

Country Profile

A look at the
Pharmaceutical Industry in

INDIA



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with ISPE India



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Dear ISPE Members,

On behalf of the ISPE India Affiliate, I am pleased to present the profile of the Indian pharmaceutical industry as it has evolved over the past few decades.

A profile of the healthcare system in India would be incomplete without a mention of the two renowned ancient Indian ayurvedacharyas, Sushruta and Charaka. Indians have always been health and medicine conscious giving the Indian pharmaceutical industry a strong base. Roots are very strong.

The profile also discusses how the Indian industry has developed in the last 50 years. The proactive functioning of various associations and bodies, which have enhanced the growth of the Indian pharmaceutical industry, also deserve mention.

The profile also looks at the regulatory systems in India at present with a focus on the Drugs Controller General of India (DCGI) and his role in price control of various preparations. The aim in the Indian setting is to provide effective drugs and affordable prices. Hence today the pharmaceutical industry in India is faced by numerous challenges. But there are many opportunities as well. The Indian pharmaceutical sector is fast being recognized by international markets and is expected to emerge as the global driver in the coming years. Research and development, a key factor for progress of any drug industry, also has been discussed in sufficient detail.

With strong roots, and a proactive present, India has tremendous future potential. India has taken a significant step forward in achieving the goal of becoming a globally competitive market in the 21st century. India is also taking fledgling steps into the global arena by forging contacts with research and marketing based companies. Alliances with both companies and institutions like ISPE are giving Indian companies an opening into the world's global research networks and the chance to gain access to new technologies like Process Analytical Technology (PAT).

We hope this profile succeeds in its intention to give a contemporary overview of the pharmaceutical industry in India.

Yours truly,

Ajit Singh

President
ISPE India Affiliate



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*Pharmaceutical
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designed so that
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are published.**

**Look for the
Country Profile
on Thailand in
the January/
February issue of
*Pharmaceutical
Engineering*.**

A Look at the Pharmaceutical Industry in India

by Shabbir Badami, Pharmacist, ACG Worldwide and Rajshri Srinivasan, Free-lance Journalist and Copywriter

The History

The healthcare industry in India is one of the oldest known to mankind and is steeped in tradition. *Ayurveda* (Sanskrit: ayu: life; veda: knowledge of) or ayurvedic medicine is a comprehensive system of medicine based on a holistic approach that is more than 6,000 years old. This art of healing had been held in high esteem in ancient India. It was elevated to a divine status and Dhanvantari the practitioner of this art was defined as the God of Medicine. Even ordinary practitioners of this art the Ashwinikumaras - were given a special status in mythology and folklore.

Two early texts (from centuries BC) of Ayurveda are the Charaka Samhita and the Sushruta Samhita. They outline remedies for practically every conceivable condition starting from cancer, diabetes, cholesterolemia to fever, pain, and depressive disorders. The main objective of Ayurveda is *removing the cause of illness with little or no side effects and not just curing the symptoms*. With such strong roots, Indians have always been health and medicine conscious, thus, putting the pharmaceutical industry on a firm footing from ancient times.

A Country of Contrasts

India is a country of contrasting cultural and economic backgrounds. Because of the vast cultural and economic diversities, disease profiles and subsequently treatment measures are very distinct and disparate. Diversities in India are not restricted only to culture, language, and tradition, but are also reflected in lifestyle patterns. Hence these affect the way the pharmaceutical market behaves. The pharmaceutical industry in India manufactures drugs and medicines to cater to the needs of a variety of disease conditions for patients from various economic strata of society. Medicines are accessible at registered retail outlets, in urban as well as rural areas, covering every corner of the country.

This huge contrast poses challenges as well as opportunities to the pharmaceutical sector. They are like two faces of one coin, two poles of one magnet. The challenges and opportunities that the Indian pharma-

ceutical industry is encountering currently have never been so gigantic. Nevertheless, because of its large and youthful human resource, low-cost, diversity, and democracy, it is becoming evident that this century is *'India's Century.'* It is not only that most of the jobs are coming to India; even for most of the developed countries it is essential to keep attracting Indian human resources for their betterment.

The Pharmaceutical Industry

Today, the pharmaceutical industry in India is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It holds a leadership position in the third world in terms of technology,

Continued on page 4.



A Look at the Pharmaceutical Industry in India

Continued from page 3.

