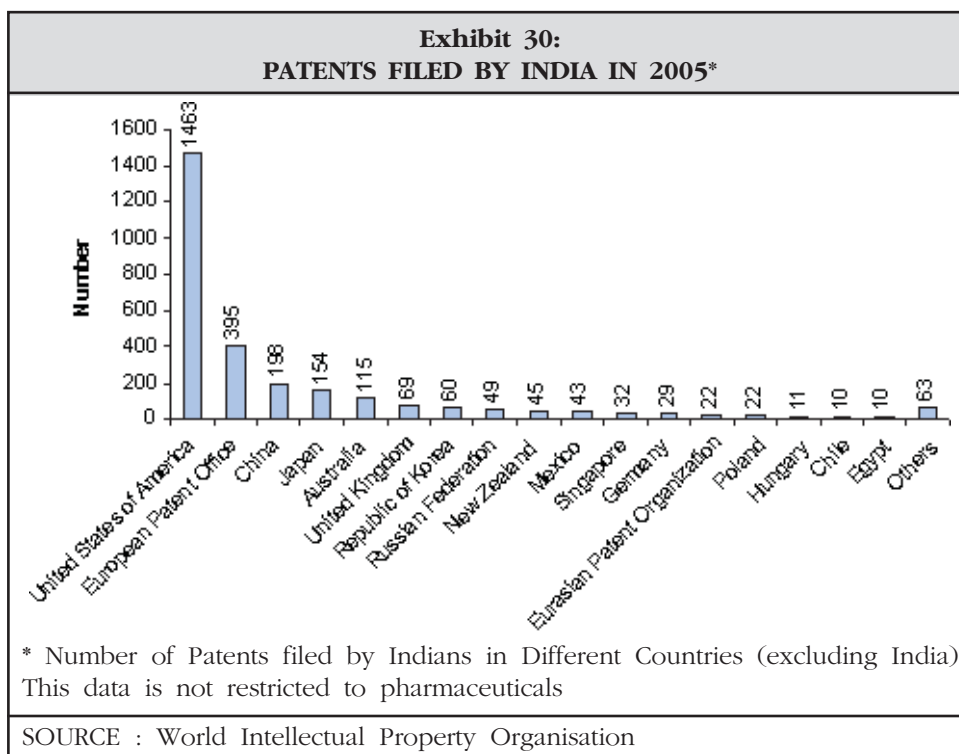
Increasing R&D investment has been showing positive results in the pharmaceutical industry. The patents filed by and granted to Indian pharmaceutical companies have been increasing significantly. Indian companies have made large numbers of Drug Master Files and Abbreviated New Drug Application (ANDA) filing with US-FDA. Exhibit - 29 shows the increasing number of patents filed by India over the years. However, over 90% of the patent filings by India are in the Indian patent office as resident. A significant number among them belong to the pharmaceutical sector. It is reported that companies such as Aurobindo Pharma, IPCA

Laboratories and Matrix Laboratories have made 205, 95 and 44 patents filings, respectively, till now¹⁸. With regard to patent filings outside India, in 2005, USA tops the list with over 52% share, followed by European Patent Office (14%), China (7%), Japan (6%), Australia (4%) and UK (2%). These are illustrated in Exhibit - 30.

Indian firms have comparative advantage in patent filings due to the prevalence of high intellectual base and low cost R&D. In the Global Competitiveness Report, 2006-07, India got high score for the parameter on capacity for innovation. This is due to the high quality of scientific research and number of scientists and engineers available in the country.



¹⁸ Annual Reports of respective companies.



Increasing R&D expenditure has shown considerable results in recent times. Many Indian companies have introduced a number of new drugs in the domestic as well as in the overseas markets. Patent filing by Indian companies has also increased significantly. The Indian pharmaceutical industry has filed the largest number (260) of Drug Master Files (DMFs) by 2005 with the USFDA¹⁹. Mid-sized pharmaceutical companies have accounted for significant share of DMF.

PUBLIC-PRIVATE PARTNERSHIP IN R&D

Another important feature in the current trend of R&D activities in India is public private partnership. Many Indian companies, besides setting up their own R&D base, are collaborating with the research laboratories such as Central Drug Research Institute (CDRI), Lucknow; Indian Institute of Chemical Technology (IICT), Hyderabad; and Centre for Cellular and Molecular Biology (CCMB), Hyderabad. Some such initiatives are listed in Table – 20.

¹⁹ Organisation of Pharmaceutical Producers of India.

**Box 7:
DRUG MASTER FILE**

A Drug Master File (DMF) is a submission to the US Food and Drug Administration (US-FDA) that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The submission of a DMF is not required by law or FDA regulation. A DMF is submitted solely at the discretion of the holder. The information contained in the DMF may be used to support an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or amendments and supplements to any of these. However, a DMF is not a substitute for an IND, NDA, ANDA, or Export Application. It is not approved or disapproved. Technical contents of a DMF are reviewed only in connection with the review of an IND, NDA, ANDA, or an Export Application.

There are five types of DMF's:

- ❖ Type I - Manufacturing site, facilities, operating procedures, and personnel;
- ❖ Type II - Drug substance, Drug substance intermediate, and material used in their preparation, or drug product;
- ❖ Type III - Packaging material;
- ❖ Type IV - Excipient, colorant, flavor, essence, or material used in their preparation;
- ❖ Type V - FDA Accepted Reference Information

SOURCE: US Food and Drug Administration

**Table 20:
SELECT PUBLIC-PRIVATE PARTNERSHIP INITIATIVES IN
PHARMACEUTICAL R&D IN INDIA**

CDRI (Lucknow)	IICT (Hyderabad)	CCMB (Hyderabad)
Nicholas Piramal India Ltd	Dr. Reddy's Laboratories	Dr. Reddy's Research Foundation
Ranbaxy Laboratories Ltd	Cadila Laboratories	Shantha Biotechnics Pvt Ltd
Cipla Ltd	Sun Pharmaceutical Ltd	Bangalore Genei Pvt Ltd
Wockhardt Ltd	Cipla Ltd	Dabur Research Foundation
Torrent Pharmaceutical Ltd	Orchid Chemicals	Biological Evans Ltd
IPCA Labs Ltd	Unichem Laboratories Ltd	
Unichem Laboratories Ltd	Torrent Pharmaceutical Ltd	

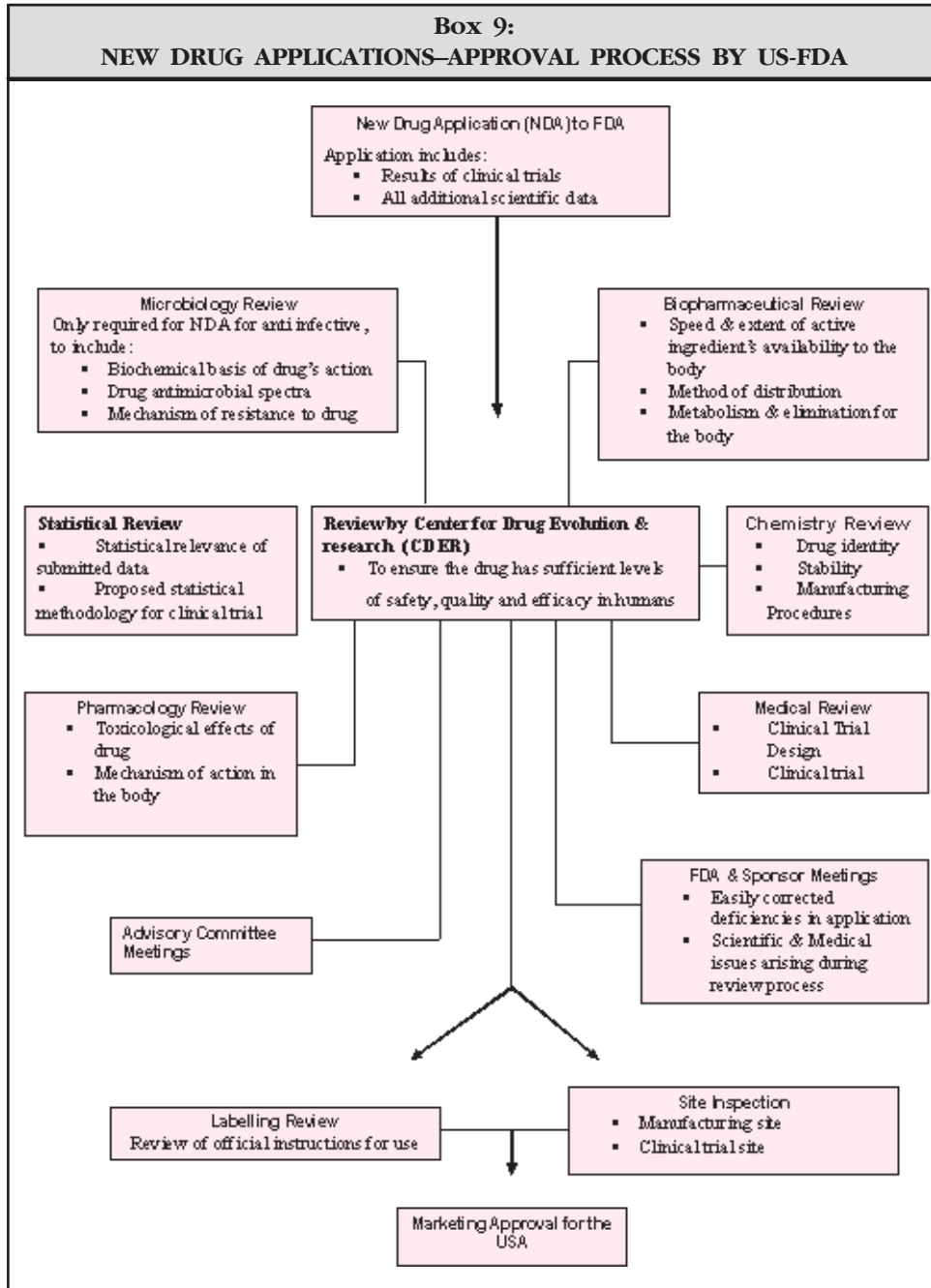
SOURCE: 'Competitiveness of the Indian Pharmaceutical Industry in the New Product Patent Regime', FICCI Report for National Manufacturing Competitiveness Council (NMCC), March 2005

