



# Pharma Update



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## Indian Pharma on Global Stage

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The Indian Pharmaceutical Industry has come a long way from waiting for imports of bulk drugs from global majors for re processing to becoming an industry which is driving product development and breaking new grounds in medicine research worldwide. This transformation can be better gauged in terms of volume numbers where in the industry which was earlier stagnating is now expected to touch a turnover of INR250 billion (\$5.7 billion) at the end of the 10th Five Year Plan (2002-2007). The pharma industry has grown at 1.5-1.6 times the growth of the economy over the past couple of years. India with its inherent competitive advantages, has now become one of the most preferred destinations for contract research and manufacturing services (CRAMS) at present, the global manufacturing outsourcing opportunity is estimated at USD 20billion and is expected to reach USD 31 billion by 2010. The industry has grown at a CAGR of 13% from 2002-2007 and is expected to grow at a CAGR of 16% over 2007-2011.

The Indian Pharmaceutical industry has been witnessing phenomenal growth in recent years, driven by rising consumption levels in the country and strong demand from export markets. The pharmaceutical industry in India is estimated to be worth about US\$ 10 bn, growing at an annual rate of 9%. In world rankings, the domestic industry stands fourth in terms of volume and 13th in value terms. The ranking in value terms may also be a reflection of the low prices at which medicines are sold in the country.

The industry has seen tremendous progress in terms of infrastructure development, technology base and the wide range of products manufactured. Demand from the exports market has been growing rapidly due to the capability of Indian players to produce cost-effective drugs with world class manufacturing facilities. Bulk drugs of all major therapeutic groups, requiring complicated manufacturing processes are now being produced in India. Pharma companies have developed Good Manufacturing Practices (GMP) compliant facilities for the production of different dosage forms.

A paradigm shift occurred in the Indian pharmaceutical industry with India becoming a signatory to the WTO order, ushering in the Product Patent Regime. Earlier, with the enactment of The Patent Act, 1970, only process patent was applicable for pharmaceuticals. Factors favouring the industry are a vast resource of technical people, state of-the-art manufacturing facilities, low cost and the advantage of the English language. As part of government's support to increase exports, duty free zones have been set up and several manufacturers of bulk drugs have been shifting their facilities to these areas. As a result, the diverse spread has now started getting consolidated and concentrated in certain regions across the country.

Domestic demand has been showing significant growth; the rise in consumption being primarily attributed to the rising population, rise in income levels and increasing health awareness among people. New product launches by the Indian and multinational companies have also catalyzed market demand. Moreover, the favourable regulatory environment, increased expenditure on R&D and improved technical skills in the field of chemical synthesis has also played an important role.

In the pharmaceutical industry, new product launches create new demand. After the introduction of product patent in India, the domestic industry has witnessed a fresh spell of new product launches. Some of the key issues the domestic industry is facing are- Increasing span of price control, Price erosion in generics, Low R&D productivity. The changing global pharmaceutical industry has transformed prospects of Indian pharmaceutical companies. The leading pharma companies in India have been actively extending the frontiers of scientific knowledge and going global through mergers and acquisitions. In 2005, acquisitions by the Indian pharmaceutical companies were the highest, with 20 buyouts abroad. A similar trend was observed during 2006, which include Dr Reddy's buyout of Germany's Betapharm and Ranbaxy's purchase of Romania's Terapia. Europe has emerged as the most preferred destination for acquisitions by Indian companies.

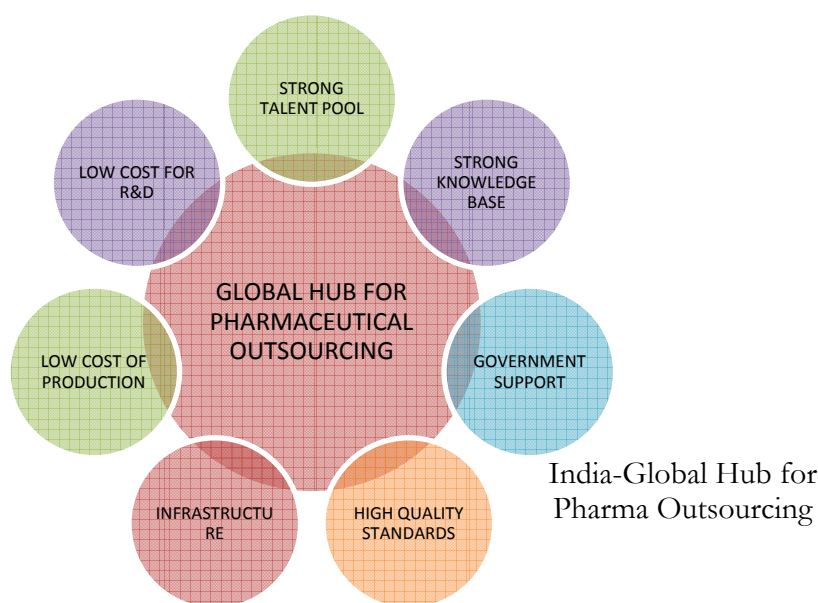
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#### Future Outlook and Potential

The Indian pharmaceutical industry is passing through a transformation and industry players are organizing themselves to avail of the immense opportunities that have opened up globally. The sector is set to report impressive growth in the years to come and outlook for the industry remains strong. Indian pharmaceutical industry can be defined as a success story providing employment for millions and ensuring that essential drugs are available at affordable prices to the vast population of Indian sub-continent. The Indian pharmaceutical industry has witnessed a growth rate of about 10% over the last few years and is expected to touch US\$ 12 billion by 2010. Pharmaceutical industry has given employment to approximately 2.86 million people and has around 20,053 units. Globally, India is 4th in terms of volume (8% of world's production), 13th in terms of value, and 17th in terms of pharmaceutical export value. The drugs and pharmaceuticals exported are worth over US\$ 3.8 billion. The industry has grown at a CAGR of 13 per cent during 2002-07 and over the last couple of years, the industry has grown at about 1.5-1.6 times the growth of the economy. India produces bulk drugs related to various therapeutic areas. Indian pharmaceutical industry manufactures over 400 bulk drugs and roughly 60,000 finished medicines used in different formulations.