Type	Quantity
Medicine	302
Chemistry	1,799
Biological Science	221
Analytical Technique	90

Table A. India's patent count.

quality, and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex biotechnology derived products, almost every type of medicine is available in India. The industry has about 10,000 active units, out of which 300 are in large and medium sectors. More than 400 Active Pharmaceutical Ingredients (APIs) and more than 60,000 formulations in 60 therapeutic categories are manufactured here.

The organized sector of the pharmaceutical industry has played a key role in promoting and sustaining development in this vital field. International and Indian companies associated with this sector have stimulated, assisted, and spearheaded this dynamic development in the past 57 years and helped to put India on the pharmaceutical map of the world. Several Multi-National Companies (MNCs) produce a large volume of the world's production in India. The value of the pharmaceutical market in India was US \$5 billion in 2003. It grew by 5.1% over 2002. Globally, the ranking of the Indian pharmaceutical industry is 4th in volume terms and 14th in value terms. Its share of the global pharmaceutical market is 1.8% in value and 8% in volume terms. The differential is largely due to the much lower market selling prices in India.

The pharmaceutical units in India are hi-tech hi-GMP and the industry has the largest number of US-FDA approved units outside the US, while the number of Drug Master Files filed with the US FDA was 126, higher than Spain, Italy, China, and Israel put together in 2003. In addition, the Indian pharmaceutical sector is mature and is supported by a strong manufacturing base.

Turnover in US\$ Billion	Number of Companies		
	2002	2003	2004
> 1.11	6	6	5
0.55 - 1.11	16	15	21
0.208-0.55	19	21	20
0.113-0.208	33	32	33
0.577-0.113	31	36	32

Table B.

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For the year 2004, the Indian pharmaceutical industry registered an annual turnover of US \$5.97 billion with a growth rate of 6.4%. Exports accounted for US \$4.06 billion with a growth of 10.2%. 300 bulk drugs were manufactured and the bulk drug production was valued at US \$2.08 billion. More than 60,000 formulations were manufactured in 60 therapeutic categories. The OTC market was valued at US \$0.93 billion and the alternative medicine market touched US \$0.97 billion. The export of bulk drugs and formulations in 2003 were to the extent of US \$3.1 billion. The US \$0.051 billion vaccine market is growing at the rate of 20% annually.

2004 saw six additional companies added to the US \$0.55-1.11 billion bracket - Table B.

The Indian pharmaceutical market has some unique advantages. The country has a solid legal framework and strong financial markets. More than 9000 companies are publicly listed. It has a good network of world-class educational institutions and established strengths in IT. The country is now committed to an open economy and globalization. Above all, it has about 200 million middle class individuals with growing entrepreneurial spirit. India has the third largest English speaking scientific and technical manpower in the world. For the first time in many years, the international pharmaceutical industry is finding great opportunities in India. The process of consolidation, which has become a general phenomenon in the world pharmaceutical industry, has started taking place in India. With its rich scientific talents and research capabilities, India is well set to mark its place as the sunrise industry.

The Indian pharmaceutical industry is a success story providing employment for millions. It has a pool of personnel with high managerial and technical competence, as well as a skilled workforce. The employment is provided directly by the organized and small scale units or indirectly through the trade and ancillary industry. The organized sector, which comprises of MNCs and indigenous companies, employs 0.29 million individuals, while the small scale units hire 0.17 million persons. The area of distribution and trade offers job opportunities to nearly 1.65 million persons while the ancillary industry hires 0.75 million persons. Hence the pharmaceutical industry offers job openings for nearly 2.8 million persons in the country.

The Pharmaceutical and Allied Industries

The ancillary industry is also very well developed. All



A Look at the Pharmaceutical Industry in India

manufacturing equipment and machineries are locally available. While some excipients continue to be imported, India is self sufficient and well developed in the ancillary industry requirements.

A full range of pharmaceutical manufacturing equipment is locally produced as are glass bottles and vials, empty two-piece capsules, as well as soft capsules, blister and packaging films, aluminum and laminated tubes, and almost all other requirements for a fast growing vibrant formulation and bulk drug industry. India is important among the world leaders in the volume of production of most such items. India is an important exporter to both advanced as well as developing countries.

Research and Development *Investing in R&D, Contract Manufacturing, and Biotech Research*

India's track record and development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules, is excellent. The industry offers tremendous opportunity in the area of research and development without compromising quality. The R&D in itself is emerging as a rapidly growing industry with an estimated annual revenue of US \$1.25 billion. There are almost a dozen major companies engaged in innovative research to produce New Chemical Entities (NCEs). The R&D expenditure is US \$0.26 billion, 4% of sales (some companies are spending 6% of their sales on R&D).