**Box 8:
REGULATORY FRAMEWORK IMPOSED BY FOOD AND
DRUG ADMINISTRATION OF USA (US-FDA)**

The FDA relies on registration, listing, and agent information for administering many key programs, including post-marketing surveillance; user fee assessments; monitoring of drug shortages and availability; and determining products that are being marketed without an approved application. FDA regulations include:

1. All domestic and foreign establishments that manufacture, repack, or re-label drug products in the United States are required to register with the FDA;
2. Domestic and foreign drug manufacturers, repackers or re-labelers are also required to list all of their commercially marketed drug products;
3. The listing must include the trade name or proprietary name, if any, of the drug, dosage and route of administration, ingredients, package information, and the National Drug Code. Drug products which are not listed are misbranded and may be subject to regulatory action;
4. All foreign establishments that manufacture, repack, or re-label drug products and import or offer for import drug products to the United States must register with the FDA and identify a U.S. agent, who may be an individual, firm or company. The U.S agent must be included as part of their initial and updated registration information;
5. All drugs imported into the United States must be listed by the foreign firms or its designated U.S. agent.
6. Each registrant will designate only one U.S agent and this agent should represent the registrant and all products that will be imported or offered for import into the United States.
7. Both foreign and domestic manufacturing establishments are covered under the compliance programme of US-FDA. The compliance programme provides guidance for establishment inspections and related investigations and for laboratory evaluations of methods and analysis proposed by applicants in NDA and ANDA submissions.
8. Before any application is approved by the Centre for Drug Evaluation and Research (CDER of US-FDA), it will be determined through pre-approval inspections that the manufacturing establishments are in compliance with cGMP guidelines. Method validations, method verifications and profile analysis will also be performed during the pre-approval inspections to confirm the authenticity of the pre-approval product and to ensure that it can be accurately assayed with the proposed regulatory methods. Post approval inspections will monitor and enforce these requirements.
9. Various approval mechanisms of US-FDA take the following time-frame:
 - a. Product registration and listing requirements – 30-60 days;
 - b. New drug application – standard review time of 10 months, followed by site inspection procedures;
 - c. Time for factory audits – approximately 6 months to 1 year.

SOURCE: Centre for Drug Evaluation and Research, US-FDA



LEVERAGING BIOTECHNOLOGY

Biotechnology is one of the areas that are showing promising future in the Indian healthcare sector. Biotechnology drugs represent a significant part of the new innovative medicines launched worldwide. Bio-pharmaceuticals account for more than 10% of global pharmaceutical industry and India has emerged as one of the leading biotech players. Bio-pharmaceuticals in India, comprising vaccines, therapeutics and diagnostics, have recorded over US\$ 1.05 billion revenues in 2005-06. Bio-pharmaceuticals thus account for over 70% of Indian biotech industry. Share of India in global bio-pharmaceuticals market thus works out to nearly 2%. Many Indian pharmaceutical firms have been leveraging their expertise in biotechnology including manufacture of bio-generics.

INORGANIC GROWTH STRATEGY – ACQUISITIONS / JOINT VENTURES ABROAD

The global pharmaceutical industry has been undergoing the consolidation mode driven by increasing competition, and pressure on pricing and margins, on the one hand, and desire for geographical diversification and growth in market share, on the other. Indian

companies have also adopted the inorganic growth strategy since recent times and have undertaken several mergers and acquisitions (M&A) activities. There are various reasons, which motivate companies to go for M&As or setting up of joint ventures abroad. These include:

- ❖ A company may have strong product portfolio but it may lack access to overseas distribution network. In such cases a firm may acquire a foreign company to have a sound distribution network. Thus, the acquisition helps the acquirer to explore new markets;
- ❖ The reason for acquisition may be firm specific also. Acquisition may take place to gain control over new product, brands, technology and skills. Companies can acquire strong research expertise and boost their capabilities through consolidation;
- ❖ The recent trend in acquisitions also shows an attempt for vertical integration by many firms, which are specializing in generics production to get into API production. This has been driven by sharp erosion of margin in finished dosage products and intense pressure on pricing experienced by generics manufacturing²⁰.

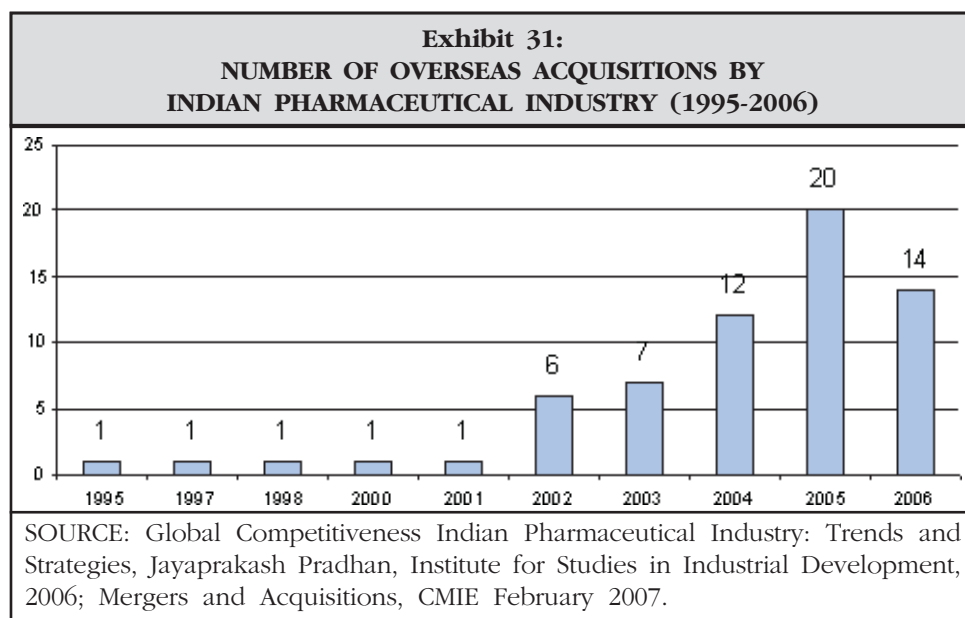
²⁰ 'Health Quotient: Making Idea Meet Opportunities' Ernst & Young Report, 2007.

Exhibit - 31 shows the trend in overseas acquisitions by Indian pharmaceutical firms since 1995. (Annexure - 4 gives a detailed list of acquisitions by Indian Pharmaceutical firms) Though the acquisition trend has started from 1995, Indian firms have started aggressively acquiring foreign firms since the beginning of the decade. The year 2005 witnessed the highest number of overseas acquisitions by Indian pharmaceutical firms.

Ranbaxy, one of the largest Indian pharmaceutical firms made 12 acquisitions during this period, in different countries like USA, Germany, UK, Japan, and France. Other firms that have made considerable number of overseas acquisitions include Glenmark and Nicholas Piramal (5 each); Dr. Reddy's Laboratories; Sun Pharmaceuticals and

Jubilant Organosys (4 each); Strides Arcolab and Matrix Laboratories (3 each); and Wockhardt, Alembic and Aurobindo Pharma (2 each).

The USA and Europe together constitute the biggest pharmaceutical market in the world. In order to remain globally competitive it becomes extremely necessary to have foothold in these markets. Acquisition of Europe and the US based firms has been adopted as a strategy by many Indian firms to enter these markets. Wockhardt was one of the first India-based firms to make major pharmaceutical acquisition in UK; It acquired Wallis Laboratory in 1998. Since then Indian pharmaceutical companies have succeeded in acquiring many companies in Europe. For example, out of 12 acquisitions of Ranbaxy during the analysed period, 7 of them are in Europe. In



terms of individual countries, USA tops the list with 15 acquisitions followed by UK (8), Belgium (5), Germany (4), China, Japan, South Africa and Spain (3 each).

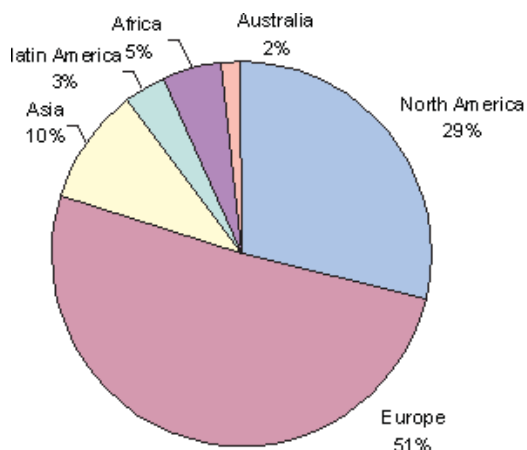
Ranbaxy which has a strong presence in generics manufacturing acquired unbranded generic business of Allen S.p.A, a division of

GlaxoSmithkline (GSK) in Italy, in 2006. As the acquired generic business of GSK complements Ranbaxy's product portfolio, it would help the company to penetrate in the European market further. Ranbaxy's other recent acquisitions such as 'Terapia' in Romania, 'Ethimed NV' in Belgium are also guided by similar objectives. Such acquisitions give

Company Name	No. Of Acquisitions
Ranbaxy	12
Glenmark Pharmaceutical Ltd.	5
Nicholas Piramal	5
Dr. Reddy's	4
Sun Pharma	4
Jubilant Organosys Ltd	4
Strides Arcolab	3
Matrix Laboratories	3
Aurobindo Pharma	2
Wockhardt	2
Alembic	2
Dishman Pharmaceuticals	1
Enzyme Technologies	1
Indegene Life systems	1
Ipca Laboratories	1
Lupin Ltd	1
Malladi Drugs	1
Marksans Pharma	1
Natco Pharma	1
Solvay Pharma India	1
Suven Pharmaceuticals	1
Torrent pharmaceuticals	1
Wanbury Ltd	1
Zydus Cadila	1

SOURCE: Global Competitiveness Indian Pharmaceutical Industry: Trends and Strategies, Jayaprakash Pradhan, Institute for Studies in Industrial Development, 2006; Mergers and Acquisitions, CMIE February 2007.

