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An Introduction to the Indian Pharmaceutical Industry

An In-Depth Study of India's Domestic and Outsourced Pharmaceutical Market

October 2007

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Abstract

The Indian pharmaceutical industry addresses domestic and global markets through goods and services that encompass finished drug dosages (Formulations), Active Pharmaceutical Ingredients (API), Research and Development (R&D), and related contract services.

The domestic market comprises manufacture and sales of various formulations and APIs. The global market consists of export of formulations, APIs, and outsourcing services related to R&D and manufacturing, also known as Contract Research and Manufacturing Services (CRAMS).

Domestically, major revenue sources are the production and sales of Active Pharmaceutical Ingredients and generic drugs. Most of the drugs sold in India are generic formulations. Manufacturers' preference for generic drugs is attributable to the low cost of research and the absence of an enforceable product patent regime prior to 2005. With more than 24,000 companies, the Indian pharmaceutical market is highly fragmented. This market – which in 2006 reached revenues of $ 6.2 B and is growing at a compound annual growth rate (CAGR) of 13.5% -- is projected to reach $ 10.3 B in revenues by 2010. Contributing factors to industry growth include increasing population, an increasing consumer base especially in the middle and upper income brackets, the need for improved healthcare infrastructure, and Indian companies' reverse-engineering skills. Among the major identified therapeutic segments, the bulk of Indian pharmaceutical sales is attributable to anti-infective drugs (18%), gastro-intestinal drugs (11%), and cardiovascular drugs (10%).

India also is the destination for a large and growing volume of outsourced production and R&D by Multinational Pharmaceutical Companies (MPCs). Key factors that make India an attractive outsource include its lower costs of production and R&D, the highest number of plants certified by the US FDA outside the US (75), and highly skilled professionals. The services of these Indian companies include Contract Manufacturing Organizations (CMOs), Contract Research Organizations (CROs) and other related services. The Indian pharmaceutical outsourcing market shows a healthy CAGR of 37.6% and is expected to increase from $ 929 M in 2006 to $ 3.33 B by 2010.

In 2006, the Indian pharmaceutical CRO market was worth $ 265 M, with clinical trials contributing more than half of revenue. Projected figures for 2010 are $ 600 M, with a CAGR of 22.7%. Most of these companies are developing first-rate facilities for pre-clinical trials as well as expertise in research-biology and research-chemistry. This is expected to further accelerate growth in the near term. The Indian pharmaceutical CMO market was worth $ 620 M in 2006, and derives 60% of revenues from chemical synthesis. It is well set to reach $ 2.5 B by 2010 with a CAGR of 41.7%. Indian companies offering other pharmaceutical-related outsourced services (accounting, sales and marketing, etc.) yielded revenues of $ 44 M in 2006 and have the potential to generate revenues reaching $ 229 M by 2010.

India's share in the global pharmaceutical outsourcing industry is expected to increase from 1.8% (in 2006) to 4.4% (in 2010). The various advantages offered by the Indian pharmaceutical outsourcing industry are attracting global investment on a scale that will spur the growth of the Indian pharmaceutical industry as a whole.

Indian pharmaceutical industry addresses domestic and global markets

The Indian Pharmaceutical Industry—a Focused Study of Domestic and Outsourced Markets

The Indian pharmaceutical industry addresses the needs of two broad categories of market—domestic and global.

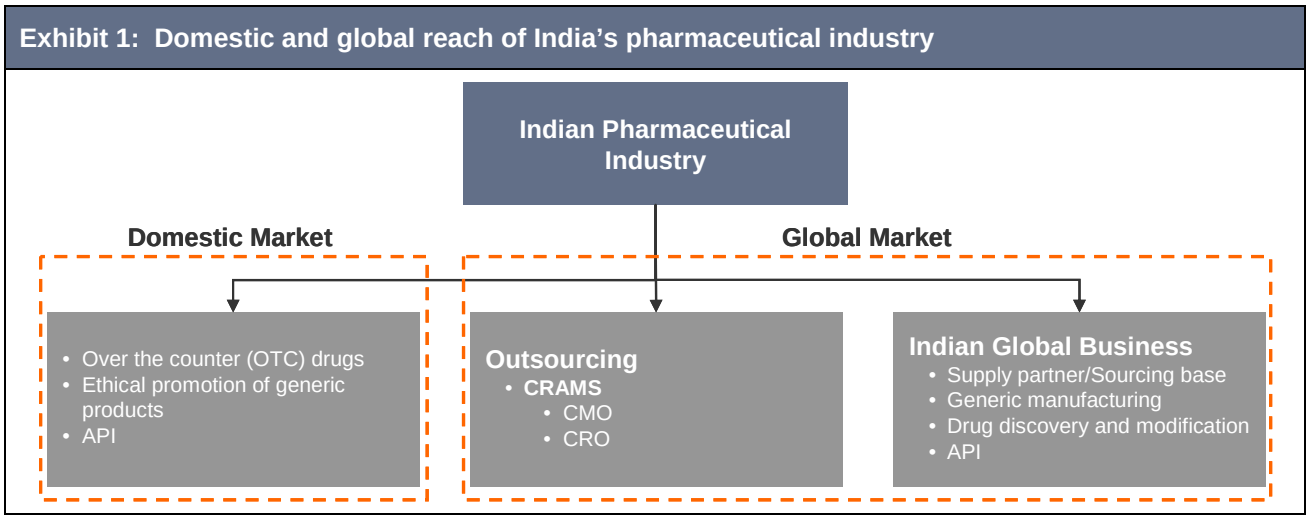
Domestic revenue is generated through sales and promotion of various drug categories. These include:

- Ethical drugs (available only with written instructions from a doctor to a pharmacist)
- Over-the-Counter (OTC) drugs
- Active Pharmaceutical Ingredients (APIs).

Global market needs are met with services that include:

- Outsourced R&D and manufacturing services, also known as Contract Research And Manufacturing Services (CRAMS), implemented by Contract Manufacturing Organizations (CMO) and Contract Research Organizations (CRO).
- Manufacturing and sale of generics and APIs for the overseas market
- Drug discovery/modification.

Exhibit 1: Market for the Indian pharmaceutical industry[1]



Diversity of generic drugs in the Indian pharmaceutical market

An Introduction to India's Domestic Pharmaceutical Market

Generic drugs form the bulk of what is sold in the Indian domestic pharmaceutical market. The various forms of generics include **"plain vanilla"** (standard unaltered form), **value-added drugs** (developed using innovative pharmaceutical techniques), and **branded generics** (generic drugs marketed by the company which developed the original molecule). An absence of product patent protection until the year 2005, low average disposable incomes of Indian drug purchasers, and the vast R&D investments of time and capital required to introduce new patented drugs are the chief reasons for the industry's focus on generic products rather than the more

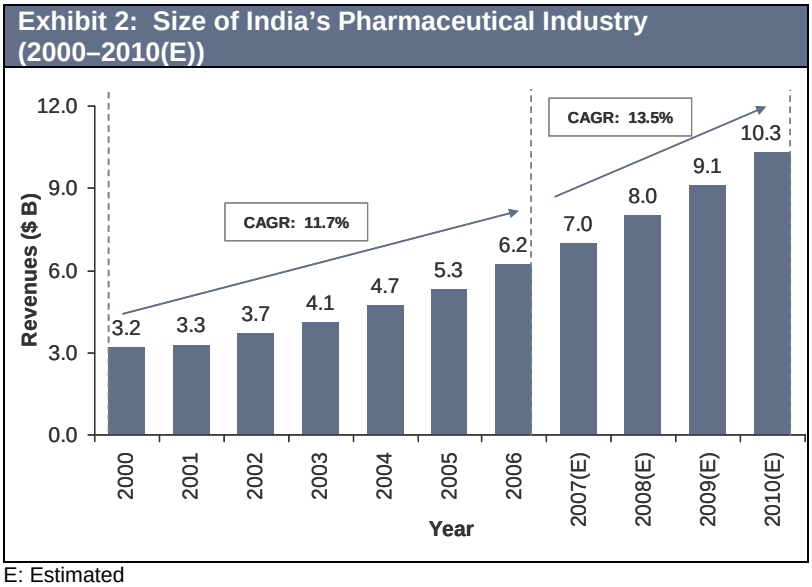
expensive research-based products of regulated markets in the US, Europe, and Japan. For instance, while Lipitor (Pfizer's cholesterol-lowering drug) costs 46 ¢ per tablet to a patient in the US, the generic form is available at only 6 ¢ per tablet in India. This price gap explains why India, despite having the world's second largest population, has a domestic pharmaceutical revenue ($ 6.2 B in 2006) lower than that of smaller countries like Japan ($ 60 B) and Germany ($ 27 B)

The Indian pharmaceutical market showed a CAGR of 11.7% between 2000–2006

Dynamics of the Indian Domestic Pharmaceutical Market

In 2006 the Indian pharmaceutical industry was worth $ 6.2 B. The 2000-2006 CAGR of 11.7% is projected to rise to 13.5% by 2010, yielding a $ 10.3 B market. In 2005, the Indian pharmaceutical industry ranked 13th in terms of value and 4th in terms of volume in the global market.

Exhibit 2: Industry growth between 2000–2010(E) ($ B)[2]



E: Estimated

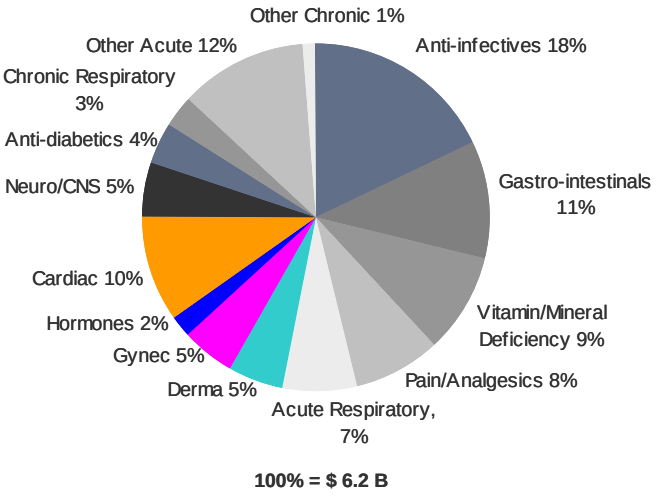
Key therapeutic segments

The key therapeutic segments are **anti-infectives (**18%**), gastro-intestinals** (11%)**, cardiovascular** (cardiac**), vitamins/minerals, analgesics, respiratory, dermatological** drugs**, gynecological** drugs**, hormones, neurological/CNS** drugs**,** and **anti-diabetics.** Among these, anti-infectives have conventionally been the highest-selling segment in the Indian market and are expected to continue to dominate the market in the near future with a growth rate of 20%. They are followed by gastro-intestinals, with a growth rate of 18%, and cardiac drugs, with a growth rate of 13%.

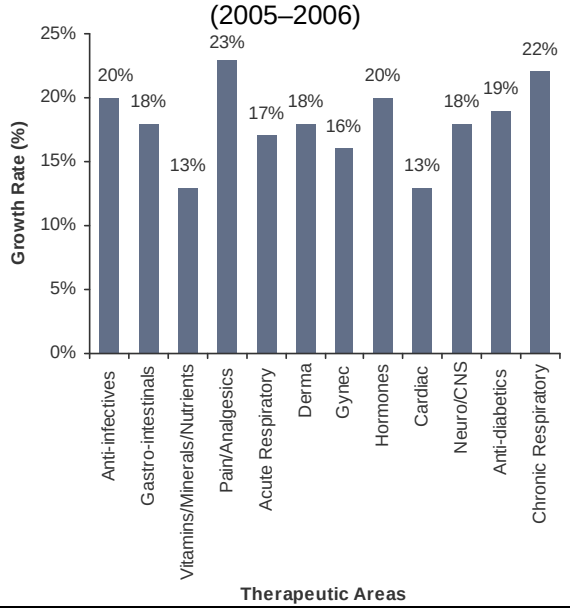
Exhibit 3: Area-wise sales and growth rates in 2006[3]

Exhibit 3: Area-wise Sales and Growth Rates in the Indian Pharmaceutical Industry in 2006

Area-wise Pharmaceutical Sales (2006)



Growth Rate of Therapeutic Segments (2005–2006)



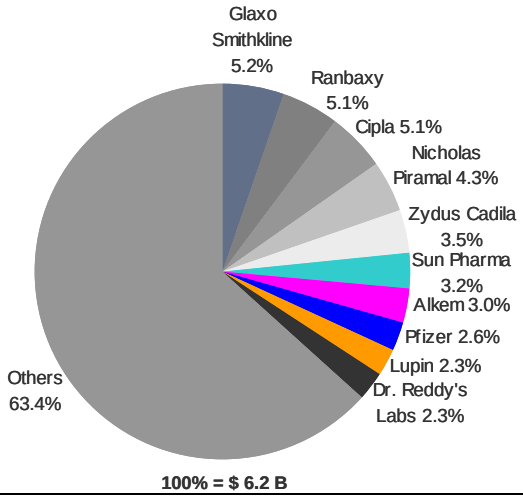
The top 10 players account for a market share of 36.6% with the leader contributing 5.2%

The Indian pharmaceutical market remains highly fragmented.[3],[4] Approximately 24,000 companies of various sizes vie for a share of the $ 6.2 B market. Of these, around 300 belong to the organized sector, and 15,000 to the small-scale (unorganized) sector. The rest of the companies are too small for economies of scale.