Similar is the case of contract manufacturing. Because of economics, a genetically diverse population, a significant number of qualified providers with expertise in conducting and supervising clinical trials in accordance with global standards, India is emerging as an important hub for Contract Research and Manufacturing with patenting and certification activities assuming a prominent position in the country. In the changing scenario, acquisitions and mergers are no longer rare.

The biotechnology industry in India is in the nascent stages. About 85% of the fast growing biotechnology market is contributed by six products, all of which are

manufactured in India for captive consumption. Among these are Erythropoeitin, Hepatitis B vaccine, Growth Hormones, Interferons, and Insulin. The total biotech market in India is estimated to be US \$1.4 billion. About 60% of this market is accounted for by biopharmaceuticals; however, today, this market is gaining increasing importance.

Regulation of Medicines

About five decades back, when the Indian pharmaceutical industry was in its early stages, it depended heavily on imports. Today, the industry has evolved tremendously. It is at a level where it is almost completely self-sufficient and has also developed a sizable exports market globally. The regulatory apparatus has evolved along with the industry. While industry occasionally reports red-tape and over-regulation, in a huge diverse and democratic country like India, both regulation and distribution present their own challenges.

The industry has a well-evolved regulatory system and a well-defined legislation, which operates on the principles of licensing all activities related to drug manufacturing distribution and sales. It has defined systems to monitor the import of drugs, new product introductions, and good clinical and laboratory practices. The legislation also provides separate rules for psychotropic and narcotic drugs. The Indian Pharmacopoeia (IP) is an independent body, the work of which is looked after by the pharmacopoeial commission. Ayurvedic, siddha, unani, and homoeopathic medicines have separately defined legislation and GMP requirements. The legislative requirements are continuously reviewed and upgraded due to fast and

Company	Market Share (%)			Growth (%)		
	2002	2003	2004	2002	2003	2004
Cipla	5.25	5.51	5.51	15	11	7
GlaxoSmithKline	5.92	5.64	5.44	-2	1	3
Ranbaxy	4.63	4.70	4.48	7	7	2
Nicholas Piramal	3.39	3.41	4.25	9	6	3
Sunpharma	2.92	3.08	3.29	18	11	14
Dr. Reddy's	2.80	2.64	2.43	20	-1	-2
Zydus Cadilla	2.41	2.45	2.42	17	7	5
Aristo	2.10	2.19	2.32	12	10	13
Abbott	2.32	2.29	2.31	7	5	7
Alkem	2.26	2.17	2.18	12	1	8

Table. Top ten companies in the Indian market.

Continued on page 6.

A Look at the Pharmaceutical Industry in India

Continued from page 5.

complex growth and with an eye on evolving international requirements.

The law defines products under price control and drug related advertisements are monitored through the Drugs and Magic Remedies Act.

The pharmaceutical industry has quality producers and many units are approved by regulatory authorities in the US, UK, and other advanced countries. India has the largest number of US FDA approved manufacturing facilities outside of the US. About 70 units have been cleared by US FDA and nearly 253 units have an approval from well-recognized international agencies. A large number of our new modernized units meet global standards. Newer and innovative dosage forms have been developed.

The prime mover in influencing the operating environment of the pharmaceutical industry is the government's drug policy. Currently, the Drug Policy of 1986 as modified and rationalized in 1994 is in force. The Drug Price Control Order (DPCO) outlines the classification of controlled and decontrolled products and methods of price fixation and revision. The DPCO has a three-tier control: on bulk drugs, formulations, and overall profitability. At present, there are 74 drugs under price control (40% of the retail market).

The National Pharmaceutical Pricing Authority (NPPA) monitors the fixing and revising of the prices of a number of drugs. Policy makers have realized the need for giving incentives for R&D to the Indian pharmaceutical industry. They also believe that the

import liberalization process will assist the industry to further improve its quality and competitiveness.

Future Potential

The Indian pharmaceutical industry is mounting up the value chain. From being a pure reverse engineering industry focused on the domestic market, the industry is moving toward basic research driven, export oriented global presence, providing a wide range of value added quality products and services. Government policies will play an important role in defining the future of the pharmaceutical industry. The effect of product patent regime coming into effect from January 2005 is being watched with interest.