**Exhibit 32:
REGIONAL DISTRIBUTION OF ACQUISITIONS BY INDIAN
PHARMACEUTICAL INDUSTRY (1995-2006)**



SOURCE: Global Competitiveness Indian Pharmaceutical Industry: Trends and Strategies, Jayaprakash Pradhan, Institute for Studies in Industrial Development, 2006; Mergers and Acquisitions, CMIE February 2007.

Ranbaxy's already existing sound network to explore these markets. Acquisition of Terapia would also give Ranbaxy access to two manufacturing plants and over 150 drugs.

Another major Indian pharmaceutical company, Dr. Reddy's Laboratories, has also made a number of overseas acquisitions. Its acquisition of German generic drug maker Betapharm Arzneimittel GmbH in 2006 is considered to be one of the biggest overseas acquisitions by an Indian pharmaceutical company. Betapharm Arzneimittel GmbH is one of Germany's top generic manufacturers and this acquisition is expected to

give Dr. Reddy's Laboratories a significant platform for global product development, as also the marketing infrastructure for strengthening its generics business in Europe. Earlier, Dr. Reddy's Laboratories had acquired UK -based BMS Laboratories and its wholly owned subsidiary Meridian Healthcare. In 2004, it acquired Roche's API Business at the state-of-the-art manufacturing facility in Mexico. This would boost its activities in the API segment.

Aurobindo pharmaceuticals acquisition of UK based generic company Milpharm helped it to integrate into the formulation business in Europe.

Companies sometimes adopt the strategy of buying out products from overseas companies to strategically enter the target markets. Nicholas Piramal's tie-up for Rhodia's Inhalation Anaesthetics (IA) business provided sales and marketing rights for Rhodia's IA products -Halothane and Isoflurane. Thus, the move has given Nicholas Piramal a complete access to Rhodia's sales and marketing network of exclusive pharmaceutical distributors in over 90 countries – including the U.S., Europe, Japan, Australia and many emerging markets. Glenmark pharmaceuticals adopted a similar approach by acquiring seven products from P D Pharmaceuticals Ltd in South Africa. The acquired drugs include anti-diarrhoeal, anti-inflammatory, analgesic, expectorant, anti-protozoal, anti-acid and multi-vitamin products. Before such a move, Glenmark had acquired Bouwer-Bartlett, a sales and marketing company in South Africa, which is the largest and the fastest growing pharmaceutical market in Africa. Such acquisitions is expected to benefit Glenmark in the long run. In 2007, Glenmark pharmaceuticals again acquired 90% stake in Czech company Medicamenta, which has sales and marketing operations in the Czech Republic and Slovakia. This acquisition would give Glenmark a strategic entry point to these two fastest growing European markets. Besides, Medicamenta facility, being centrally located, is expected to help

Glenmark's other distribution activities in Europe.

Another strategy adopted by Indian generics firms is to acquire specialty pharmaceutical operations, by utilizing the cash flow from generic sales. Many firms have acquired proprietary drug development capabilities or facilities that only focus on one therapeutic market. Nicholas Piramal is one such firm, which is actively seeking to acquire custom technologies, drugs and manufacturing facilities in overseas markets. The company acquired Avecia Pharmaceuticals (UK) in 2005, which is a global manufacturer of customized products providing custom chemical synthesis and manufacturing services for the innovating pharmaceutical and biotechnology companies. This acquisition is expected to add not only new clients to Nicholas Piramal's product portfolio but also to give access to critical technologies.

Many Indian pharmaceutical companies have also gone for establishing joint ventures and wholly owned subsidiaries in select markets. For instance, Aurobindo Pharma has established joint ventures in USA, and wholly owned subsidiaries in countries such as China, Brazil, South Africa, Thailand and Netherlands²¹. Such an approach has helped the company to effectively complete backward and forward integrations. The production units provide cost

¹ <http://www.aurobindo.com/docs/boardapproves.html>

advantage as well as ensure stability in source of supplies and consistency in quality. Marketing linkages give the necessary capacity to reach the customer much faster. The wholly owned subsidiaries in China and Brazil will increase the presence of the company in non-regulated markets. The plant, set up in the USA as part of a joint venture, would be involved in production of cephalosporin injectable drugs, which has emerged as a lucrative product for USA market. Another company, Dr. Reddy's, has joint venture in Russia, where it produces formulations from the bulk drugs supplied from India. Cadila Pharmaceuticals has entered into joint ventures in South Africa and Ethiopia in order to tap the expanding pharmaceutical market in the African continent. Similarly, Nicholas Piramal has entered into joint ventures with Allergan Inc of the USA in 1994, and with Boots Plc of the UK, with the objective of gaining leadership in the areas of Ophthalmology and OTC medicines, respectively.

Setting up of joint ventures or wholly owned subsidiaries is not only restricted to top pharmaceutical companies like Ranbaxy or Dr. Reddy's. Medium sized firms like Unichem Laboratories, Torrent Pharmaceuticals are also making aggressive forays abroad. Recently, many Chinese pharmaceutical companies have shown interest in entering into joint ventures, strategic

alliances and research collaborations with Indian firms. The Chinese pharmaceutical industry, which till now focused mainly on consumer oriented business strategies, has realized the importance of synergies with Indian firms that have strengths in generics, formulations and research services. At least 50 odd Chinese companies are currently in talks with Indian companies, R&D organizations and allied industry players, for cooperation.

DIVERSIFICATION OF MARKETS

India is exporting pharmaceutical products to an increasingly large number of countries. Over the years Indian pharmaceutical companies have been successful in increasing its exports to the traditional export destinations as well as entering into newer destinations. In the beginning of 1990s, Russia was the largest market for Indian pharmaceutical products accounting for 25% of India's total pharmaceutical exports. However over the years, there has been a decline in India's pharmaceutical exports to Russia to reach a level of 5% share in India's total pharmaceutical exports in 2006-07. Nevertheless, Russia is still the third largest destination for pharmaceutical exports from India.

Share of exports to the USA has shown gradual increase from 10.8% in 1991-92 to more than 16% by 2006-

07. USA has emerged as the largest export destination for Indian pharmaceutical products. USA, being the largest pharmaceutical market in the world, is obviously a target market for most of the Indian pharmaceutical companies also. Germany is another major export destination for India, accounting for over 5% of India's total pharmaceutical exports. However it also has experienced decline in its share from 13% in 1991-92.

China is a country, which has of late become an important export destination for Indian pharmaceutical products. From a level of 0.1% share in 1991-92 (ranked at 18), India's export of pharmaceuticals to China has increased to around 2.6% by 2006-07. It is the 6th largest export destination for Indian pharmaceutical products.

Another significant trend in India's pharmaceutical export scenario is diversification in export destinations. In recent years, many new countries have emerged as important export destinations for Indian pharmaceutical companies. These countries include Brazil, South Africa, Turkey and Ukraine. Till 1990s, most of these countries were not target markets for Indian pharmaceutical products. But in the recent years many such countries are being targeted by Indian pharmaceutical industry as potential target markets. Annexure-5 discusses in detail the changing destination of India's pharmaceutical exports

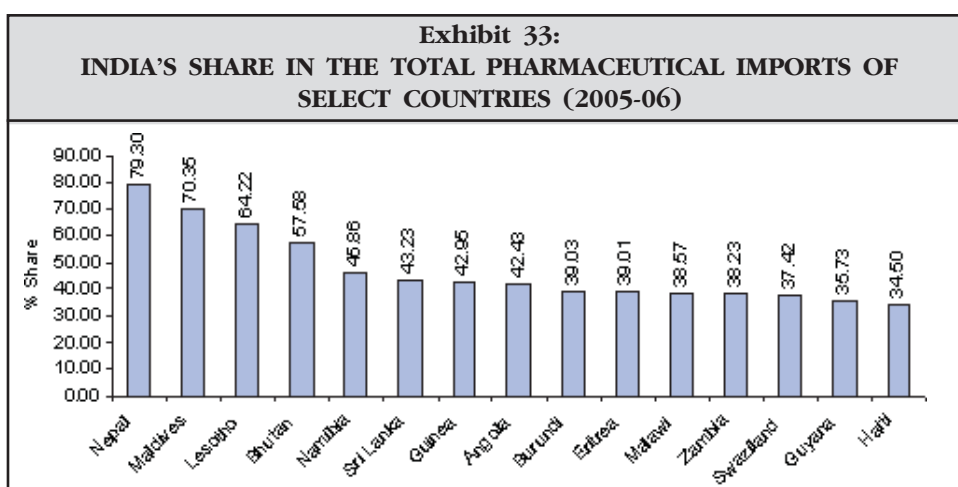
For many countries in Africa and South Asia, India is one of the principal source countries for

Countries	Rank		Share in Total Exports	
	2006-07	1991-92	2006-07	1991-92
USA	1	3	16.10	10.8
Germany	2	2	5.05	12.9
Russia	3	1	4.92	25.6
UK	4	5	3.31	3.4
Brazil	5	18	2.99	0.1
China	6	Below 20	2.61	NA
Nigeria	7	6	2.37	2.9
Canada	8	Below 20	2.13	NA
South Africa	9	Below 20	1.17	NA
Turkey	10	Below 20	1.17	NA

SOURCE: Directorate General of Commercial Intelligence and Statistics.

pharmaceutical imports. Nepal, Maldives, Bhutan and Sri Lanka in South Asia; Lesotho, Namibia, Guinea, Angola, Burundi, Eritrea, Malawi, Zambia, Swaziland in Africa, source large share of their pharmaceutical import requirements from India. However, in large developed country markets such as USA, UK, Canada and

Germany, India's share is insignificant (less than 1 percent). Thus there is still immense potential for growth as India's share in the total pharmaceutical import of many of these countries is still very low. These markets provide Indian pharmaceutical companies growth opportunities to expand business.