India is emerging as a global leader in the area of outsourced clinical research and contract manufacturing & research. Contract research is increasing at the rate of 25% per year, and is expected to touch US \$380 billion by 2010. The highly fragmented Indian pharmaceutical industry has around 30,000 players, out of which 330 are in organized sector. Indian pharmaceutical industry exports its products to more than 200 countries, including highly regulated markets of Europe, Japan, USA and Australia. The Good Manufacturing Practices (GMP) developed by the industry facilitates the production of different dosage forms.

Pharmaceutical companies today operate in multiple markets spanning multiple segments and with varied business models. Collaborations will be the key success in such a dynamic business environment. For multinational pharma companies that are augmenting their market presence by utilizing industry's skills and infrastructures to boost their research and manufacturing activities, partnerships will be crucial.

## Newer Horizons for Generic Drugs in India

Indian firms taking the advantage of their low-cost manufacturing is scoring over others to win a huge market size in the generic drug space of African countries. Africa in future will be providing huge opportunities to Indian drug-manufacturers following the withdrawal of the patent suit filed by 39 global pharmaceutical companies against the South African government, which allows the sale of cheaper generic versions of branded drugs. The first and foremost aim of the Indian pharmaceutical industry now is to take its business to those regions where Indian presence is not well represented. The Indian pharmaceutical industry is a highly fragmented industry with the market leader Ranbaxy holding just 7% market share. About 70% of the market is well distributed among 250 large companies. Apart from these 250 large companies, there are about 8000 small units and 20,000 registered units. Although India's domestic market is strictly regulated on pricing, the export opportunities are coming in a big way. By 2009, drugs worth \$65 billion will go off patent. Indian companies are strongly positioned to grab the new opportunities in the generic drug market as they have the benefit of low-cost manufacturing, world-class production skills and availability of quality manpower. Domestic production costs in India are almost 50% less compared to developed countries. The Indian pharmaceutical industry is likely to grow to \$25 billion by 2010, according to other industry estimates. The Indian pharmaceutical industry is likely to grow to \$25 billion by 2010, according to other industry estimates. The recent changes in the Indian patent laws are also changing the dynamics of the industry. With the introduction of the product patent, multinational pharmaceutical companies are now looking at India as a preferred investment destination as they want to cash in on the huge human resource here as well as the massive domestic market. India accounts for 22% of the world market of generic drugs. The new patent regime is also encouraging the Indian drug-makers to step up their own research and development activities.

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## Japan's Pharma sets up its base in India

For the first time Japan is setting up significant operations in the pharma sector on a considerate scale. Japan's \$8bn Daiichi Sankyo Company, ranked two, is establishing a subsidiary in India called Daiichi Sankyo India Pharm. This firm will eventually conduct manufacturing of drug products and formulations, primarily in the areas of cardiology and diabetes, for the domestic market. The project initially comprises an investment of around \$6.4m. The company also holds plans to set up an R&D operation at a future date. Until the new manufacturing unit is up and running, Daiichi Sankyo indicated it would be utilising the services of local contract manufacturers. This is the first time Japan is venturing for a big assignment. Initially Japanese pharmaceutical industry has largely resisted the temptation to follow the lead of a number of western pharmaceutical companies who have been using India as a low-cost hub to conduct manufacturing and clinical trials. However, in recent times, Japanese firms are increasingly warming to the idea of using the country to either outsource various business functions or set up infrastructure and take advantage of India's burgeoning, low cost pharmaceutical industry. In other news, MSN Laboratories, an Indian active pharmaceutical ingredients (APIs) and formulations manufacturer, has announced an expansion programme to strengthen its contract research and manufacturing (CRAM) capabilities - a business area that it has decided to focus on. Over the next 18 months the firm will invest \$25.5m on its plans, part of which it hopes to raise through private equity. Further down the line MSN Laboratories also intends to begin building a new contract manufacturing facility. The company already has three manufacturing plants in operation and one that is likely to become so in the next year. India is emerging as a competitive outsourcing hub and is playing a major role in the global pharmaceutical industry in manufacturing APIs and intermediates for drug makers. As a result, the global pharma majors are establishing long term relationships with Indian pharma companies and the contract manufacturing market in India is worth about \$500m and has an annual growth rate of 25 per cent. There are around 150 dedicated contract manufacturing units in India that are contributing to 60 per cent of total contract manufacturing business, according to analysts.

SHARE OF GLOBAL SALES: VALUE 1%, VOLUME 8%  
 DOMESTIC MARKET: \$ US 4.5 BN  
 GROWTH RATE: 9.5%  
 EMPLOYMENT: 5 MN DIRECT, 24 MN INDIRECT  
 CAPITAL INVESTMENT: \$ 1.2 BN  
 R&D EXPENDITURE OF 50 MAJOR COMPANIES: \$495.19 MN  
 (GROWTH RATE 26%)  
 INDIAN PHARMA PRODUCE: 22% OF WORLD GENERIC DRUGS  
 NEW PRODUCTS: 12% OF OVERALL MARKET GROWTH  
 PRODUCTION COST: LOWEST IN THE WORLD, 70% LESS THAN THE WEST  
 CLINICAL RESEARCH MARKET: \$ 200 MN IN 2007 (\$ 1 BN BY 2010)

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