Exhibit 4: Market share and growth rate of key players [3]

Exhibit 4: Market Share and Growth Rate of Key Players in the Indian Pharmaceutical Industry

Market Share of Key Players (2006)



Growth Rate of Key Players (2005-2006)

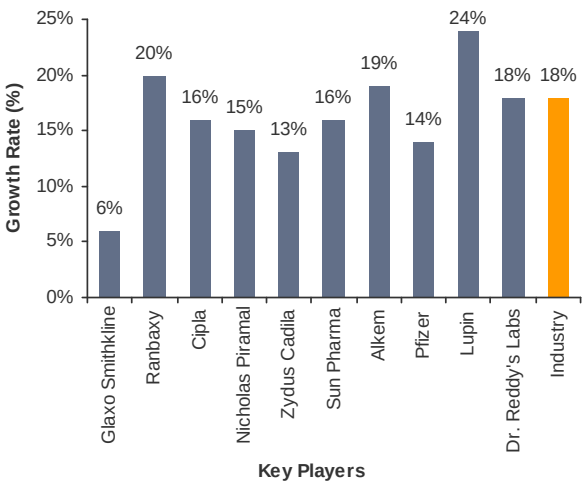


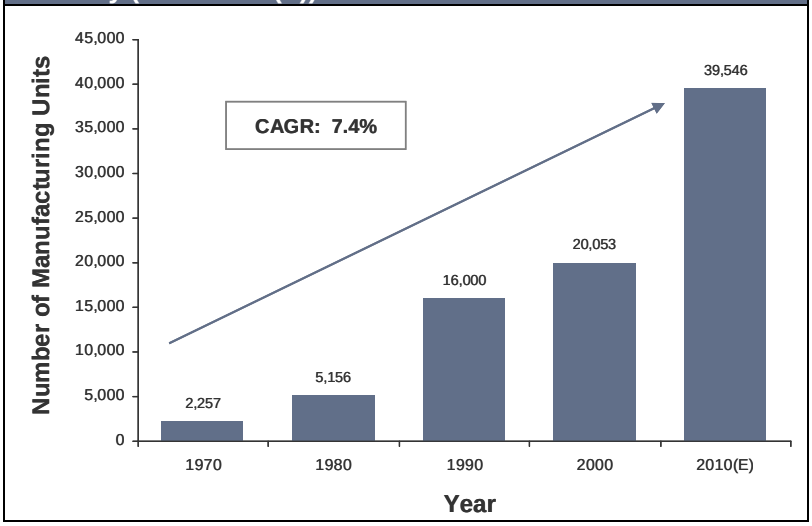
Exhibit 4 shows that the key players of the Indian pharmaceutical market are **GSK, Ranbaxy, Cipla, Nicholas Piramal, Zydus Cadila, Sun Pharma, Alkem, Pfizer, Lupin, and DRL.** These ten companies account for a market share of 36.6%. GSK, the largest player, contributes 5.2%, followed by Ranbaxy (5.1%) and Cipla (5.1%).

Despite the limits to growth caused by the market's fragmented nature, 2006 saw the pharmaceutical industry grow at a rate of 18% over the previous year. This is attributable to an increase in consumer expenditure on healthcare, as well as growth in health insurance. A detailed discussion of these positive drivers follows in the section titled "Growth Drivers of the Indian Domestic Pharmaceutical Market."

Market fragmentation is also reflected in the growing number of manufacturing units. Exhibit 5 shows that the number of manufacturing units has increased steadily from 2,257 in 1970 to 20,053 in 2000, and is expected to reach 39,546 by 2010 at a CAGR of 7.4%.

Exhibit 5: Manufacturing units in the Indian pharmaceutical industry 1970–2010(E)[1],[4]

Exhibit 5: Manufacturing Units in the Indian Pharmaceutical Industry (1970–2010(E))



There are several reasons for this spurt in the number of units.

Disparity in quality control investments between smaller units and larger players

Poor Regulatory Standards Result in Low Entry Barriers for Smaller Players.

The average investment of a small firm is $ 26,829. That of a larger unit averages $ 675,609. The Total Output/Net Fixed Investment is 52.1 for smaller units as compared to 30.8 for larger units, showing that productivity of small plants is unhampered by size. The output value per dollar invested in smaller plants is 69% higher than that of larger units, although the larger units enjoy various scale benefits like purchase of raw materials. Our research shows that lower investment of smaller units indicate a lack of investment in manufacturing infrastructure such as air control devices to check contamination, air conditioning, and effluent treatment plants.

Excise duty based on production costs helps smaller players

Excise Structure and Trade Margin

Up until January 2005, excise was levied on the cost of production. This worked against organized players, since excise on their higher production costs elevates overall product cost. On the other hand, this excise provided additional benefits to the low-cost manufacturers and further increased the manufacturing cost gap between small and large manufacturers. This gap is expected to widen as a result of the prevalence of under-invoicing among small manufacturers.

For small players with their own regional brands, there is a wide disparity between maximum retail price (MRP) and ex-factory costs. For small companies that sell unbranded generics, the MRP can be four to seven times the ex-factory prices.

Small marketers/manufacturers also gain by passing on a portion of the differential between the MRP and ex-factory cost to the trade channels (in some cases, including doctors) to encourage volume sales.

Growth-Drivers of the Indian Domestic Pharmaceutical Market

Despite fragmentation, the Indian pharmaceutical industry showed a CAGR of 11.7% during 2000–2006. Further growth is expected because of a number of key factors.

Increased life expectancy will boost the future growth of the Indian pharmaceutical industry

Life expectancy is on a rise[4],[5],[6]

The average life expectancy in India is 63 years as compared to 78 years in developed countries. However, India's improving healthcare delivery infrastructure has ensured the continued rise in life expectancy and maternity child care measures. There has been a strengthening of specific programs, such as the Expanded Program on Immunization (EPI) and the introduction of Oral Rehydration Therapy (ORT) in 1986–87. Ongoing measures seek to control local endemic diseases.

The consequent increase in life expectancy drives the growing proportion of an aging population -- the 60+ age-group will account for 11% of total population by 2021. This will further boost growth of the pharmaceutical industry.

Exhibit 6 Gender-wise change in life expectancy (2000–2005)[5]

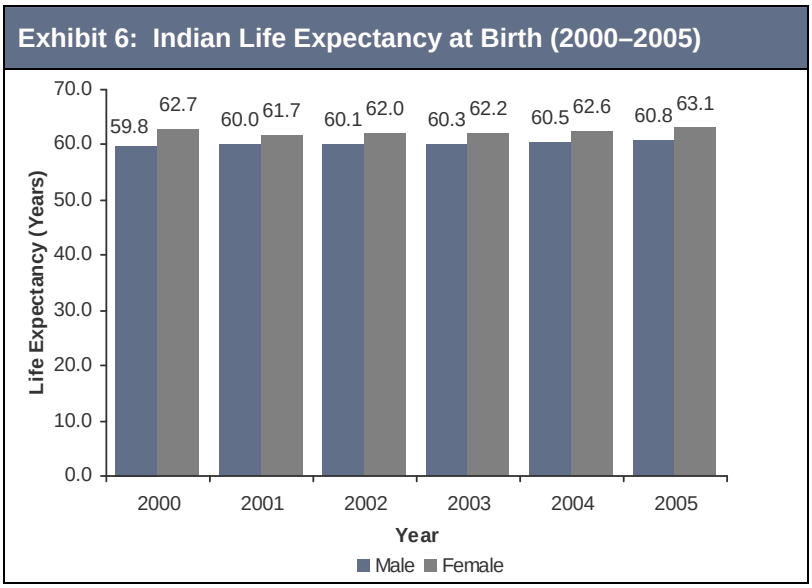
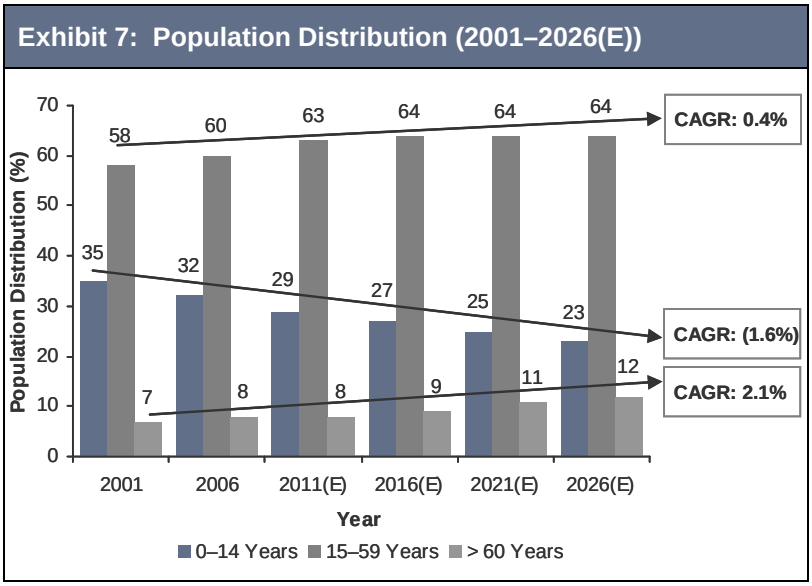


Exhibit 7 Age-grouped distribution of population[6]

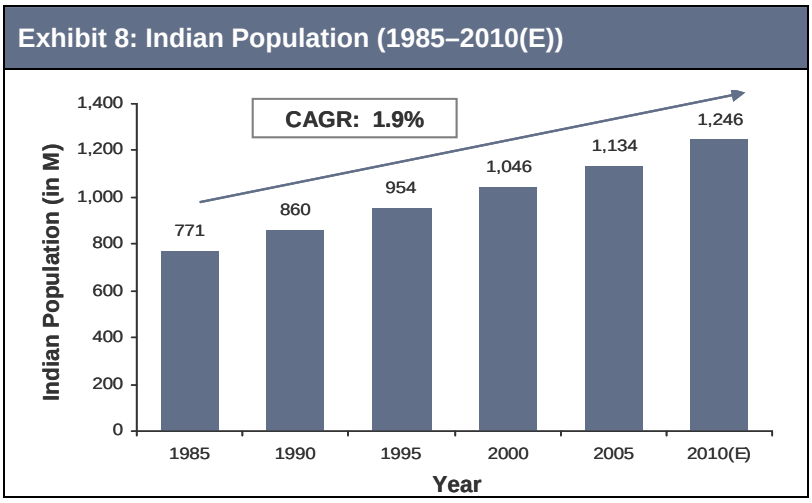


The growing elderly population is likely to boost the pharmaceutical industry

Rising population

With a population approximating 1.2 B, India is potentially a vast market for the pharmaceutical industry. The growing middle-class of around 300 M people has an increasing disposable income and higher healthcare expectations. Around 1/3rd of the middle class can afford quality private healthcare services, and this number is constantly growing. This points to increased healthcare spending and greater opportunities for the pharmaceutical market.

Exhibit 8 Indian population growth (1985–2010)[1],[6]



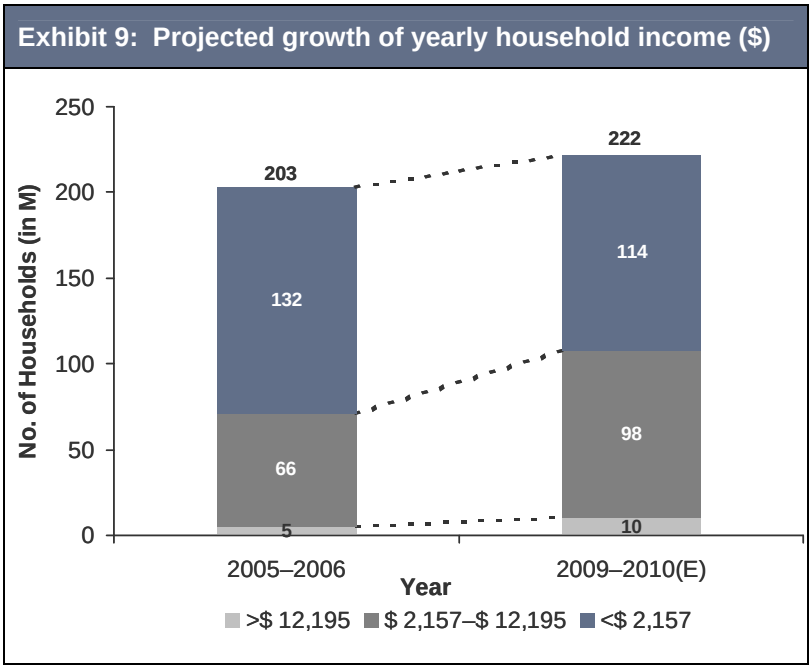
Number of middle-income households projected at 98 M by 2009–2010

Rising Income of Indian Households

Exhibit 9 shows that the number of middle-income households (income $ 2,275–$ 12,500) is expected to rise significantly.