The Indian pharmaceutical companies have been doing extremely well in developed markets such as the US and Europe, notable among these being Ranbaxy, Dr.Reddy's Labs, Wockhardt, Cipla, Nicholas Piramal, and Lupin. Such companies have their strategies in place to leverage opportunities existing in formulations, bulk drugs, generics, novel drug delivery systems, new chemical entities, and biotechnology. By the year 2010, the R&D revenue is expected to touch US \$4.89 (The Boston Consulting Group) while projection for the pharmaceutical market is US \$25 billion (The McKinsey report).

With a prodigious knowledge pool and skilled manpower expertise in process chemistry and proven leadership in the field of IT, India has the necessary ingredients to become a dominant player in pharmaceuticals.



A Look at the Pharmaceutical Industry in India

Moreover, the Indian pharmaceutical industry is passing through a wave of consolidation with the objective of strengthening brand equity and distribution in what is essentially a branded-generics market. In the period 1995-98, the Indian pharmaceutical industry witnessed as many as 20 mergers, acquisitions, and takeovers.

In the coming years, India is poised to become a major player in the global healthcare industry. Quality coupled with the availability of technical and non-technical manpower availability makes India the ideal global center for pharmaceutical outsourcing.

Sources

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- Ernst and Young report
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- Interview with Mr. Ashwini Kumar, Drugs Controller General India
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- Interview with Mrs. Bhavna Shah
- ICRA Industry watch series - The Indian Pharma Industry
- ISPE India Affiliate Web site - www.ispeindia.org
- IDMA, OPPI, and BDMA Web sites

About the Authors

Shabbir Badami is a pharmacist and works with the corporate marketing team of ACG Worldwide. He has been associated with the Indian pharmaceutical industry for more than two decades and has worked with several multinational and Indian companies like Schering Plough (Fulford), Zydus Cadila, and Intas Pharmaceuticals. He has been responsible for brand promotion and marketing activities within India, as well as on a global level, giving him broad experience in the pharmaceutical industry.

Rajshri Srinivasan is a free lance journalist and copywriter. In her career span, she has interviewed eminent medical and pharmaceutical personalities and edited and written articles for financial, medical, and pharmaceutical journals and newspapers. During her time in the pharmaceutical industry, she also has trained field staff on various aspects of disease and drug profiles. Her work has taken her to nearly all parts of India. 



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Pharmaceutical Associations and Organizations in India



The Indian pharmaceutical industry is represented by various associations prime among them are: the Organization of Pharmaceutical Producers of India (OPPI), the Indian Drug Manufacturers' Association (IDMA), and Bulk Drug Manufacturers' Association (BDMA). These bodies effectively represent the pharmaceutical industry and issues facing it today. Another association that represents the industry are the trade associations Retail Drug Manufacturers' Association (RDCA) which represents and tackles issues facing the trade, retail, and distribution outlets. The Indian Pharmacy Association (IPA) represents all the aspects of pharmacy and pharmacy education including hospital pharmacy, community pharmacy, institutional pharmacy, and retail pharmacy.

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Organization of Pharmaceutical Producers of India (OPPI)



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The OPPI was first established on 27 December 1965 with Dr. Homi R. Nanji as the first President. This association was set up with the aim of promoting development of the pharmaceutical industry in India. The first annual report was published on 31 December 1966.

Today, OPPI is a premier vibrant and knowledgeable organization. Its scope of activities include OTC, animal health products, biotechnology among others. OPPI members (70 in number) manufacture 300 bulk drugs. OPPI members adhere to the code of pharmaceutical practices

Indian Drug Manufacturers Association (IDMA)



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IDMA was founded in 1961. Today, it is a premier association of the Indian pharmaceutical industry and has come to be regarded in government, media and industry circles as the Voice of the National Sector. IDMA members comprise large, medium, and small companies from all over India, manufacturing bulk drugs and formulations. IDMA plays a vital role in the growth and development of

the industry, by taking up with the government major issues such as price control, patents, and trade mark laws, quality and GMP, R&D, Exports, etc. and promoting better understanding with the consumer organizations, the press and other media on problems faced by the industry.

Bulk Drug Manufacturers Association (BDMA)



C-25, Industrial Estate
Near SBH
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The BDMA India was formed in 1991 with Hyderabad as its headquarters. This is an all India-body representing all the bulk drug manufacturers of India. The Association works for the consolidation of gains of the industry and serves as a catalyst between the government and the industry on the various issues for the growth of the industry. 