**Table 23:
EMERGING EXPORT DESTINATIONS FOR INDIAN PHARMACEUTICAL
PRODUCTS**

Country	Share in total exports	
	1991-92	2006-07
Brazil	Negligible	2.99
Canada	Negligible	2.13
Israel	Negligible	2.09
Ukraine	Negligible	1.92
South Africa	Negligible	1.77
Turkey	Negligible	1.77
Mexico	Negligible	1.66
UAE	Negligible	1.36

SOURCE: Directorate General of Commercial Intelligence and Statistics.

Table 24: INDIA'S SHARE IN TOTAL PHARMACEUTICAL IMPORTS OF SELECT COUNTRIES	
Countries	Share
USA	0.84
Germany	0.24
UK	0.83
Belgium	0.03
France	0.11
Netherlands	0.41
Italy	0.07
Canada	0.20
Japan	0.15
Switzerland	0.07
Australia	0.56

SOURCE: Directorate General of Commercial Intelligence and Statistics.

Many Indian companies are experiencing significant growth in their overseas sales and are constantly exploring new markets. Table - 25 shows the share of overseas sales in the total earnings of select companies. It may be noted that for most of these companies more than half of their earnings come from overseas operations. USA is the major market for most of the global pharmaceutical companies due to the market size and growth opportunities.

Ranbaxy sells 96 products in the USA approved by the US-FDA. For Divi's Laboratories the share of exports in total earnings is as high as 90%. Out of which almost 40% comes from the USA and another 34% from European market. Research based pharmaceutical companies like

Table 25: SHARE OF EARNINGS FROM OVERSEAS MARKETS (2005-06)		
Sl. No	Companies	% Share
1	Divi's Laboratories	90
2	Dr. Reddy's Laboratories	66
3	Ranbaxy Ltd	75
4	Matrix Laboratories	67
5	Wockhardt Ltd	63
6	IPCA Laboratories	53
7	Aroubindo Pharma	53
8	Cipla Ltd	50
9	Glenmark Pharma	42
10	Sun Pharma	38

SOURCE: Annual Reports of the companies

Glenmark Pharmaceuticals are also experiencing high revenue growth from overseas operations. Africa also shows great potential for Indian pharmaceutical companies. Ranbaxy, the first Indian company to venture into African continent is generating about US\$ 100 million every year, which is 7% of the company's global revenue.

Different companies focus in different therapeutic segments to enter the global market. Many have strategic motives behind such moves. Wockhardt for example obtained regulatory approvals in the US to sell its diuretic Furosemide injection, which is a widely used drug to remove excess water from body. Focusing on injectables is a strategy on the part of the company as

regulatory process for approvals of sterile injectables are complex, which limits the number of competitors.

CONTRACT RESEARCH

Two major concerns (though independent but have links to each other) for many big pharmaceutical firms in the recent years are:

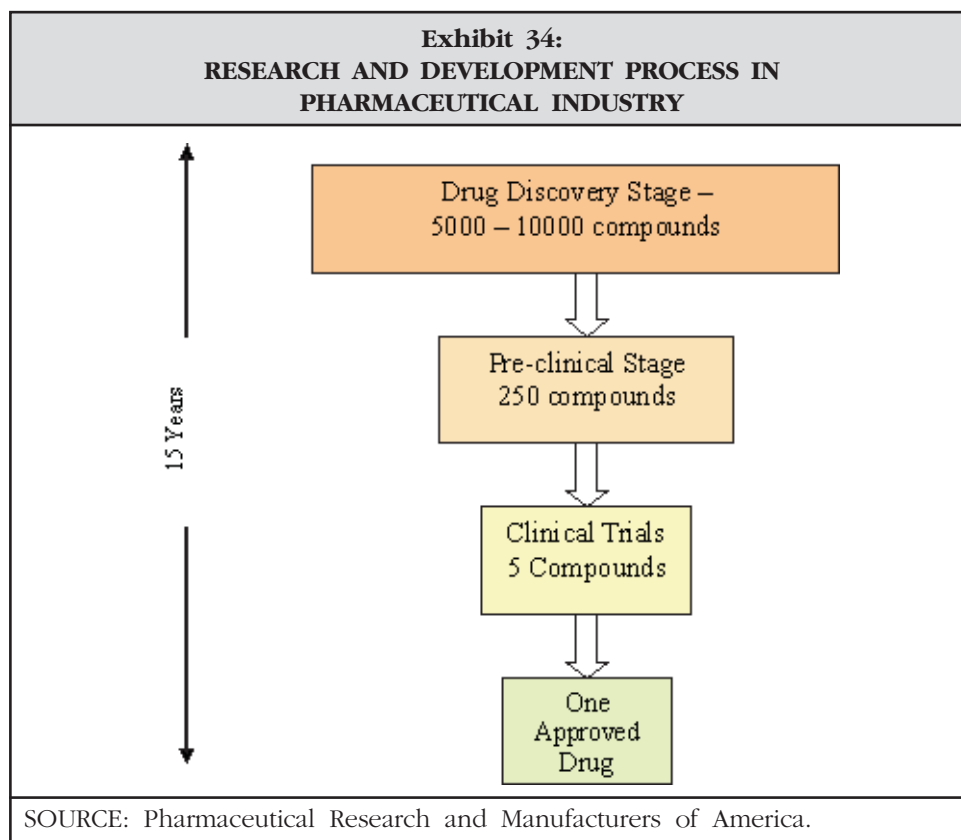
- a) Many blockbuster drugs are going off-patent in the coming years putting pressure on top pharmaceutical companies to undertake greater level of R&D activities to keep-up the growth of both top-line and bottom-line;
- b) Increasing timeline of drug discovery and development, prolonged regulation-mandated testing, complex review processes, rapidly escalating R&D expenditures and competition are compelling pharmaceutical companies to outsource various R&D related activities.

Many studies have pointed out that developing a new medicine is a long and costly process, while the chances of success are very low. There are also estimates of the cost of developing a drug, including cost of capital and failures, which is estimated to be over US\$ 800 million. Cost of developing a biologic medicine is estimated to be US\$ 1.2 billion. Statistics show that only 1 out

of 5000 compounds tested eventually reaches the consumers, and only 3 out of 10 drugs that reach the market would earn enough money to recover the cost incurred on R&D. Thus, many top ranking pharmaceutical firms are increasingly facing the pressure to bring out new products into the market while endeavouring to reduce cost for R&D. It is estimated that globally, on an average, 20% of R&D is sourced outside the company either on a contract basis or on an investment basis. This trend provides possibilities of outsourcing the R&D work to low cost destinations like China and India.

Contract research includes drug discovery and pre-clinical as well as clinical research. Clinical trials are used to determine whether a new drug or treatment is safe and effective. Globally the market size of contract research was around US\$ 10 billion in 2005 and is expected to exceed US\$ 20 billion by 2009. The contract research business in India is valued at US\$ 100 - 120 million. India has certain advantages in this regard, which include:

- ❖ A well-developed pharmaceutical industry with manufacturing base;
- ❖ Low R&D cost;
- ❖ Availability of qualified scientific man power;
- ❖ Large patient population base for clinical trials.



All these parameters have made India an attractive destination for many big pharmaceutical companies to source out their R&D activities, particularly clinical trials. Besides, being a member of WTO, India has moved towards TRIPS compliance, and clinical trials conducted in India are no longer confined to evaluating new medicine for their own market. Many companies are outsourcing contractual arrangement with Indian firms as also undertake R&D activities by setting up wholly owned Indian subsidiaries.

Given the pressing need to develop new drugs, many big pharmaceutical companies are tying up with Indian producers to develop NCEs for global market. For example, GSK and Ranbaxy have entered into an arrangement for drug discovery and clinical development, covering a wide range of therapeutic areas. According to the deal, Ranbaxy will identify potential drugs and develop them in initial stages, while GSK will take care of the later stages of clinical trials. Similarly, AstraZeneca has tied up with Torrent pharmaceuticals Ltd for research and discovering drugs for

treating hypertension. Another firm Aurigene Technologies Ltd, a subsidiary of Dr. Reddy's Lab has announced two separate tie-ups to discover potential drugs; one with a US company, Forest Laboratories Holdings Ltd, to develop novel small molecule drug candidate for obesity and metabolic disorder, and the other one with Merck Serono International S.A to work on identifying small molecule drugs to treat autoimmune diseases.