This will translate into greater spending power in healthcare, further boosting the pharmaceutical industry.

Exhibit 9 projected growth of yearly household income (2005–2006 and 2009–2010(E))[6]



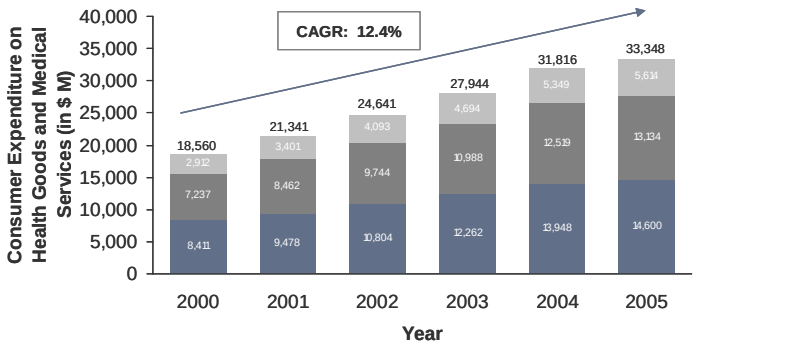
Consumer expenditure on healthcare showed a CAGR of 12.4% in 2000–2005

Increased Consumer Expenditure on Healthcare[5]

The years of 2000-2005 saw a shift in the Indian consumer's mindset, as evidenced by the increasing priority accorded to healthcare as a proportion of overall consumer expenditure. During this period, consumer expenditure on health goods and medical services showed a CAGR of 12.4%. There was an increase in consumer expenditure on pharmaceuticals, medical appliances/equipment (11.7%) as well as on outpatient services (12.7%). At 14%, consumer expenditure on hospital services showed the highest increase during 2000–2005. This reflects the primacy of healthcare as a growing concern for the Indian consumer.

Exhibit 10 Consumer expenditure on health goods and medical services[5]

Exhibit 10: Consumer Expenditure on Health Goods and Medical Services in India (2000–2005)



The growing numbers of healthcare insurance premium policies is likely to spur the Indian pharmaceutical market

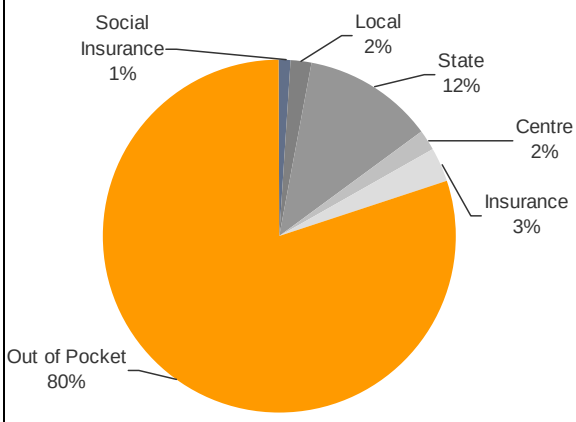
Increasing Penetration of Health Insurance[4],[7],[8]

In stark contrast to the US, where insurers pay more than 80% of the individual's healthcare cost, Indian insurers contribute a very small proportion. At present only 3% of the healthcare cost of an Indian patient is paid by insurers; 80% of costs are borne by the individual (refer exhibit 11). However, the insurance sector shows significant improvement, as evidenced by the 37.3% increase in the number of policies sold in 2003–2004 compared to 2001-2002. Sales of health insurance premiums written in India totaled $ 129.1 M in 2001. By 2006, sales rose to $ 711 M, a CAGR of 40.7%. By 2012, premium sales are projected at $ 3.8 B. This rise in healthcare insurance coverage is attributable to the Insurance Regulatory and Development Authority (IRDA) bill, which has lifted entry restrictions for private players and allowed foreign players to enter the market. Additionally, the increase in consumers' disposable income further boosts India's insurance sector.

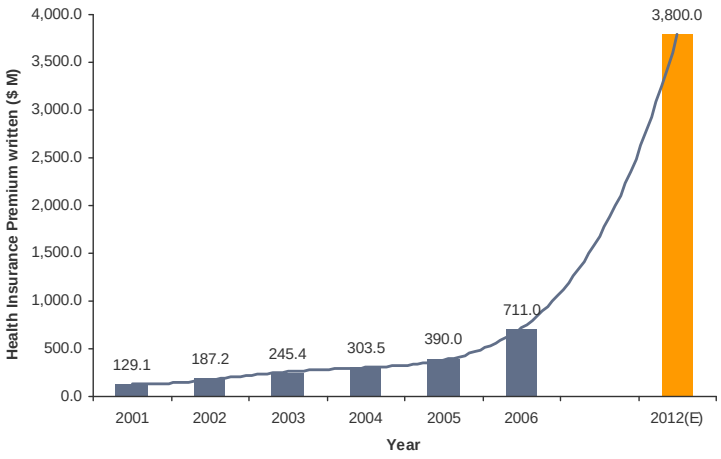
Exhibit 11 Patients' medical expenses contrasted with health insurance written in India[4],[7],[8]

Exhibit 11: Patients' medical expenses contrasted with health insurance written in India

Break-up of Medical Costs in India (2006)



Health Insurance Premium Written in India (2001–2012(E))



India's healthcare infrastructure compares unfavorably to other developing countries

Expanding Healthcare Infrastructure

Steep discrepancies exist between the healthcare infrastructure of India and that of developed countries.

Exhibit 12 Comparison of healthcare infrastructure between India and other developing and developed countries[4]

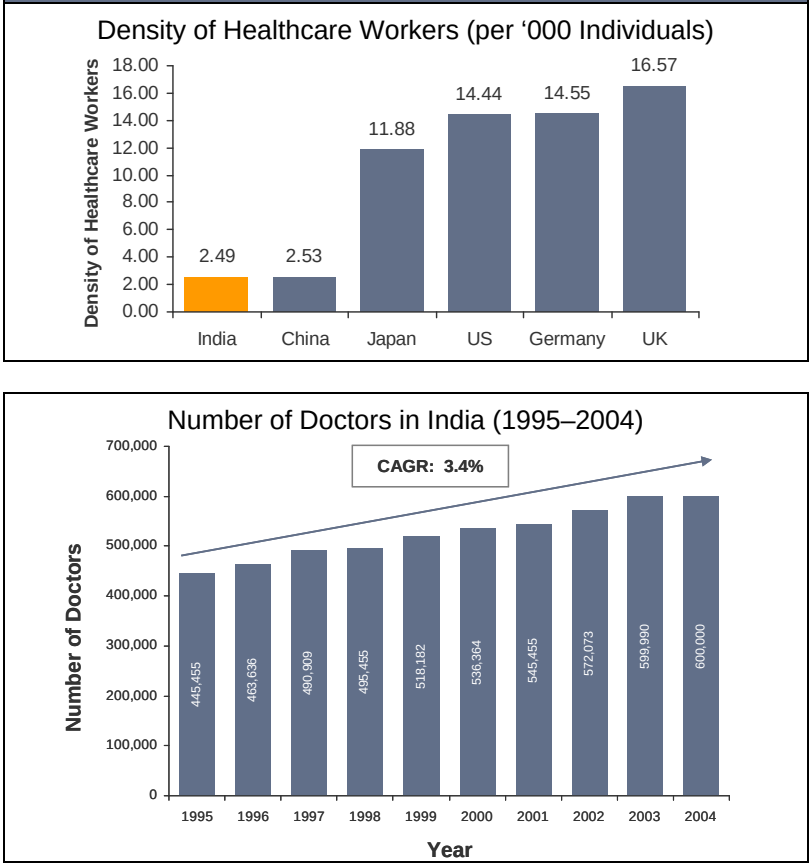
Exhibit 12: Comparison of healthcare infrastructure between India and other developing and developed countries

	India	Developing Countries	Developed Countries
Life Expectancy (Years)	63	65	78
Infant Mortality per '000 Births	70	59	6
Hospital Beds per '000 Population	1.5	4.3	7.4

India's low literacy rate and poor healthcare infrastructure are factors in the country's shortage of doctors and hospitals.

Exhibit 13 Healthcare worker density across 6 countries and number of doctors in India [1),4)]

Exhibit 13 Healthcare Workers density across 6 countries



At 1/6th that of the US, the density of healthcare workers (per '000) in India is very low. The majority of India's population lives in rural areas, and poor healthcare service penetration leaves them undersupplied and underprovided.

However, with increasing literacy rates and healthcare awareness, this trend shows signs of reversing. The number of doctors is increasing: from 445,455 in 1995 to 600,000 in 2004 (CAGR of 3.4%). The consequent increased penetration of healthcare infrastructure will add greater momentum to the overall healthcare sector.

Globally, hospitals account for 1/4th of pharmaceutical market sales. In India, the proportion is only 1/11th. An additional 780,000 beds over the next ten years will strengthen the hospital sector, thereby boosting the pharmaceutical market.

Government Incentives

Exhibit 14: Country comparison of healthcare spending by public and private sectors [4]

Exhibit 14: Healthcare spend by Public and Private Sectors (2006)

	Healthcare Spend as a Percentage of GDP		
Country	**Public Sector**	**Private Sector**	**Total**
Philippines	1.6	1.8	3.4
Pakistan	0.9	3.2	4.1
India	0.9	4.0	4.9
China	1.9	3.4	5.3
Russia	3.8	1.5	5.3
Mexico	2.5	2.9	5.4
UK	5.9	1.4	7.3
Japan	6.0	1.8	7.8
Italy	6.0	2.1	8.1
Brazil	3.4	4.9	8.3
Germany	8.0	2.6	8.6
Canada	6.6	2.5	9.1
US	5.8	7.2	13.0
World Average	**5.4**	**3.9**	**9.3**

Current statistics indicate that the Indian public sector share of healthcare as a percentage of GDP is less than that of developed nations. However, recent government measures are aimed at rectifying this situation.

The National Rural Health Mission (NRHM) launched in April 2005 seeks to provide effective healthcare to the rural population with a special focus on 18 states with weak public health indicators and/or weak infrastructure. These states are Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Himachal Pradesh, Jharkhand, Jammu and Kashmir, Manipur, Mizoram, Meghalaya, Madhya Pradesh, Nagaland, Orissa, Rajasthan, Sikkim, Tripura, Uttarakhand, and Uttar Pradesh.

In the finance bill of 2007–2008, the Government allocated a sum of $ 3,822 M to healthcare, a 22% increase from the previous year. As a result, the government's demand for pharmaceutical products is expected to increase in the next 4–5 years.