Government of India is also taking some initiatives to encourage contract R&D by setting up infrastructure for pre-clinical research for vaccine and drug development in the country. The Indian Council of Medical research (ICMR) is setting up two such large facilities, one in Mumbai and the other in Hyderabad. Besides, the Government has also

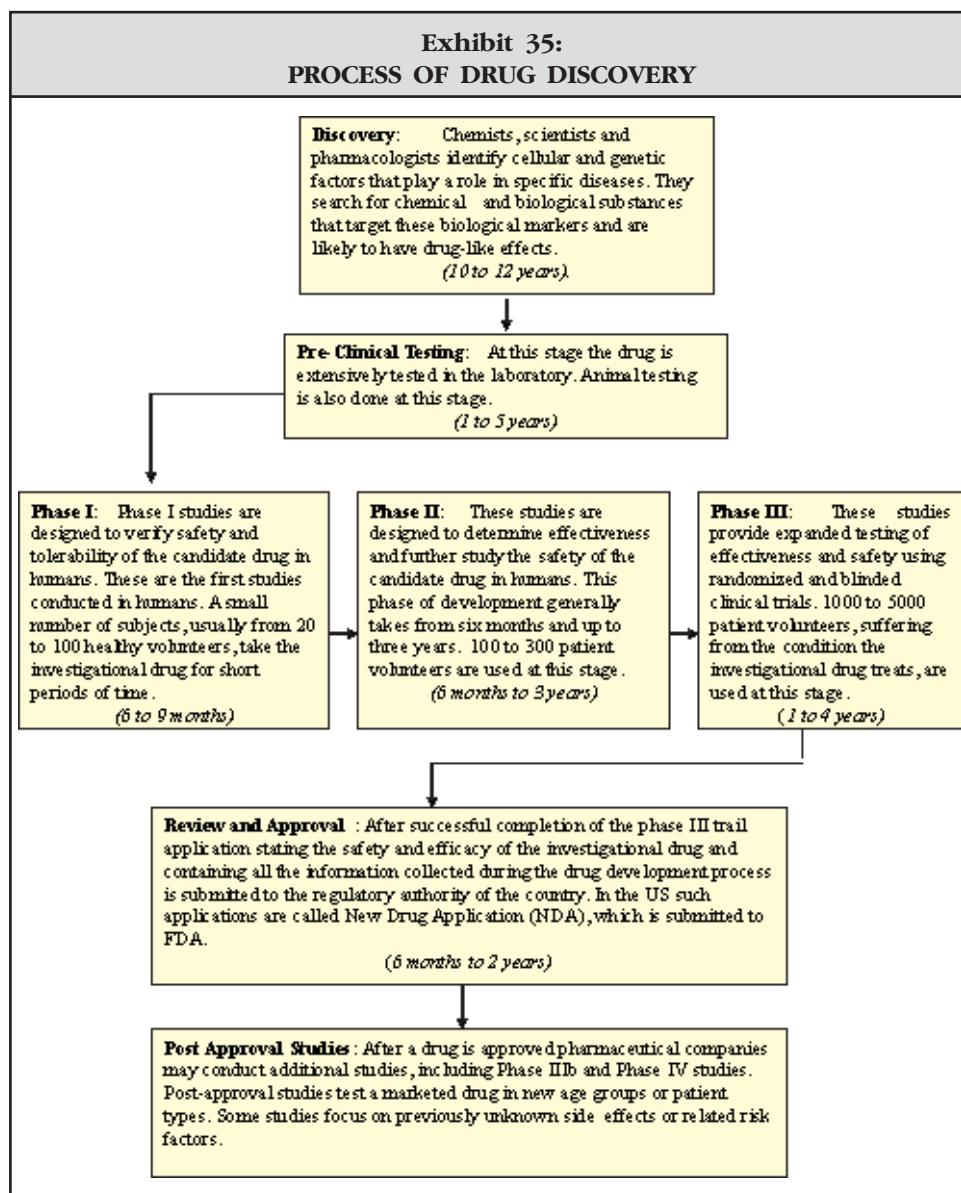
reduced the time taken for regulatory clearances to conduct clinical studies in India.

Some of the Indian pharmaceutical companies that have entered into contract research business are listed in Table - 26.

CONTRACT MANUFACTURING

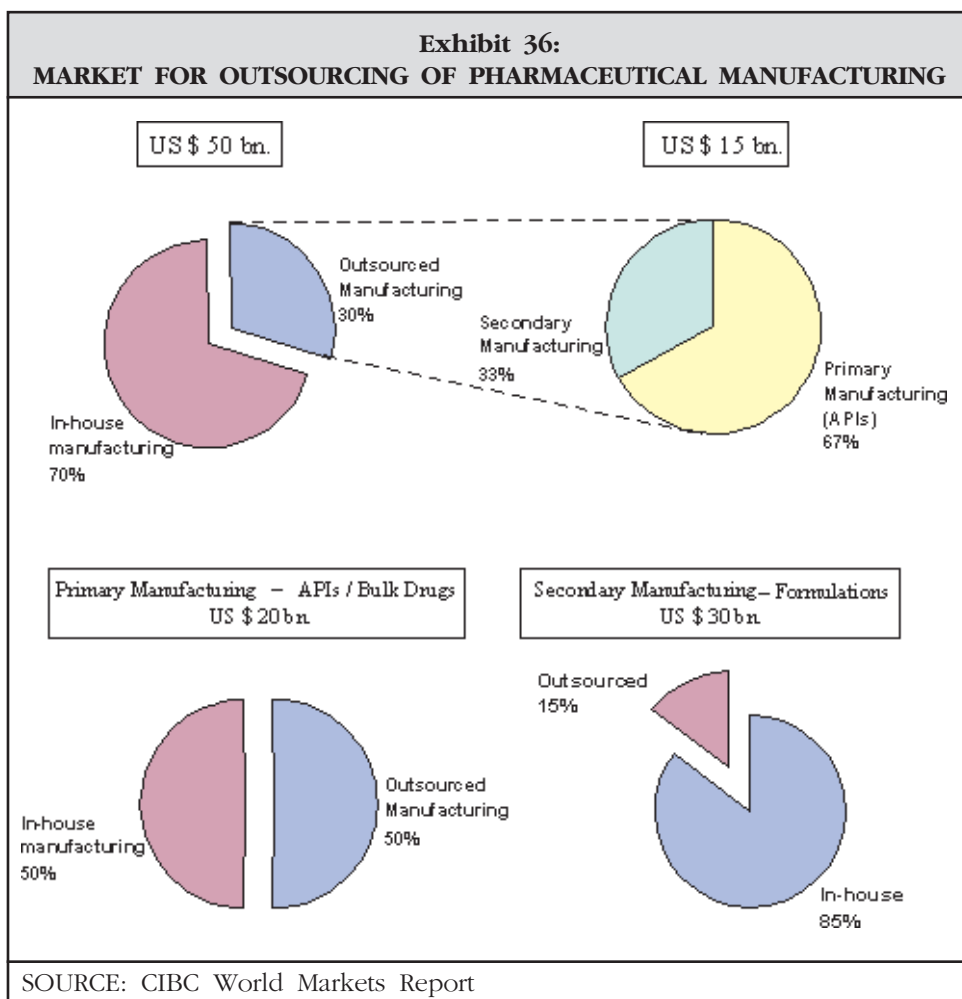
With the increasing pressure on the margins, major pharmaceutical companies are outsourcing their manufacturing activities (along with R&D activities) to low cost destinations like India and China. It has been estimated that almost 30% of the global manufacturing activities are outsourced in the pharmaceutical sector. Out of the total manufacturing activities outsourced, more than two-thirds are related to outsourcing of primary

Table 26: INDIAN PHARMACEUTICAL COMPANIES IN CRAM BUSINESS	
Companies in Contract Research (excluding Clinical Trials)	Clinical Trials
Nicholas Piramal	Clingene (Biocon)
Aurigene (DR. Reddy's)	Jubilant Clinsys (Jubilant Organosys)
Syngene (Biocon)	WellQuest (Nicholas Piramal)
GVK Biosciences	Synchron
Jubilant Organosys	Vimta Labs
Divi's Laboratories	Lambada
Suven Lifesciences	Siro Clinpharm
Dr Reddy's Laboratories	Relience Life Sciences
Vimta Labs	Asian Clinical Trials (Suven Life Sciences)
	CliniRx
SOURCE: IDMA, 2007	



manufacturing (APIs, intermediates) and the remaining one-third is related to outsourcing of secondary manufacturing in dosage form.

It is estimated that the cost of setting up of a FDA approved manufacturing plant in India is almost half of the cost to be incurred in USA.



Labour cost in India is cheaper by 20% to 30%, as compared to developed countries. Initial capital expenditure is also much lower in India as compared to other developed countries. India has the largest number of US-FDA approved manufacturing plants, outside USA. Automatic approval of FDI upto 100% in this sector has encouraged the outsourcing trend further. All these factors have encouraged many large

producers from developed countries to outsource manufacturing of pharmaceuticals to Indian producers.

Contract manufacturing may include manufacturing of Active Pharmaceutical Ingredients (APIs) for New Chemical Entities (NCEs) or generics. Indian pharmaceutical firms are engaged in the contract manufacturing of patented drugs, custom synthesis and scale-ups,



specialized generics, old generics and old molecules. Some of the Indian firms providing these services are illustrated below.

Nicholas Piramal has entered into contract manufacturing in 2003, investing close to US\$ 200 million in this segment. Additional investment is envisaged in the coming years towards creating additional capacity for the contract manufacturing business. The company has already announced six contracts and expects contract manufacturing to account for 50% of total revenue. GlaxoSmithKline has outsourced contract manufacturing of API to Indian pharmaceutical companies like Disham Pharma, Shasun Chemicals, Matrix Laboratories and Divi's Laboratories.

CO-MARKETING ALLIANCES

Another growth strategy adopted by many Indian firms is entering into co-marketing alliances with foreign firms to market their products in various markets. Such alliances are expected to be beneficial to both the parties. Wockhardt, for example, has entered into a marketing arrangement with Bayer AG for marketing of the anti-diabetic drug Acarbose. The company has also signed an in-licensing agreement with Crawford Healthcare of UK to market Viticolor, a skin camouflage gel for topical application for patients suffering from Leucoderma. Wockhardt is also introducing a new generation Hepatitis-A vaccine named Biovac-A, under the license from Zhejiang Pukang

Services	Companies
§ Patented drugs, custom synthesis and scale-ups	<ul style="list-style-type: none"> ● Disham Pharma ● Divi's Labs ● Matrix Labs
§ Specialized generics	<ul style="list-style-type: none"> ● Nicholas Piramal ● Shasun Drugs ● Matrix Labs
§ Old generics and old molecules	<ul style="list-style-type: none"> ● IPCA Labs ● Shasun Chemicals ● Jubilant Organosys ● Torrent Pharma ● Morepan
SOURCE : Contract Research and Manufacturing Services in India, Cygnus Business Consulting and Research, 2006	

Biotechnology Company Ltd of China.

Similarly, Lupin Ltd. signed an in-licensing agreement with ItalFarmaco, a leading Italian pharmaceutical company. As per the Agreement, Lupin will exclusively market their cardiovascular critical care product, Enoxaparin Sodium injection, in pre-filled syringes under the brand name "LUPENOX", in the Indian market. Nicholas Piramal has entered into an in-licensing agreement with AstraZeneca, to manufacture and export Tetmosol, Amonosurfuram soap, which is anti-scabies in select markets. For the domestic market also, the company has entered into in-licensing agreement with a number

of companies. One such agreement is with Biogen Idec, USA for marketing Avonex, a leading life-saving therapy for Multiple Sclerosis, in India and Nepal.

Co-marketing alliances are taking place not only among Indian and foreign producers, but also among Indian producers. Recently, Jupiter Bioscience entered into a 10-year co-marketing agreement with Ranbaxy, under which the company would license out to Ranbaxy five generic peptide drugs worth US\$ 3 billion at innovators price. It is believed that this tie-up helps Jupiter Biosciences to bring its products to international market rapidly, as Ranbaxy already has strong presence in the global market.

5. THE ROAD AHEAD

Strategies such as greater level of R&D activities, patent filings, contract manufacturing, contract research, inorganic growth strategy through acquisitions, co-marketing and co-licensing arrangements have helped the Indian pharmaceutical industry to surge as a global player. However, challenges are also ahead for the Indian pharmaceutical industry with changes in global trends and TRIPS compliant patent regime in India. These are discussed in this chapter.

STRENGTHENING R&D

R&D is crucial for the growth of pharmaceutical industry; thus success of pharmaceutical industry depends more on successful R&D activities. This factor has more relevance for India since new product patent regime has been introduced to comply with TRIPS Agreement. Many Indian pharmaceutical companies have realized the need to enhance their R&D activities well in time and accordingly raised the R&D spending considerably. In the year 2005-06, Indian pharmaceutical industry has spent over US\$ 550 million in R&D activities (both under

current and capital account). This accounts for around 5% of total sales of the industry. Though the industry level R&D intensity is well above the average R&D intensity in manufacturing sector (estimated to be 1%), compared to developed countries, such as USA, Germany, it is very low. In USA, pharmaceutical companies spend more than 17% of their sales in R&D activities. In Europe, pharmaceutical R&D accounts for 18% of their total industrial R&D expenditure. The biggest spenders among the European countries are the UK, Germany and France. Thus, it is important for Indian pharmaceutical industry to scale up their R&D intensity to strengthen their position in the global market place.

MARKET PENETRATION: ACQUISITIONS IN LDCs

During the last decade, the activities of the Indian pharmaceutical companies have expanded globally. Enhancement of activities have not only been limited to exports but also by way of the industry's presence in manufacturing / marketing activities in various

countries. Many Indian pharmaceutical firms have made a number of acquisitions in various countries. More than two-third of these acquisitions have been in the developed country markets of Europe and USA. However, there lies the scope for further penetration in other countries, especially least developed countries. Under the TRIPS Agreement, such countries have been granted with longer transition period (upto 2016) to become TRIPS compliant. Indian generic producers can play a big role in these markets, through acquisitions and penetrate further in such markets.

BIOPHARMA CONVERGENCE

Biopharmaceuticals have witnessed significant growth in recent times. The size of world biopharmaceuticals industry has been estimated at over US\$ 60 billion in 2005 with more than 200 drugs being marketed. India is being recognized as one of the important players in the biopharmaceuticals market. Many Indian pharmaceutical firms are going for convergence with biotech industry for development of new drugs. However, it is indeed very important to accelerate the level of convergence and the pace. It may be mentioned that by 2010, more than US\$ 10 billion worth of biopharmaceutical products are expected to lose patent protection in developed country markets.

Recently, USA has passed Food and Drug Administration (FDA) Revitalization Act to allow drug makers to sell generic version of biopharmaceuticals after 12 years of exclusive marketing rights by the innovator company. This will give ample opportunities for Indian pharmaceutical firms to tap this large biogenerics market.

MORE THRUST ON PATENT FILING

Indian pharmaceutical industry has comparative advantage in R&D due to its high intellectual base and low cost of R&D. However, number of patents filed by and approved for India is lower as compared to many developed as well as developing countries. World Intellectual Property Organisation (WIPO), in its Report on Worldwide Patent Activities (2006) has analysed the patent filings / holdings of various countries with other indicators such as population of the country, GDP, and R&D spending. Such analysis allows for more meaningful cross-country comparisons by weighting the number of patents by different measures of country size and economic activity.

Differences in the use of the patent system across countries may account for some of the differences in numbers of patent filings. Therefore, differences in patent filings per population, GDP or research and

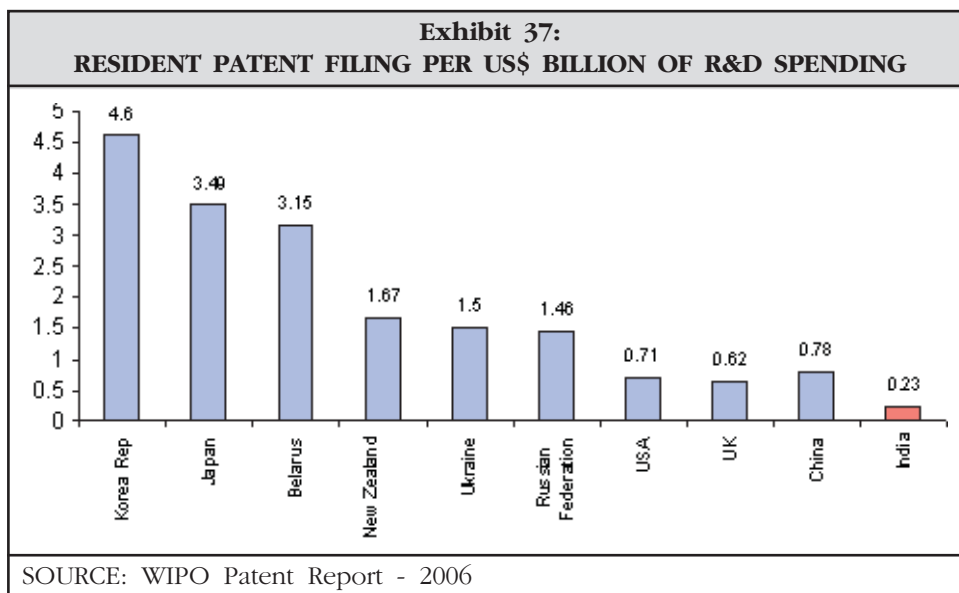
development expenditure do not necessarily mean that one country is more inventive than another or more efficient in its allocation of expenditure. However, measuring patent filing with other national indicators enables the researchers to understand the potential that could be tapped in a country.

Japan and the Republic of Korea have the highest rate of resident patent applications per million of population at 2,884 and 2,189, respectively. The corresponding data for India is only 7. Similarly, Japan and Republic of Korea have highest resident patent filings per US\$ billion of GDP at 107 and 116, respectively

**Table 27:
RESIDENT PATENT FILING BY SELECT INDICATORS**

Country	Resident Patent Filings Per Million Population	Resident Patent Filings per Billion of GDP*
Japan	2884	107.3
Korea RP	2189	116.2
USA	645	17.2
Germany	587	22.6
China	51	9.4
India	7	2.3

* Measured in constant prices for the year 2000 in PPP terms
SOURCE: WIPO Patent Report - 2006



as compared to India's 2.3. Going by the resident patent filing per US\$ billion of R&D spending, India occupies only the 30th position. Countries like Republic of Korea and Japan are much ahead of India when compared even by this indicator. Thus Indian companies need to intensify their patent filing activities to remain globally competitive.

SAFETY AND PRODUCT QUALITY: MENACE OF SPURIOUS DRUGS

Ensuring safety and quality of the products produced and marketed by the pharmaceutical industry is another major concern. In recent times, a number of FDA approved blockbuster drugs like Vioxx (developed by Merck Inc.) had to be withdrawn from the market as questions were raised regarding their safety standards. In addition to safety and quality, in the Indian context, the problem of spurious drugs has become a cause of concern. It is alleged that a large percentage of the world's spurious drugs are produced in India. It is estimated that in the domestic market about 20% of drugs sold are alleged to be spurious. The problem is more acute in remote areas like villages. Traditionally, antibiotics, anti-protozoals, anti-malarial, anti-hormone and steroids were the candidates for faking. Of late, even lifestyle drugs (such as nutritional, anti-diabetes, anti-hypertensives and

cancer drugs) are also allegedly produced. Though, spurious drugs may not endanger the life, they can be ineffective in curing the patients. Re-usage of drugs past their expiry date is yet another menace. Filling spurious drugs in used medicine bottles is also allegedly prevalent. This calls for stricter safety and product quality regulations for the industry.

PRICING STRATEGIES

Pricing strategies for launching of pharmaceutical products have never been more of a key issue as it is right now. Globally there is a trend of falling bulk drug prices. According to industry sources, bulk drug prices have been falling over the years due to highly competitive environment. Till few years ago, competition from China used to drive the falling of global bulk drug prices. However, of late the prices of Chinese bulk drugs have been showing an increasing trend. This may primarily be due to phasing out of incentives and support mechanism to Chinese pharmaceutical industry by the Government. At present, the intense competition amongst Indian bulk drug manufacturers in various markets is the prime driver of falling cost of bulk drugs in global market.