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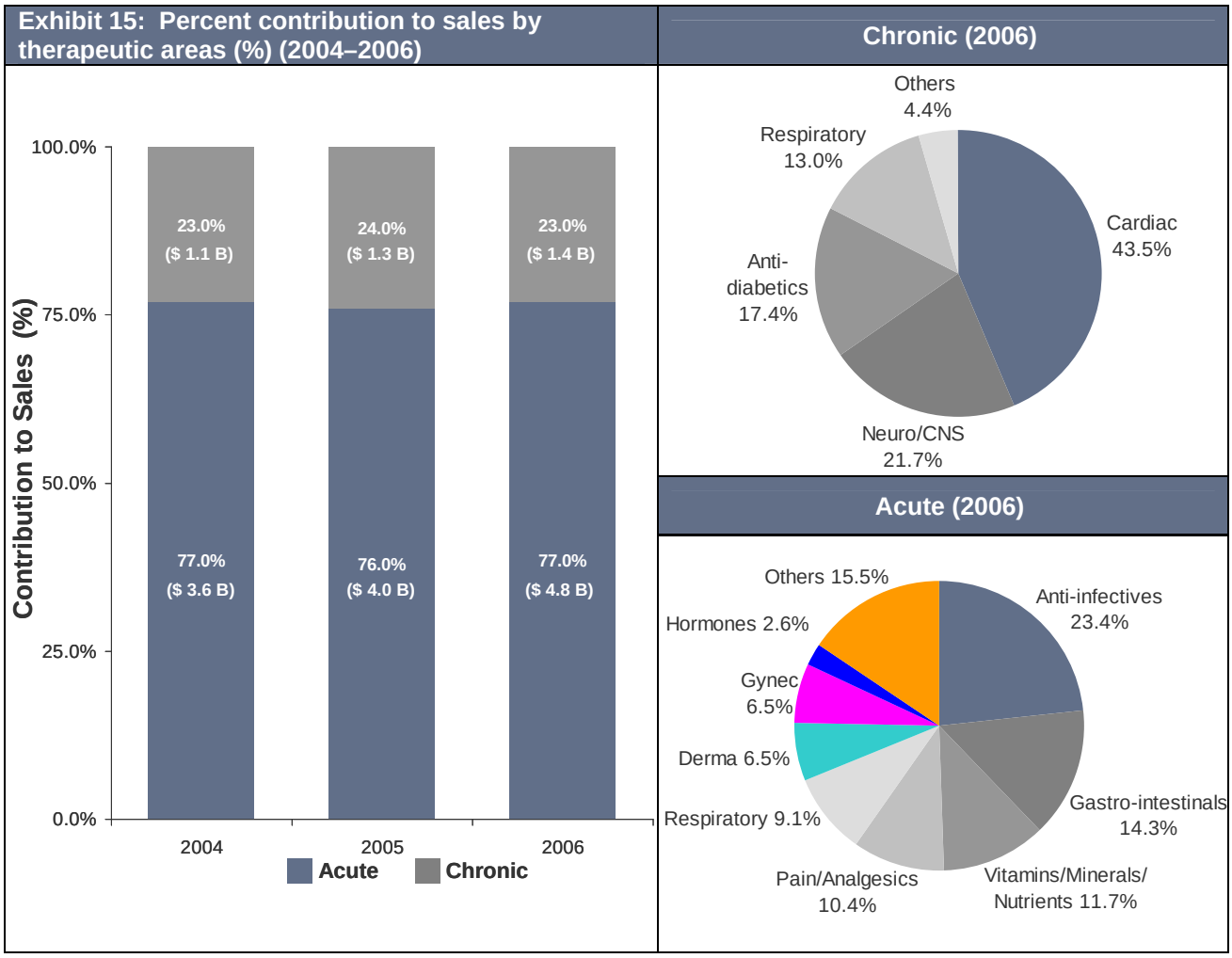
Drug Sales for Acute and Chronic Diseases[1],[3],[9]

As shown in Exhibit 15, revenues from the chronic and acute segments showed a consistent increase in 2004–2006, a trend that is expected to continue.

Exhibit 15: Percentage of contribution to sales by major therapeutic areas[1],[3]



Although the market is dominated by drugs used to cure acute diseases, the chronic segment is expected to reverse this trend and drive growth in the long term

Increasing Urbanization Is Leading to a Surge in Chronic Diseases

India's population is expected to show an increase in lifestyle-related diseases such as high blood pressure, diabetes, etc. According to the census of 2001, the urbanization rate of 27.78% is expected to rise to 41% over the next 20 years. Consequently, lifestyle-related diseases are expected to increase. By 2020, these diseases are likely to be responsible for nearly 50% of drug sales in India as compared to only 23% in 2006. Cancer, diabetes, and cardiovascular disease are projected at 1/3rd of the incremental demand during 2007–2020. Owing to the recurring nature of ailments in the chronic segment, an increased demand for medicines is foreseen; in most cases, treatment is required for the patient's lifetime.

Indian pharmaceutical companies historically relied upon reverse-engineering skills

Increase in Manufacturing Facilities

The Indian Patent Act of 1970, which came into force in 1972, granted only process patents; product patents were not recognized. This encouraged reverse-engineering practices among domestic pharmaceutical players. Products manufactured in other countries were recreated using alternative processes distinct from the original method. This is borne out by the rise in the number of pharmaceutical companies' manufacturing units which grew from 2,257 in 1970 to 20,053 in 2000. Despite speculations of slower growth after the introduction of product patents in 2005, the number of manufacturing units has grown. This trend is likely to continue for two major reasons:

1) Generic drugs constitute 90%–95% of the drugs sold in India; very few patent-protected drugs are presently marketed in India. Consequently, the post-patent ruling is unlikely to hurt the existing infrastructure.
2) An increase in contract manufacturing outsourced to India is likely to encourage growth of pharmaceutical manufacturing units.

Once patent-protected drugs are popularized, the mid to long-term may witness consolidation of small to medium-sized manufacturing units to meet regulatory and infrastructural requirements.

Advantages of Outsourcing Pharmaceutical Activities to India

Low production and R&D costs, a constant supply of qualified skilled professionals, government support, and improved infrastructure that answers to global pharmaceutical needs are among the numerous benefits of outsourcing pharmaceutical activities to India.

India as a Favorable Destination for Pharmaceutical Outsourcing

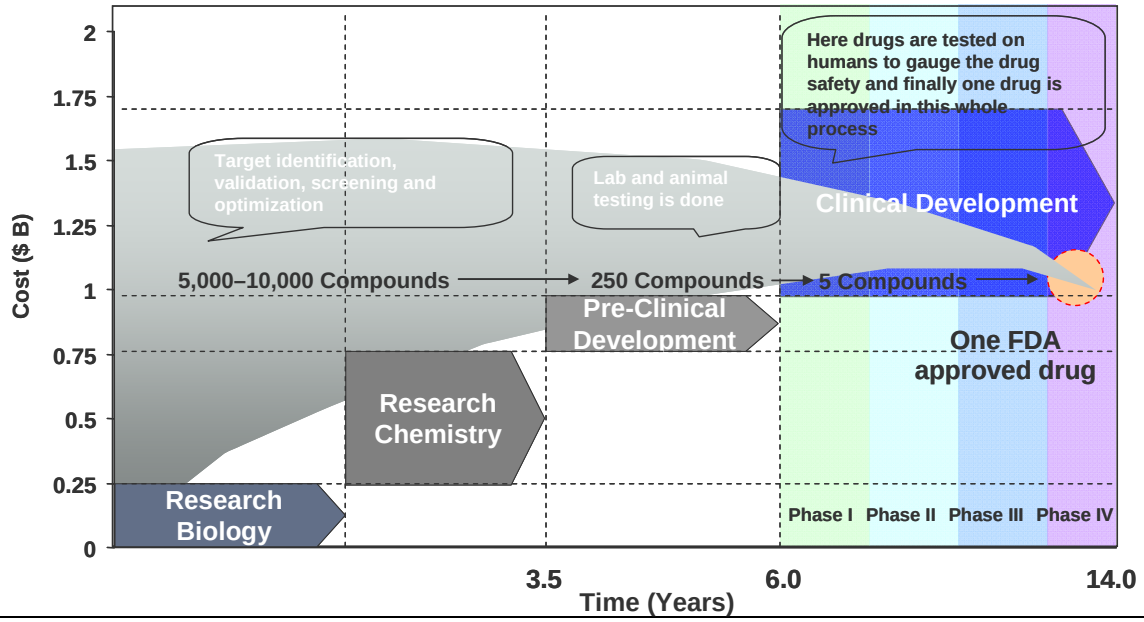
India is increasingly a favorable destination for foreign players primarily because of low costs supported by a stable economy and an abundant talent pool.

Low Production and R&D Costs

Outsourcing achieves average cost savings of 35% and 60% for manufacturing and R&D respectively. The process of drug discovery and development places considerable demands on a company's resources and capital. Extensive process stages are involved in the development of an FDA-approved drug. In the US and Europe, it takes 14 years and around $ 1.7 B to develop a drug, of which $ 0.75 B is incurred in the clinical development timeframe.

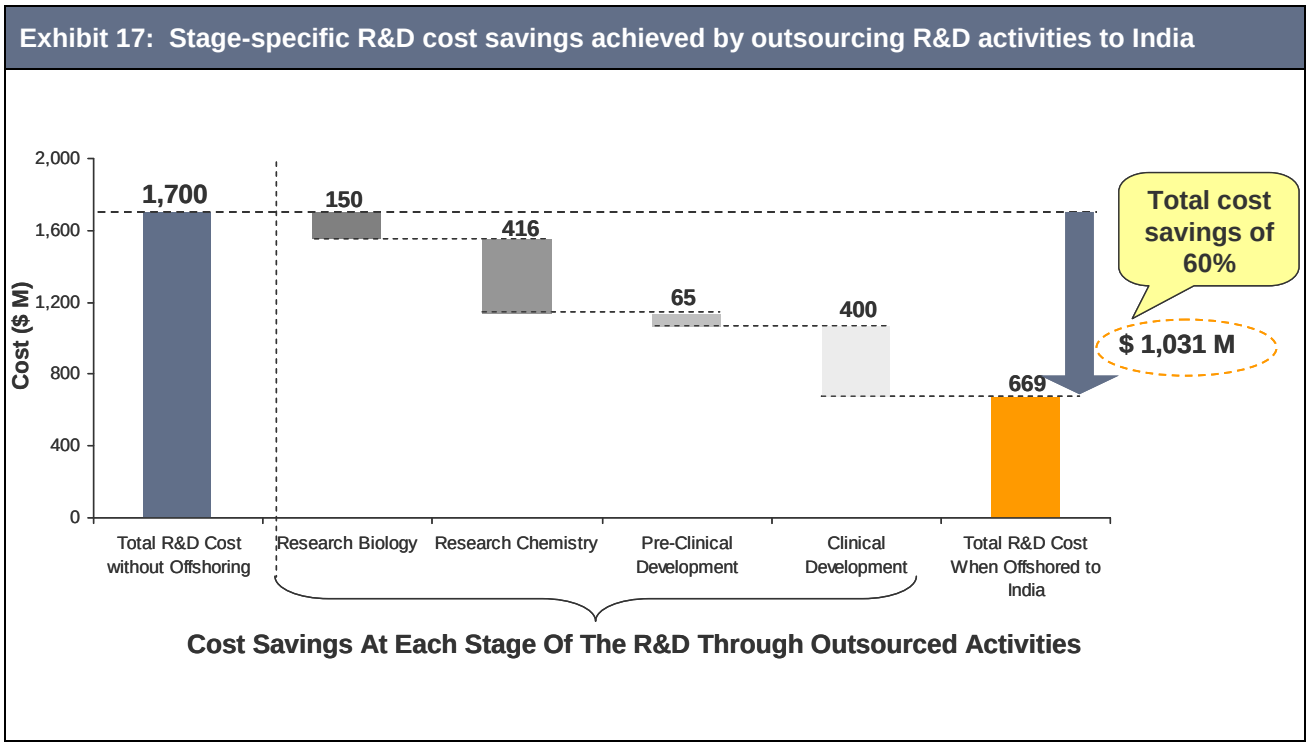
Exhibit 16: Timeframes and costs for process stages across the value chain for R&D and development of an FDA approved drug[1],[10]

Exhibit 16: R&D—Drug Discovery and Development



In contrast, Exhibit 17 shows that the same drug discovery and development process when conducted in India saves companies around $ 1 B per drug. Due to low production costs and availability of talent, the greater part of cost saving occurs in the research chemistry phase of the drug discovery and development process. Additionally, with Indian labor wages at 1/7th the levels in developed countries, outsourcing to India brings the wage differential into play, and translates into 35% cost savings compared to the US and Europe.

Exhibit 17: Stage-specific R&D cost savings gained by outsourcing R&D activities to India[A],[1],[10]



Good educational standards and growing numbers of educational institutions are building a talent pool of skilled workers

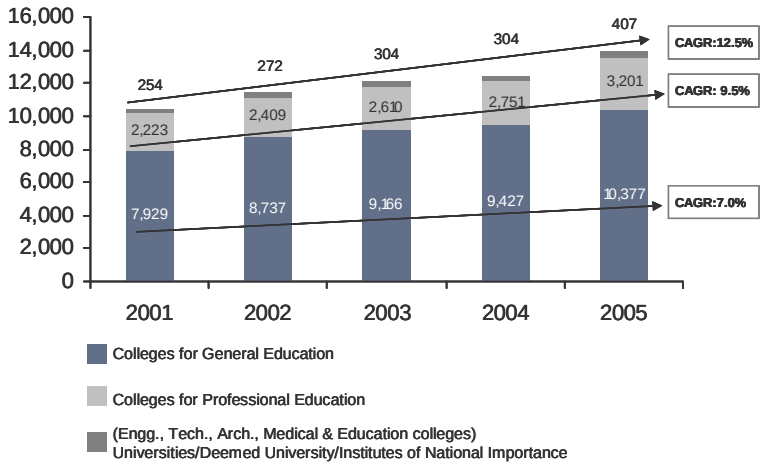
India as a Consistent Source of Qualified Skilled Professionals

Low costs and an abundant talent pool combine to make India an attractive hub for outsourcing activities in the pharmaceutical domain.