Indian pharmaceutical industry is in the process of developing many potential new pharmaceutical products for world markets. While

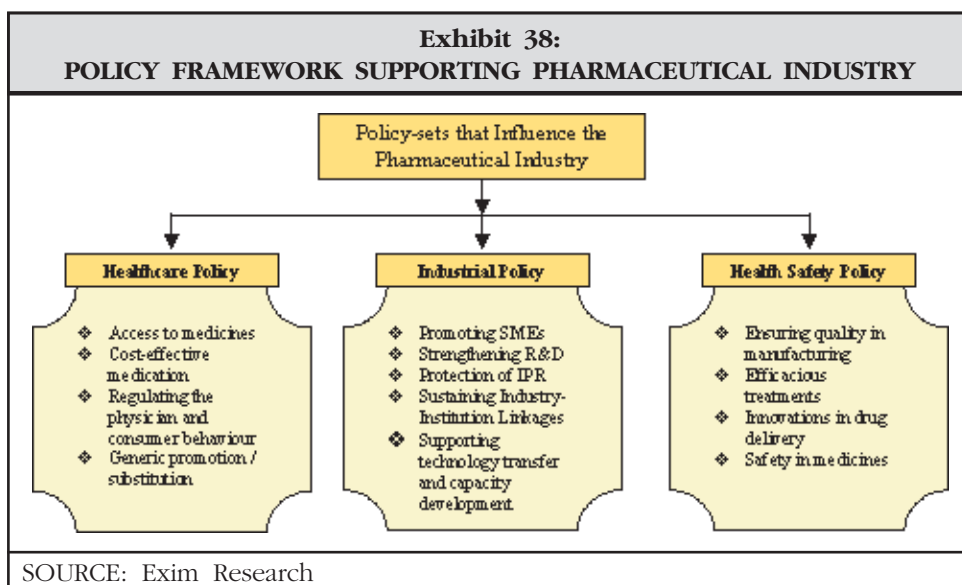
some of them are in early stages of development, others are well on their way to commercialization. Business wisdom dictates that early assessment of a product's concept and its potential to generate acceptable investment returns is crucial when deciding allocation of funds for undertaking R&D activities. In addition, there are flexibilities provided under WTO to control prices through compulsory licensing and parallel importation. Therefore it is crucial to consider optimal pricing strategies while determining the viability of launching a drug. The need for viable pricing strategies increases in an era of rising R&D costs.

REGULATORY / POLICY REFORMS

Policies that influence Indian pharmaceutical industry can be broadly categorized into healthcare policy, industrial policy and health

safety policy. Some of the concerns of the industry, regulators and end users are addressed through such policy framework. These include: accessibility and affordability of medicine by common man, ensuring quality and efficacy of medicines, strengthening the growth of generic medicines, promoting R&D, technology transfer, strengthening industry-institutional linkages and capacity development.

It may be noted that reforms are required at regulatory / policy level too. At present, both central and state Governments regulate Indian pharmaceutical industry. While the state regulatory authorities are responsible for regulating manufacturing, sales and distribution of drugs, the national regulator approves new drugs and clinical trials, controls import of drugs and also coordinates among the state bodies. A Task Force, headed by Dr. Pronab



Sen, set up by the Government of India (for exploring options other than price control for achieving the objective of making life saving drugs available at affordable levels) has also recommended that in the long run functions of drug regulation and price control should be with the same agency, so that an integrated regulatory system exists in the economy.

Strengthening of regulatory system is also required in the context of new patent regime. There is a need to simplify procedures and shorten the timeline for various approvals. Strengthening of regulatory system with respect to data protection is also crucial. Such measures will help in attracting R&D outsourcing to India. With India emerging as a major hub for contract research, particularly clinical trials, it is important to ensure good clinical practices in the country. Most of such issues are addressed in Draft Pharmaceutical Policy also.

TACKLING PATENT INFRINGEMENT CASES

The growth path of the generic players is witnessing turbulence with increasing number of IPR related litigations. Legal cost associated with challenging of patent infringement cases turn out to be very high for many pharmaceutical companies. Problems associated with increasing number of patent infringement cases should be tackled by the Indian

firms through proper understanding of the patent laws and move towards greater compliance. Another approach, which has already been adopted by many pharmaceutical companies is 'out of the court settlement', which may prove to be much cheaper and faster to resolve patent related disputes. There are various methods of settling a patent case out of the court. In some cases, the generic company agrees to delay its entrance in the market in exchange of certain benefits, such as licenses to other patents. In some cases, there may be reverse payments, in which the innovator company prefers to pay a lump sum amount to keep away the generic manufacturer from the market. In some other cases, both innovator firm and generic player agree to sell the product at a price fixed by the innovator and erode competition.

SKILL DEVELOPMENT

Pharmaceutical industry is highly R&D intensive. In order to remain globally competitive the industry requires pool of highly skilled manpower. India has already made its mark in scientific research in the world, with large pool of scientific man-power. The education system in India with wide network of universities providing quality science education has helped immensely in this regard. However, with the changing composition of economic growth there is an emerging trend

of students not preferring science stream for career opportunities. This may lead to shortage of qualified manpower in highly research oriented economic activities such as pharmaceuticals. The problem of skilled professionals migrating to developed countries is also prevalent in India. It is estimated that OECD countries are likely to witness shortage of skilled professionals in the years to come. In such a scenario, 'Brain Drain' to OECD countries is likely to increase from developing countries like India. This would increase the shortage of skilled professionals in the domestic market, especially in knowledge-oriented sectors like pharmaceuticals. Thus, it is important to devise policies that would attract more students to the science stream. Many countries give both financial and fiscal incentives in the form of grants and preferential loans, to encourage

students to opt for science streams. Establishing strong industry academia linkages will also play a significant role in this regard.

SUM-UP

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

SELECT DEFINITIONS

Formulation	A medicine processed out of, or containing without the use of any one or more bulk drug or drugs.
New Chemical Entity	A drug compound that meets novelty criteria, as defined in national law.
Active Pharmaceutical Ingredient (API)	The primary, active ingredient (s) of a final pharmaceutical product, produced in the first stage of pharmaceutical production and usually in bulk quantities.
Generics	A generic drug is an off patent drugs, which have received market approval based on proof of bio-equivalence to the originators product. It is a copy that is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.
Blockbuster drugs	Product with very large sales – usually US\$ 1 billion or more.
Regulated market	Markets with more established system of patent laws and relatively more sophisticated regulatory systems for drug quality control.
Unregulated or (Less regulated) markets	Markets with less established systems of patent laws and relatively less sophisticated regulatory systems for drug quality control.
Abbreviated New Drug Application (ANDA)	The registration application of a product that is less novel than a NCE – e.g. a variant on an existing formulation, a new dosage form or a new indication for an existing product.
New Drug application (NDA)	The registration application for a more novel product than those products that would qualify for an ANDA application.
Drug Master File (DMF)	The registration application of an API

**ANNEXURE 1: SHARE OF PHARMACEUTICAL
EXPORTS IN TOTAL
MERCHANDISE EXPORTS OF
SELECT COUNTRIES**

Country / Year	2000	2001	2002	2003	2004	2005
USA	1.68	2.12	2.33	2.65	2.93	2.86
Switzerland	12.98	16.39	16.73	17.33	18.21	19.20
China	0.72	0.74	0.71	0.65	0.55	0.50
Canada	0.44	0.56	0.62	0.86	0.94	0.97
Japan	0.57	0.68	0.67	0.68	0.63	0.56
India*	4.35	4.70	5.02	5.18	5.00	4.74
Germany	2.49	3.16	2.84	3.49	3.74	3.86
UK	3.77	4.66	5.36	6.37	6.52	5.85
Spain	1.83	2.10	2.70	2.81	2.72	3.08
Italy	2.65	3.01	3.52	3.42	3.19	3.52
Netherlands	1.90	2.17	2.98	2.90	3.13	2.73

SOURCE: World Trade Organisation
* SOURCE for India DGCI&S.

**ANNEXURE 2: SHARE OF SELECT
COUNTRIES IN GLOBAL
PHARMACEUTICAL EXPORTS**

Country / Year	2000	2001	2002	2003	2004	2005
USA	12.09	11.63	9.67	9.37	9.70	9.54
Switzerland	9.62	10.15	9.19	8.86	9.05	9.24
China	1.65	1.49	1.39	1.40	1.31	1.39
Canada	1.13	1.09	0.93	1.14	1.21	1.28
Japan	2.52	2.06	1.68	1.56	1.43	1.22
India*	1.77	1.56	1.59	1.61	1.61	1.79
Germany	12.67	13.62	10.48	12.80	13.76	13.80
UK	9.92	9.58	8.99	9.50	9.16	8.27
Spain	1.94	1.85	2.03	2.14	2.01	2.18
Netherlands	4.08	3.78	4.36	4.19	4.52	4.07
Italy	5.88	5.54	5.37	5.00	4.56	4.83

SOURCE: World Trade Organisation
* SOURCE for India DGCI&S.