The number of colleges for general education is growing steadily. Selected educational statistics of the Ministry of Human Resource Development, Government of India, listed close to 13,500 colleges for professional and general education in 2005.

Exhibit 18: Number of institutes (by type) in India (2001–2005)[11]

Exhibit 18: Educational institutes in India (2001–2005)



The pharmaceutical industry requires a constant supply of skilled professionals. Each year, approximately 257,000 students enroll in Medicine, Dentistry, Nursing, Pharmacy, Ayurvedic and Unani, Homeopathy, etc.

The government contributes to the growth of R&D through partnerships and by offering benefits to companies

Government Support

India's Department of Biotechnology (established in 1986) has funded more than 1,800 R&D projects, helped in the development of 12 vaccines, and transferred 54 technologies to the biotech industry, of which 17 have been commercialized.

It typically takes 3-4 months to get approval for pre-clinical and clinical trials. The Government is taking steps to expedite the process. For example, two government-sponsored breeding centers will supply genetically modified animals to Indian vendors. Thus, facilities for testing non-human primates are now available to the public sector through government-funded research centers like the Central Drug Research Institute, Lucknow.

India has world-class facilities and infrastructure for drug manufacture

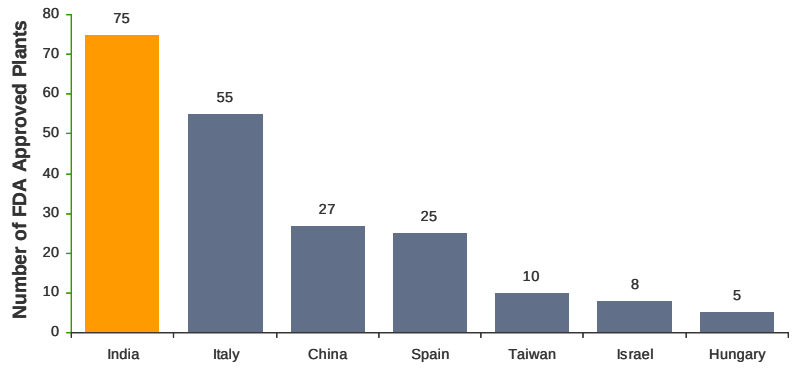
Improving infrastructure

India has the world's largest number of FDA-approved plants (75) located outside of the US. India has almost three times the number of FDA- approved plants as China.

Our research shows that US FDA-approved plants can be set up in India at half the cost of instituting similar plants in the US or Europe.

Exhibit 19: Number of FDA-approved plants in various countries[12],[13]

Exhibit 19: Number of FDA-approved plants (2006)



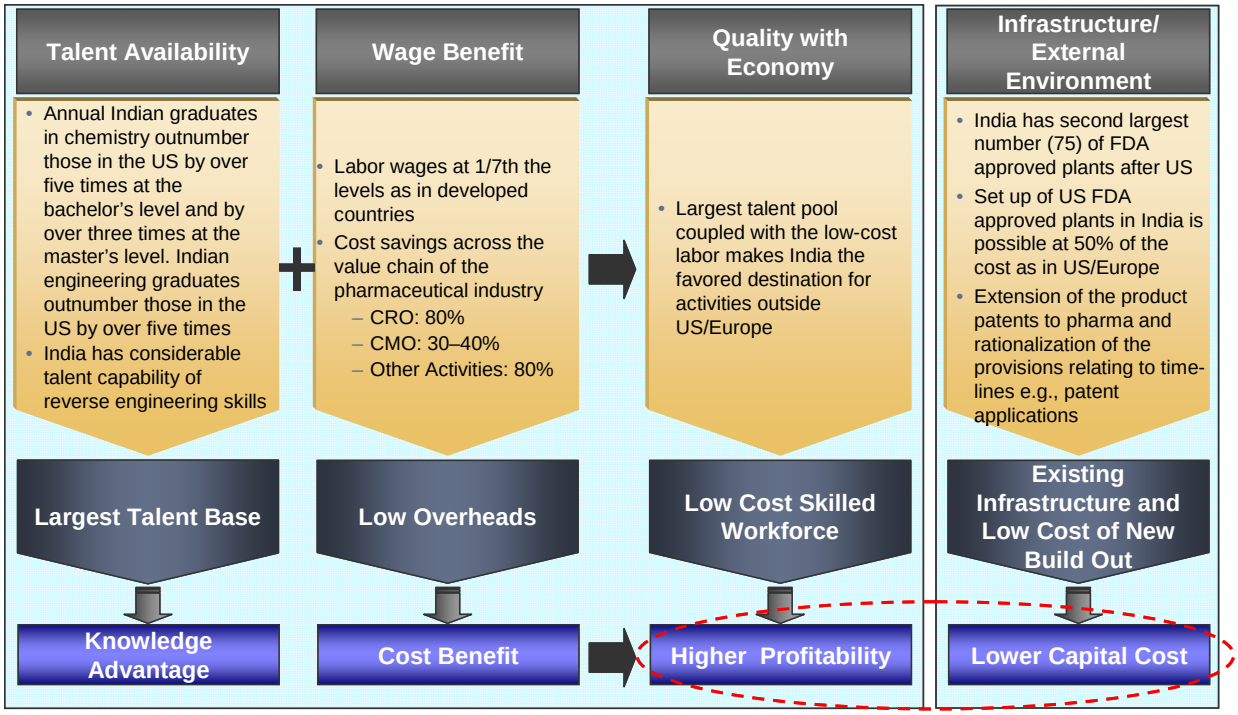
Additionally, Indian **Good Manufacturing Practice (GMP)** norms are becoming increasingly strict. The Mashelkar Committee report of November 2003 confirms that governmental amendments to Schedule M, which defines the standard manufacturing practices, are bringing bring Indian standards closer to GMP norms of the WHO.

However, since these GMP norms reduce cost competitiveness, small manufacturers are reluctant to adopt them. While the majority of large units have already taken steps to adapt to the mandatory manufacturing standards of highly regulated markets like the US, Europe, and Australia, small firms show reluctance to follow suit, owing to the heavy investments entailed in updating existing units. There has been a clear tendency among small firms in the Confederation of Indian Pharmaceutical Industry (CIPI) to delay the implementation of Schedule M. In response to these reservations, the Government extended the deadline for implementation of Schedule M from December 31, 2003 to December 31, 2004, and then again to June 30, 2005. Major steps have been put in place to develop quality standards and uniformity across manufacturing practices.

The factors outlined above contribute towards making India a preferred hub for pharmaceutical activities. The overall benefits are summarized in Exhibit 20.

Exhibit 20: Economical service of high quality and good infrastructure make India an attractive outsourcing destination[1],[14]

Exhibit 20: India—an attractive outsourcing destination



India plays an important role in the supply of pharmaceuticals to global markets

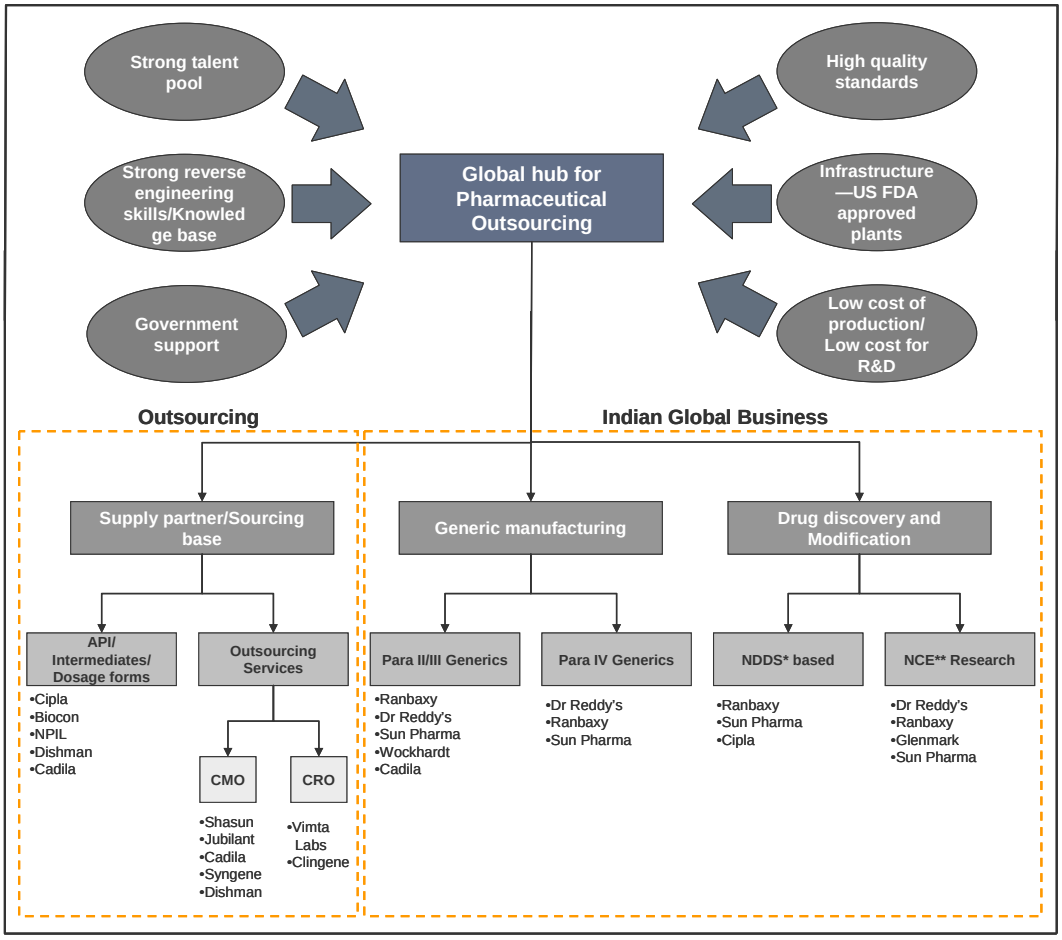
Indian Pharmaceutical Industry Catering to the Globe

India serves global clients through various business models and offerings, such as outsourcing of services (including R&D) and manufacturing. Strong reverse-engineering skills, a robust talent pool, government support for exports, low production and R&D costs, and world-class infrastructure to assure high quality standards are some of the factors that enable India to play a pivotal role in the global pharmaceutical market. India is considered a global destination for supplies of high-standard APIs.

A central factor in India's place in the global pharmaceutical market is its reverse-engineering expertise, whereby a drug made by foreign pharmaceutical companies after years of R&D is formulated at a much lower cost. The innovator-company patent is challenged in the US through a Para IV filing, which is made when the applicant believes that its product or the use of its product does not infringe on the innovator's listed patents.

Exhibit 21: The Indian pharmaceutical industry addresses globe needs[1],[15]

Exhibit 21: India Catering to the Globe



NDDS*New Drug Discovery and Search; NCE**New Chemical Entity

The Indian pharmaceutical industry's competence attracts production and research outsourcing from several foreign players

Indian companies with extensive foreign operations are **Ranbaxy, Sun Pharmaceuticals** and **Dr. Reddy's Laboratories.** These companies are involved in the field of new drug discovery and modification ventures as well as Para II/III/IV filings (A Para II filing for the launch of a generic drug is made when the drug is already off-patent. A Para III filing is made when the applicant does not plan to sell the generic drug until the original drug is off-patent).

Wockhardt is chiefly involved in generic manufacturing. **Cipla** and **Glenmark** focus on new drug discovery and research.

In the outsourcing space, the main players concerned with supply are **Cipla, Biocon, NPIL, Dishmman** and **Cadila.** Key players in the outsourcing services market include **Shasun, Jubilant, Dishman, Syngene, Clingene** and **Vimta Labs.**

The chief business model evolved through these capabilities is outsourcing. The following section focuses primarily on the various facets of outsourcing.

Outsourced Pharmaceutical Activities [16]–[21]

CROs and CMOs receive the bulk of their revenue from outsourcing

Pharmaceutical outsourcing constitutes contract research, contract manufacturing and other support activities.

Contract research: Contract Research Organizations (CROs) provide services that form the pharmaceutical R&D value chain, including drug discovery, product development and formulation, pre-clinical and clinical trial management spanning phases I–IV. The share of CROs in the industry's research operations is 27%.

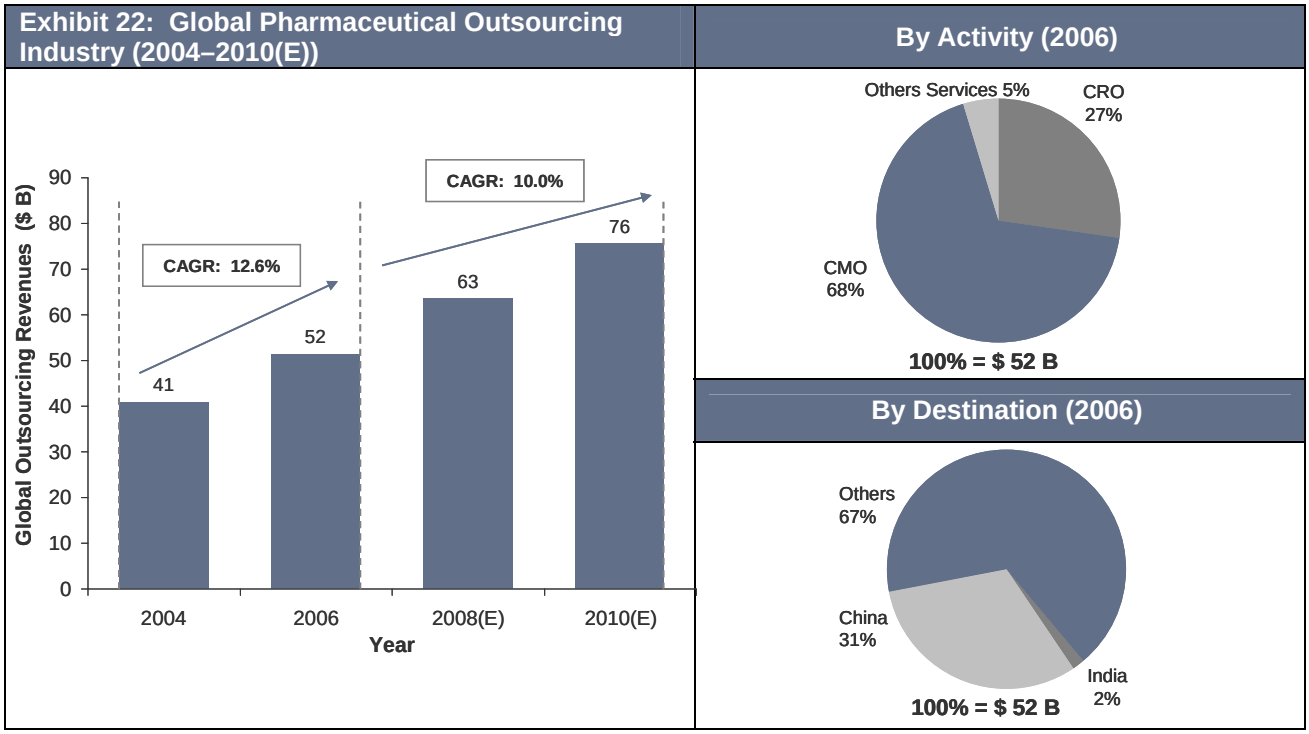
Contract manufacturing: Contract Manufacturing Organizations (CMOs) concern themselves with drug manufacture. These services are further integrated into the pharmaceutical supply chain with the provision of value-added services like process development and process optimization. The share of CMOs in the industry's manufacturing operations is 68%.

Other services: the Indian pharmaceutical industry offers support services including sales and marketing, information technology, finance and accounting, human resources, procurement, and Customer Relationship Management (CRM).

Global Pharmaceutical Outsourcing Market

The global pharmaceutical outsourcing market was worth $ 52 B in 2006. It is expected to reach $ 76 B by 2010, at a CAGR of 10.0% in the 2006–2010 period. In 2006, CMO activity accounted for the major share (approx. 68%) of the total global outsourcing market.

Exhibit 22: Revenues of the 2004-2010 global pharmaceutical outsourcing market (by value); contribution based on activity and outsource destination[22],[23],[24]



India's pharmaceutical outsourcing market is expected to have a CAGR of 37.6% by 2010

The Indian Pharmaceutical Outsourcing Market

The Indian pharmaceutical outsourcing market was valued at $ 929 M in 2006. It is expected to reach $ 3.33 B by 2010, with a CAGR of 37.6% during 2006–2010. Consequently, India's contribution to the global pharmaceutical outsourcing market is expected to increase from 1.8% in 2006 to 4.4% in 2010. Exhibit 23 depicts the growing market for pharmaceutical outsourcing in India, and also captures its increasing contribution to the global outsourcing market.

Exhibit 23: The value of the Indian pharmaceutical outsourcing market (2004–2010) and its contribution to the global outsourcing market [1],[14]

Exhibit 23: India's pharmaceutical outsourcing market (2004–2010(E))

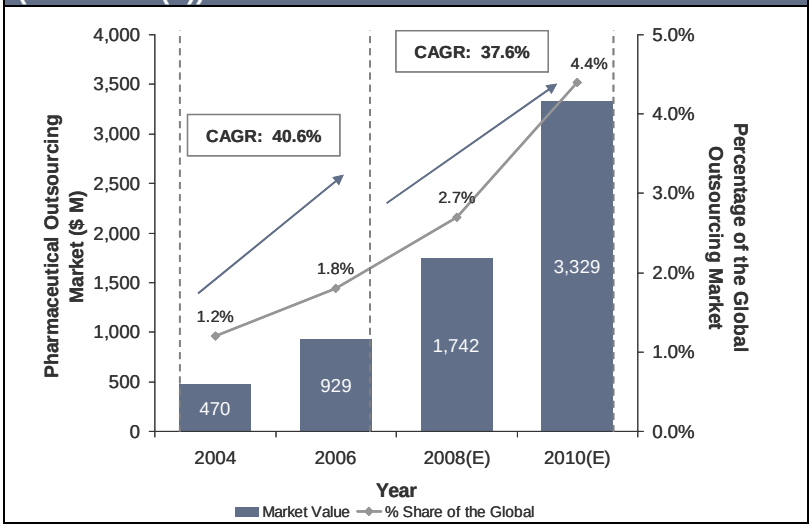
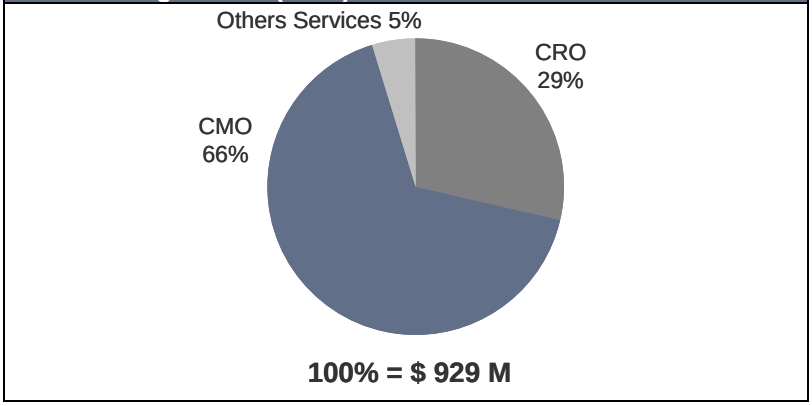


Exhibit 24: The majority market shares of CMO (66%) and CRO (29%) [1],[14]

Exhibit 24: Activity analysis of India's pharmaceutical outsourcing market (2006)



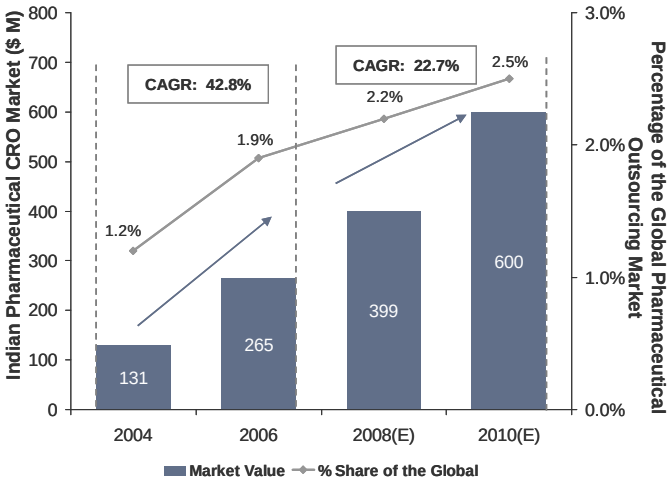
Contract Research Outsourcing in India

In 2006 the global CRO market was valued at $ 14.3 B. This figure is expected to have a CAGR of 13.8% and reach $ 24 B by 2010. In 2006, clinical trials accounted for more than 50% of outsourced activity.

The Indian CRO market stood at $ 265 M in 2006. By 2010, it is expected to have a CAGR of 22.7% and reach $ 600 M.

Exhibit 25: The CRO outsourcing market in India (2004–2010) and its contribution to the global outsourcing market [1],[14]

Exhibit 25: Indian Pharmaceutical Outsourcing Market—CRO (2004–2010(E))



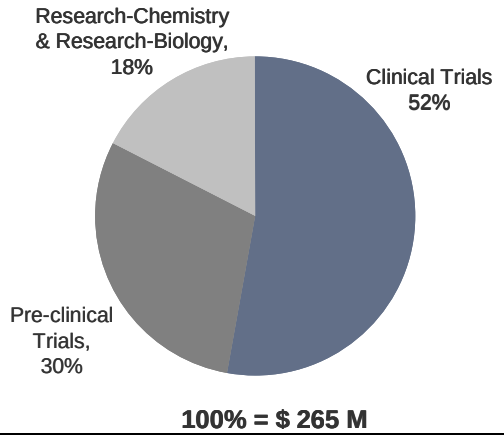
Clinical trials account for the majority (52%) of outsourced activity.

In 2006, clinical trials accounted for 52% of the total outsourcing market of CROs in India, followed by pre-clinical trials which constituted about 30%. Research chemistry and research biology together constituted 18%.

Analysis of 50 pharmaceutical companies that outsource their activities to India shows that the preferred locations for outsourced activities are **Mumbai, Bangalore, Ahmedabad, Delhi and NCR,** and **Hyderabad [A].**

Exhibit 26: The CRO outsourcing market in India in 2006[1],[14]

Exhibit 26: Indian Pharmaceutical Outsourcing Market—CRO (2006)



The R&D development value-chain includes research biology, research chemistry, pre-clinical development, and clinical development phases I–IV. (See appendix for definitions)

Exhibit 27: Activities involved in R&D value chain [24],[25]

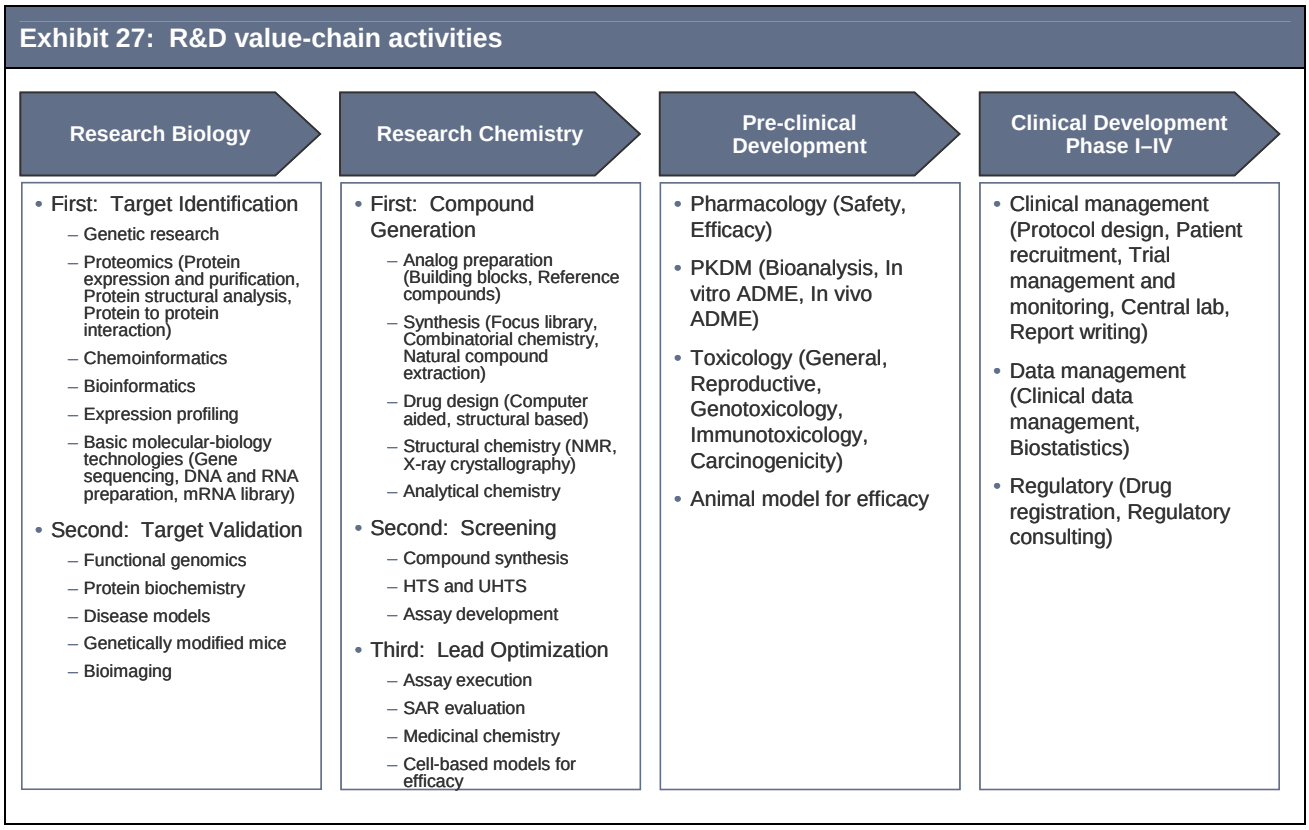


Exhibit 28: Outsourcing Scale and Skills Availability in India [1],[25]