ANNEXURE 3: SELECT DRUGS GOING OFF-PATENT (2008-09)

Sl No	Brand Name	Generic Name	Manufacturer	Patent Expiration date
1	Fosamax	Alendronate	Merck	Feb. 6, 2008
2	Camptosar	Irinotecan	Pfizer	Feb. 20, 2008
3	Effexor/XR	Venlafaxine	Wyeth	June 13, 2008
4	Zymar	Gatifloxacin	Allergan	June 29, 2008
5	Dovonex	Calcipotriene	Bristol-Myers Squibb	June 25, 2009
6	Kytril	Granisetron	Roche	July 29, 2008
7	Risperdal	Risperidone	Janssen	June 29, 2009
8	Depakote	Divalproex sodium	Abbott Laboratories	July 29, 2010
9	Advair	Fluticasone and salmeterol	GlaxoSmithKline	Aug. 12, 2008
10	Serevent	Salmeterol	GlaxoSmithKline	Aug. 12, 2008
11	Casodex	Bicalutamide	Bristol-Myers Squibb	Oct. 1, 2008
12	Trusopt	Dorzolamide	Merck	Oct. 28, 2008
13	Zerit	Stavudine	Bristol-Myers Squibb	Dec. 24, 2008
14	Lamictal	Lamotrigine	GlaxoSmithKline	Jan. 22, 2009
15	Vexol	Rimexolone	Alcon Labs	Jan. 22, 2009
16	Avandia	Rosiglitazone	GlaxoSmithKline	Feb. 28, 2009
17	Topamax	Topiramate	Johnson & Johnson	March 26, 2009
18	Glyset	Miglitol	Pfizer	July 27, 2009
19	Acular	Ketorolac tromethamine	Allergan	Nov. 5, 2009
20	Xenical	Orlistat	Roche	Dec. 18, 2009
21	Valtrex	Valacyclovir	GlaxoSmithKline	Dec. 23, 2009
22	Avelox	Moxifloxacin	Bayer	Dec. 30, 2009

SOURCE: Express Scripts and Generic Pharmaceutical Association

ANNEXURE 4: LIST OF RECENT OVERSEAS ACQUISITIONS BY INDIAN PHARMACEUTICAL FIRMS

Sl. No.	Year	Target Company	Country	Acquirer	Value (US\$ Million)
1	2002	BMS Laboratories (including Subsidiary Meridien healthcare (UK))	UK	Dr. Reddy's Laboratories	9.05
2		Veratide brand of Proctor & Gamble GmbH	Germany	Ranbaxy Laboratories	NA
3		Liquid Drug Mfg facility of Signature Pharmaceuticals	USA	Ranbaxy Laboratories	NA
4		10% stake in Nihon Japan Pharmaceutical Industry	Japan	Ranbaxy Laboratories	NA
5		Stake in Caraco	USA	Sun Pharmaceuticals	NA
6		Duvadilan Brand of Solvay Pharmaceuticals	Belgium	Solvay Pharma India	2.85
7	2003	Aurobindo Tongling (Datong) Pharmaceuticals	China	Aurobindo Pharma	NA
8		Synthon Chiralgenics Corpn	USA	Suven Pharmaceuticals	NA
9		Yutopar brand of Solvay Pharmaceuticals BV	Netherlands	Alembic	NA
10		CP Pharmaceuticals	UK	Wockhardt	10.85
11		Formulation Business of Alpharma SAS	France	Zydus Cadila	5.5 (E)
12		Das Pharmaceuticals Pty	South Africa	Strides Arcolab	NA
13		RPG Aventis SA	France	Ranbaxy Laboratories	NA
14	2004	Caroco Pharmaceutical Laboratories	USA	Sun Pharmaceutical Lds	42
15		Laboratories Klinger	Brazil	Glenmark Pharmaceutical	5.2
16		10% stake in Xechem International Inc	USA	Alembic	3.6
17		Trigenesis Therapeutics Inc	UK	Dr. Reddy's Laboratories	11
18		Esparma GmbH	Germany	Wockhardt	11
19		Dobutrex Brand Rights from Eli Lilly & Co	USA	Nicholas Piramal India	NA
20		2 FDA- Products from Clonmel Healthcare	Republic of Ireland	Glenmark Pharmaceutical	NA
21		Rhodia Organique Fine Ltd	UK	Nicholas Piramal India	14
22		Wyeth Laboratories (Sordil, Brand)	USA	Ipsa laboratories Ltd	

Sl. No.	Year	Target Company	Country	Acquirer	Value (US\$ Million)
23		80% stake in two belgium based pharmaceutical companies	Belguim	Jubilant Organosys Ltd	16
24		Two FDA approved products from Clonmel Healthcare Ltd	Ireland	Glenmark Pharmaceutical	NA
25		The global inhalation anaesthesia (IA) business of Rhodia Organique Fine Ltd	UK	Nicholas Piramal India	14
26	2005	MCHEM Pharma Group (Acquisition of 60%)	China	Matrix Laboratories	NA
27		instituto Biochimico Industria Farmaceutica Ltd (Brand acquisition-Uno-Ciclo)	Brazil	Glenmark Pharmaceutical	NA
28		generic pharmaceuticals	USA	Jubilant Organosys Ltd	8.3
29		Mchem Group (60% stake)	China	Matrix Laboratories	NA
30		Target research Associates	USA	Jubilant Organosys Ltd	33.5
31		Higuchi	Japan	Enzyme technologies Ltd	NA
32		Roche's API facility	Mexico	Dr. Reddy's Laboratories	59
33		Efarmes SA	Spain	Ranbaxy Laboratories	
34		Nihon pharmaceutical Industry (40% stake)	Japan	Ranbaxy Laboratories	NA
35		Bouwer Bartlett Pty Ltd	South Africa	Glenmark Pharmaceutical	NA
36		Able Laboratories Inc	New Jersey	Sun pharmaceutical Industries Inc (wholly owned susidiary of Sun pharmaceutical)	NA
37		Dishman Pharmaceuticals	UK	Synprotec Ltd	4
38		Novus Fine Chemicals	USA	Malladi Drugs and Pharmaceuticals	23
39		Heumann pharma GmbH & Co generica KG	Germany	Torrent pharmaceutical	30
40		Docpharma NV	Belgium	Matrix Laboratories	263
41		64% equity in Trinity laboratories Inc and its wholly owned subsidiary Trigen Laboratories Inc	USA	Jubilant Organosys Ltd	12
42		17% stake in BioSyntech Inc	Canada	Nicholas Piramal India	7
43		Sterile manufacturing facility	Poland	Strides Arcolab	8
44		70% stake in Beltapharm	Italy	Strides Arcolab	2
45		Valeant Pharma's manufacturing operations	Hungary	Sun Pharmaceuticals	10
46	2006	Nova pharmaceutical Ltd	Australia	Marksans Pharma Ltd	NA
47		Beltapharm Arzneimittel GmbH	Germany	Dr. Reddy's Laboratories	582



Sl. No.	Year	Target Company	Country	Acquirer	Value (US\$ Million)
48		Senetek Plc's (Patents, Trademarks and automated manufacturing equipment)	USA	Ranbaxy Laboratories Ltd	NA
49		Terapia SA	Romania	Ranbaxy Laboratories Ltd	324
50		Ethimed N V	Belgium	Ranbaxy Laboratories Ltd	NA
51		Artiflex Finance CVA (51% stake)	Belgium	Lupin Ltd	NA
52		Pfizer Inc's (Morpeth Plant)	UK	Nicholas Piramal India	NA
53		Mundogen	Spain	Ranbaxy Laboratories Ltd	12.5
54		Industrial Farmaceutica Cantabria S.A (acquisition of branded generic business)	Spain	Wanbury Ltd	50 (E)
55		Medcases Inc.	USA	Indegene Lifesystems	NA
56		Betabs pharmaceutical	South Africa	Ranbaxy Laboratories Ltd	70
57		Milpharm Ltd	UK	Aurobindo Pharma	NA
58		NICK's Drug store	USA	Natco Pharma	NA
59		Unbranded generic business of Allen SpA, A division of GSK	Italy	Ranbaxy Laboratories Ltd	NA
SOURCE: Mergers and Acquisitions, CMIE					

**ANNEXURE 5: CHANGES IN DESTINATION OF INDIA'S
PHARMACEUTICAL EXPORTS
(% SHARE)**

Sl No	Country	1991-92	1992-93	1993-94	1994-95	1995-96	1996-97	1997-98	1998-99	1999-00	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07
1	USA	10.8	12.6	12.0	10.7	12.4	11.7	10.9	11.5	9.9	11.2	16.6	17.1	14.7	15.5	14.1	16.0
2	Germany	12.9	15.5	11.9	11.4	10.0	8.5	7.6	6.0	4.8	4.9	5.1	6.0	6.1	5.0	4.9	5.0
3	Russia	25.6	8.8	14	11.2	8.9	8.9	7.2	3.2	7.3	5.6	4.8	4.0	4.3	4.3	4.8	4.9
4	UK	3.4	3.6	3.4	2.9	3.4	3.4	4.1	3.1	2.9	2.7	2.8	3.3	3.2	3.3	3.8	3.3
5	China	0.1	0.2	0.4	0.8	1.1	1.9	2.5	2.8	2.7	3.0	3.8	3.5	3.1	2.2	3.5	2.6
6	Nigeria	2.9	6.0	4.6	3.5	3.5	2.9	2.8	3.4	3.9	3.9	3.8	2.8	2.5	2.5	2.3	2.3
7	Italy	1.7	2.9	1.6	2.2	2.1	2.5	2.9	2.4	2.3	1.7	1.2	1.3	1.8	1.6	1.9	1.8
8	Spain	1.3	1.9	1.6	1.3	2.2	2.2	2.2	2.5	2.0	1.8	1.7	1.6	1.9	1.9	1.5	1.8
9	Netherlands	1.6	2.7	2.8	4.2	4.2	3	3.5	3.3	2.9	2.1	1.9	1.9	1.8	1.6	1.8	1.7
10	Viet Nam	0.2	0.3	0.9	2.7	2.6	2.4	10.9	11.5	9.9	2.1	16.6	17.1	14.7	15.5	1.8	1.5

SOURCE: Directorate General of Commercial Intelligence and Statistics

RECENT OCCASIONAL PAPERS	
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