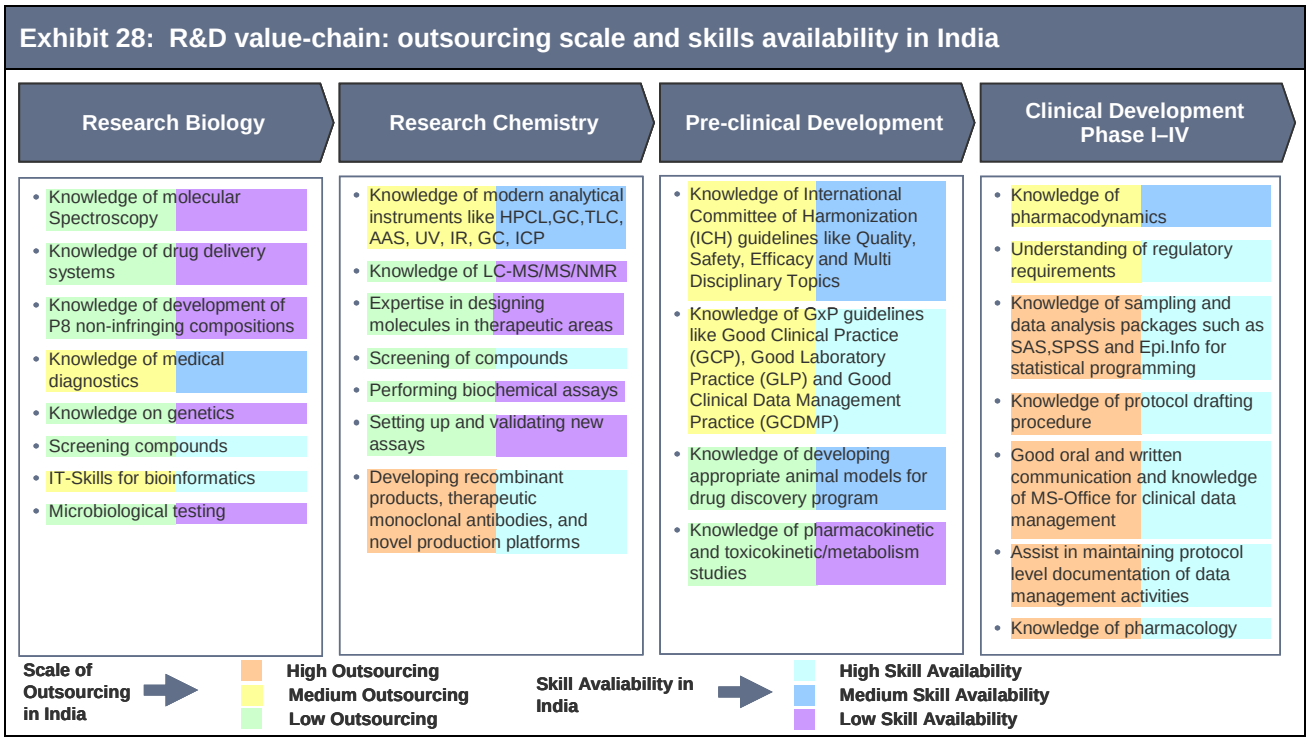


Exhibit 28 highlights the intensive research and knowledge-oriented skills demanded in research biology and research chemistry as compared to Phase IV, which chiefly entails data-management skills since it involves activities such as clinical data-management, patient recruitment, trial management, monitoring, etc. Moreover, contract research-related outsourcing is based on a skill-based maturity.

The number of global trials conducted in India has surged from 40 in 2002 to 200 in 2005. Historically, Multinational Pharmaceutical Companies (MPCs) needed to set up their captive bases in order to conduct clinical trials. Today, given the rise in the number of contract research organizations, clinical trials can be outsourced. Increased capabilities in data-management further expedite business.

Activity in the Research Biology Domain Is Likely to Gather Momentum in the Long Term

India conducts activities such as chemo-informatics and gene sequencing with expertise. However, proficiency in end-to-end activities needs to be developed. This skill-gap is attributable to the industry's traditional focus on process reverse-engineering. Consequently, growth in this innovative field has been inhibited. To encourage the requisite skill-set, the Indian government has initiated steps to promote research and development. This translates into a long-term time-frame of opportunity for research biology outsourcing to India.

Near-term Opportunities in Research Chemistry

The legacy of process reverse-engineering has served to refine the skill-sets of scale-up, process optimization and manufacturing in Indian vendors of biopharmaceutical R&D. Moreover, proven capabilities in data-management and information technology have made India a favored destination for the outsourcing of labor-intensive activities involved in clinical data management and biometrics. MPCs have used these skills and secured high quality output in chemistry, while obtaining cost savings of 80%.

Additionally, the Indian pharmaceutical industry's shift towards drug discovery has brought about improvements in chemistry research.

Contribution of research chemistry towards revenues is set to increase in the near future

Owing to governmental tax incentives, pharmaceutical companies spend heavily on R&D. This has resulted in an expansion of focus towards chemistry. The top 10 domestic companies with highest revenues have more than doubled their R&D budgets from an average of 2.8% to 7% of sales. Several have doubled their R&D personnel.

More and more vendors now offer end-to-end solutions in chemistry research. This allows large-scale rather than piecemeal outsourcing.

Evolving Capabilities in Pre-clinical Development

MPCs are increasingly confident in outsourcing pre-clinical development work to India. However, off-shoring of end-to-end work is still not a practical option in the short term, given India's limited facilities for studying non-human primates and insufficient laboratories that meet Good Laboratory Practice (GLP) standards.

Indian capabilities in pre-clinical trials have evolved primarily because of these advances implemented by domestic companies:

(i) Upgrading of laboratories and vivaria (the centers that manage and house research organisms and samples).

(ii) Development of expertise in conducting pharmacokinetic, drug metabolism, and toxicity studies in rodents and, to a lesser extent, in canines.

Indian companies are steadily attracting pre-clinical and clinical trials

As a result of India's vast population, the frequency and magnitude of patient enrollment per site is high. Further it is available to patients at 60-70% of cost. Moreover, treatment-naïveté of most patients facilitates trials.

Contract Manufacturing Outsourcing (CMO) in India

The 2006 global pharmaceutical CMO market of $35 B is expected to reach $ 48 B by 2010, at a CAGR of 8.2% during 2006–2010. In 2006, chemical synthesis constituted close to 67% of total work outsourced in the global contract manufacturing market.

The Indian CMO market stood at $ 620 M in 2006. It is expected to have a CAGR of 41.7% and reach $ 2.5 B by 2010.

Chemical synthesis constituted 60% of the total outsourcing market by CMOs in India, followed by formulation and packaging which constituted about 40%.

Exhibit 29: Value of the CMO segment of the Indian pharmaceutical outsourcing market (2004–2010) and its contribution to the global outsourcing market [(1),(23)]

Exhibit 29: India's pharmaceutical outsourcing market—CMO (2004–2010(E))

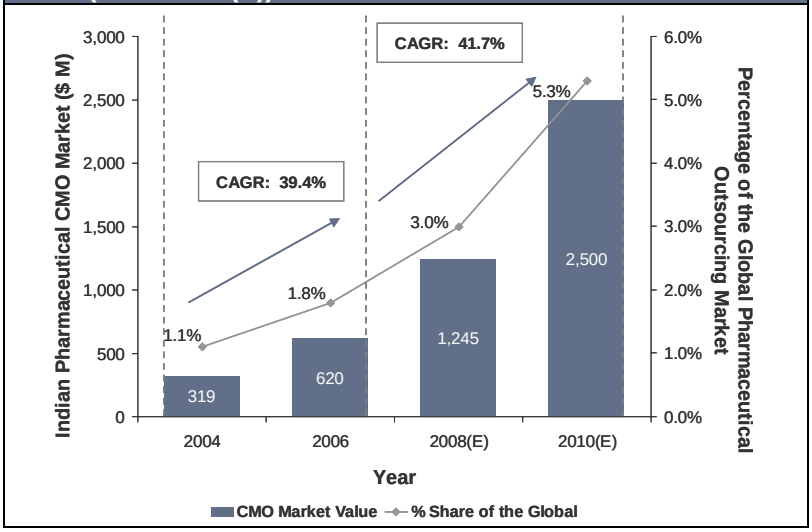
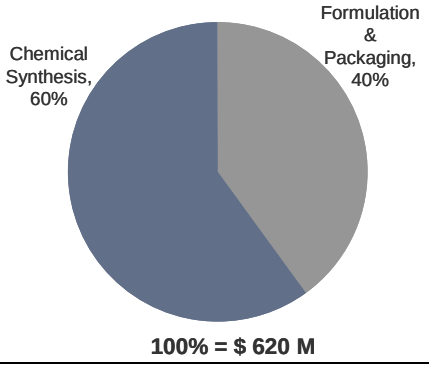


Exhibit 30: Activities in the CMO segment of the Indian pharmaceuticals outsourcing market (2006) [(1),(23)]

Exhibit 30: India's pharmaceutical outsourcing market—CMO (2006)

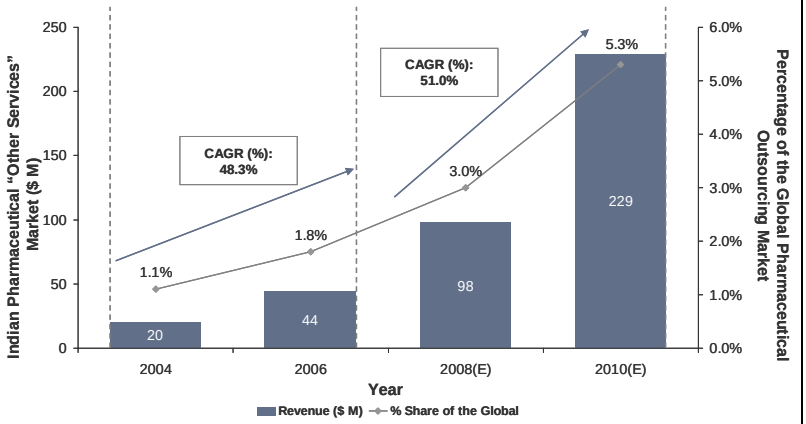


Other Services in India

Other services can be broadly classified into finance and accounting, information technology, and various support services including sales and marketing, customer relationship management, human resources, and procurement.

Exhibit 31: Value of market for supplementary services of India's pharmaceutical outsourcing market (2004–2010) and their contribution to the global outsourcing market [1],[14]

Exhibit 31: India's pharmaceutical outsourcing market—other services (2004–2010(E))



In 2006 the global pharmaceutical outsourcing market for these services was $ 2.44 B, and is expected to reach $ 4.35 B by 2010, at a CAGR of 15.6% during 2006–2010.

The Indian pharmaceutical outsourcing market for other services was $ 44 M in 2006, and is expected to reach $ 229 M by 2010, at a CAGR of 51% during the 2006–2010 period.

Exhibit 31 depicts the growth in other services of the pharmaceutical outsourcing market (2004–2010) and activity-wise share of the market in 2006.

Outsourcing 'Other Services' Can Help MPCs Reach the Last Mile

Outsourcing of sales and marketing activities can help MPCs utilize the locally established sales and distribution networks of their vendors, besides reducing sales and distribution costs. Activities such as data-management, IT strategy and transformation, and customer relationship management are outsourced heavily due to the established capabilities of business process outsourcing (BPO) service providers and the country's vast talent pool.

Conclusion

Globally and domestically, India's pharmaceutical industry has huge untapped potential in terms of supply and demand. Acute disease therapeutics currently dominate the domestic market. This sector shows 18% growth, closely followed by the 17% growth of the chronic disease market. The focus on the acute disease sector is attributable to India's growing younger population which is less susceptible to chronic disease. In the long term, lifestyle-related chronic diseases are likely to pose the greatest challenge to the industry, leading India to follow the pattern of developed countries, in which the chronic disease segment predominates.

The Indian market is presently dominated by Indian companies. Although this trend is expected to continue in near future, the foreseeable long term is likely to witness a growing presence of global companies and the launch of their research products.

India's suitability as an attractive location for the pharmaceutical outsourcing business owes to the low cost and high quality of its products. Indian contract manufacturing is expected to register a growth of 41.7% during 2006–2010. Even though further cost advantages may grab China a small share of India's CMO pie, India's US FDA-approved plants seem poised to attract substantial additional business. Additionally, with Indian CROs expected to grow at 23.7% until 2010, India remains the stronger contender for R&D-based outsourced services.

High profit margins and growth opportunities in the Indian pharmaceutical industry's service sector make India a promising focus for global mergers and acquisitions. Global generic companies already have some Indian API-based companies on their acquisition radar because of increasing demand for low-price quality APIs.

Collaboration between Indian companies active in the US and Europe and research-based global companies would facilitate the entry of authorized generics into the market. The strong R&D base, reverse engineering skills, and wide domestic distribution of companies like Ranbaxy and Dr. Reddy's render them attractive collaborators with research-based companies.

These unique features of the Indian pharmaceutical market underscore a large and growing domestic market as well as India's potentially vast role in the global pharmaceutical market.

Appendices

Exhibit A: Activities outsourced by companies to India[1],[14]

Exhibit A: Companies that Outsourced Activities in India can be Listed as Below

Type of Work	Sub-Type	Company	Activity	Vendor
R&D	Research Biology	Forest Laboratories	Discovering drug candidates for obesity and metabolic disorders	Aurigene Discovery Technologies
		Debiopharm	Target identification and validation for immuno-oncology	Aurigene Discovery Technologies
		Barr Pharmaceuticals	Bio-study	Captive
		Teva Pharma Company	Research for Central Nervous system	Captive
	Research Chemistry	Rheoscience	Assay development structure based drug design	Aurigene Discovery Technologies
		Wyeth	Synthetic Chemistry	GVK Biosciences
		Astra Zeneca	Compound Generation	Torrent Pharma
		Merck	Drug Design	Advinus Therapeutics (P) Ltd
	Pre-Clinical Development	Veeda Clinical Research	Toxicology	Advinus Therapeutics (P) Ltd
		Rottapharm	Toxicology Screening	Vastox
		Illumina	Genotoxicology	Asuragen
		AstraZeneca	PKDM-ADME	Galapagos
	Clinical Development Phase I–IV	Pfizer	Clinical Research Phase II–IV	Captive
		Eli Lily	Clinical Data Management and Biostatistics	Tata Consultancy Services
		GlaxoSmithKline (GSK)	Clinical Data Management	Tata Consultancy Services
		Bilcare	Clinical Supplies Distribution	Captive
Contract Manufacturing		GlaxoSmithKline (GSK)	Chemical Synthesis	Shasun
		Allergan	Chemical Synthesis, Formulations and Packaging	Nicholas Piramal
		Astra Zeneca	Chemical Synthesis	Ipca
		Eli Lily	Chemical Synthesis	Shasun
		AMO	Chemical Synthesis, Formulations and Packaging	Nicholas Piramal
		Solvay	Chemical Synthesis	Dishman
		Mayne	Chemical Synthesis, Formulations and Packaging	Strides
Other Services		Aventis	IT Services	IBM
		GlaxoSmithKline (GSK)	Finance and Accounting	Genpact
		Astra Zeneca	IT services	IBM
		Pfizer	IT services	Satyam, TCS, Wipro
		Pfizer	Customer support, CRM	Genpact
		Novo Nordisk	Data Management	Tata Consultancy Services
		GlaxoSmithKline (GSK)	Sales and Marketing	PDI Inc

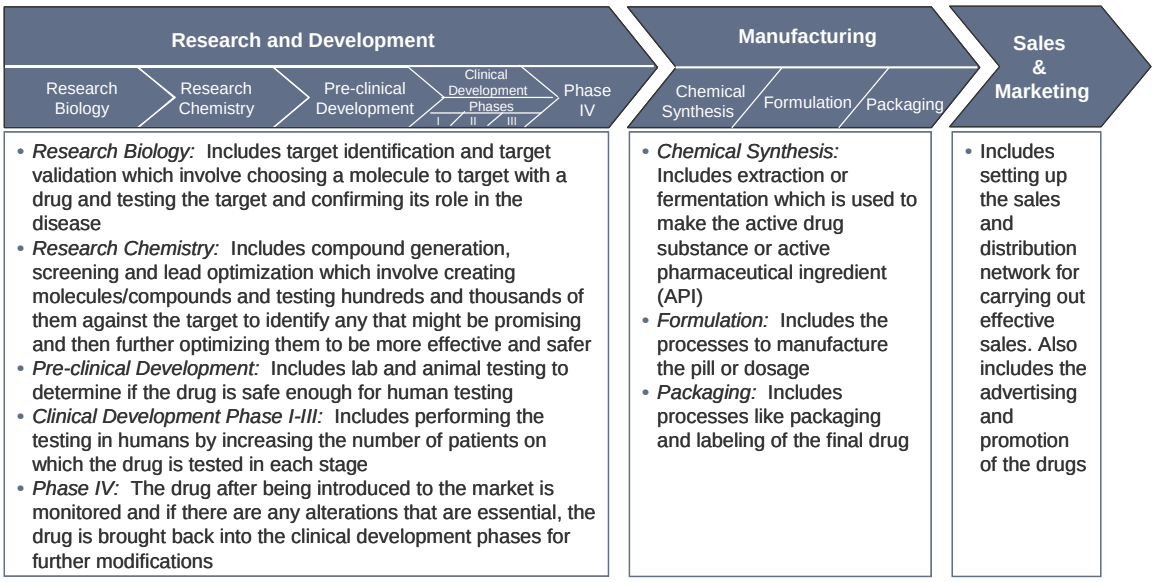
Exhibit B: Company presence in various outsourced pharmaceutical activities to India[1],14]

Exhibit B: Company-wise analysis of tasks outsourced to India

Company	Type of Work						No. of Activities Outsourced
	Research and Development				Contract Manufacturing	Other Services	
	Research Biology	Research Chemistry	Pre-clinical Development	Clinical Development			
Allergan					✓		1
AMO					✓		1
Astra Zeneca		✓	✓		✓	✓	4
Aventis						✓	1
Barr Pharmaceuticals	✓						1
Bilcare				✓			1
Debiopharm	✓						1
Eli Lily				✓	✓		2
Forest Laboratories	✓						1
GlaxoSmithKline (GSK)				✓	✓	✓	3
Illumina			✓				1
Mayne					✓		1
Merck		✓					1
Novo Nordisk						✓	1
Pfizer				✓		✓	2
Rheoscience		✓					1
Rottapharm			✓				1
Solvay					✓		1
Teva Pharma Company	✓						1
Veeda Clinical Research			✓				1
Wyeth		✓					1

Exhibit C: Pharmaceutical industry value chain and activities

Exhibit C: Pharmaceutical Industry Value Chain



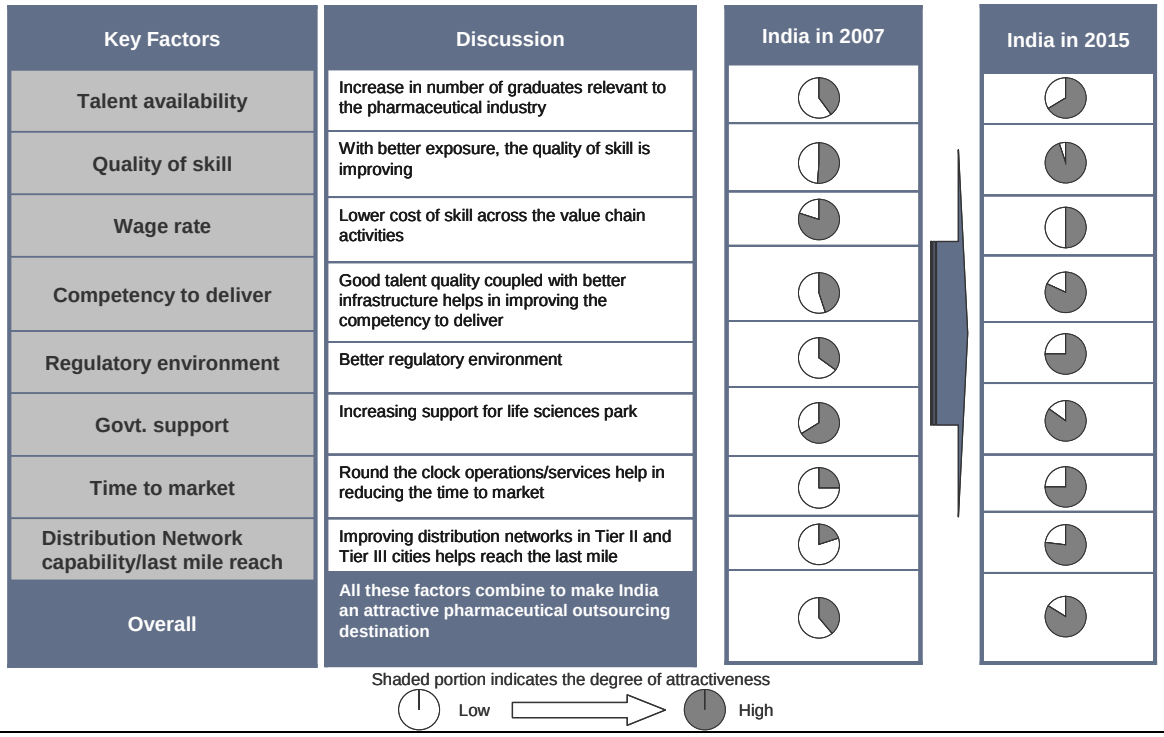
- *Research Biology:* Includes target identification and target validation which involve choosing a molecule to target with a drug and testing the target and confirming its role in the disease
- *Research Chemistry:* Includes compound generation, screening and lead optimization which involve creating molecules/compounds and testing hundreds and thousands of them against the target to identify any that might be promising and then further optimizing them to be more effective and safer
- *Pre-clinical Development:* Includes lab and animal testing to determine if the drug is safe enough for human testing
- *Clinical Development Phase I-III:* Includes performing the testing in humans by increasing the number of patients on which the drug is tested in each stage
- *Phase IV:* The drug after being introduced to the market is monitored and if there are any alterations that are essential, the drug is brought back into the clinical development phases for further modifications

- *Chemical Synthesis:* Includes extraction or fermentation which is used to make the active drug substance or active pharmaceutical ingredient (API)
- *Formulation:* Includes the processes to manufacture the pill or dosage
- *Packaging:* Includes processes like packaging and labeling of the final drug

- Includes setting up the sales and distribution network for carrying out effective sales. Also includes the advertising and promotion of the drugs

Exhibit D: Shows how India is poised to become a favorable outsourcing destination for activities in the pharmaceutical domain

Exhibit D: By 2015, India is poised to become a favorable destination for pharmaceutical outsourcing activities *(illustrative)*



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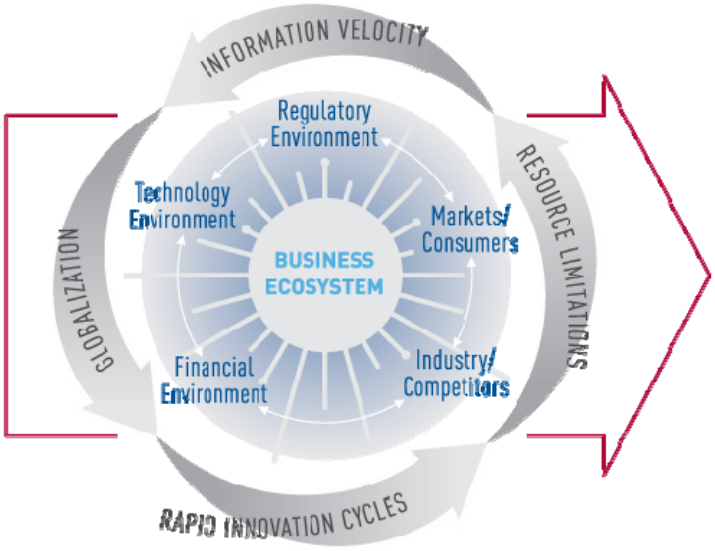
Note:

(A) Preferred locations are identified by understanding the present number of third party vendors for the pharmaceutical market in India.



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About Boston Analytics

Boston Analytics is a business and financial research and analytics company headquartered in Boston, Massachusetts, USA. Boston Analytics delivers enterprise-wide knowledge advantage by providing fully customized knowledge services as well as flexible, preconfigured knowledge products and repositories. All knowledge services and products are tailored to meet the specific needs of corporations, consultants, and financial services firms.

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