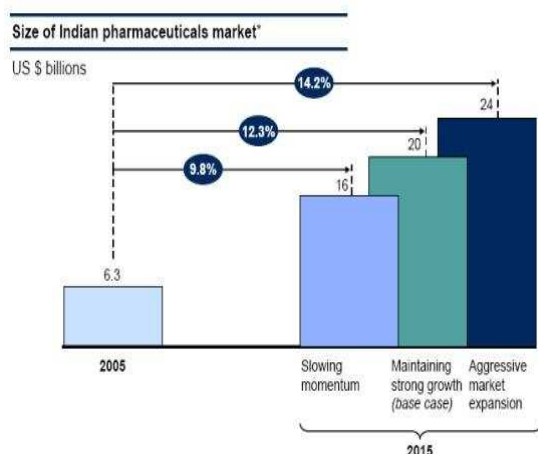


CONSULATE GENERAL OF INDIA SAN FRANCISCO

PHARMACEUTICALS – POISED FOR MORE GROWTH

A. OVERVIEW

The Indian pharmaceutical Industry has made significant progress in creating the required infrastructure, meeting global needs for supply of quality medicines and active pharmaceutical ingredients (APIs). One of the central objectives of the Department of Pharmaceuticals (DOP) is to enable the Indian pharmaceutical industry play a leading role in the global market and ensure availability of quality medicines and pharmaceutical products at reasonable prices.



The Indian pharmaceutical industry has grown from \$1.4 billion in 2000-01 to \$19 billion in 2008. The country now ranks 3rd in terms of volume of production (10% of global share) and 14th largest by value (1.5%).¹ One reason for the lower value share is the lower cost of drugs in India ranging from 5% to 50% less as compared to developed countries². In terms of global sales it has been growing at approximately 10% per year. The share of exports of pharmaceutical products to the total national exports have been in excess of 2% during each of the last 12 years ending 2007-08. It has exhibited a long term upward trend from 2.01% in 1996-97 to 2.55% in 2007-08 (source : DGCIS). For the April-November 2008 period exports grew by 19.1%

in dollar value terms. Most exports are to US, Germany, UK, Russia and Brazil.

The domestic pharmaceutical sector has expanded from Rs 330 billion in November 2004 to Rs 520 billion in November 2008. For the year ending March 2009 the sector's sales is expected to grow by 15.1% according to CMIE. The aggregate sectoral income grew by 18.9% during the quarter ending June 2008 while the growth in net profits during 2007-08 was 8.2% (source: CMIE).

The total employment is about 340,000 in the sector and an estimated 400,000 doctors and 300,000 chemists serving over 1 billion customer market. The pharmaceutical sector is estimated to have created 220,000 employment opportunities³.

From 1930, when the first Indian Pharmaceutical company was started, Bengal Chemicals and Pharmaceutical Works, till today, India has moved from being an importer of pharmaceutical drugs to become a net exporter of pharmaceuticals today. There are about 250 large pharmaceutical manufacturers which control 70% of the Indian market and about 800 small scale pharmaceutical and drug units which form the core of the Pharmaceutical industry in India.

The government started to encourage the growth of drug manufacturing in India in the early 1960's and with the Patent Act in 1970 and subsequent legislation, enabled industry to become what it is today. While the Multinational Companies (MNC) streamed out of India they were replaced by smaller Indian companies. They carved a niche in both the Indian and world markets with their expertise in new processes for manufacturing drugs at low cost. Some of the larger companies have taken steps towards drug innovation as well.

¹ USAIC US-India Bio Pharma Study

² Ibid

³ Ministry of Commerce and Industry of India

<http://pharmaceuticals.gov.in/development.htm>

India projected to be the 10th-largest market by 2015
US \$ billions



India gained its foothold on the global scene with its innovatively engineered generic drugs and Active Pharmaceutical Ingredients (API), and is now seeking to become a major player in Outsourced Clinical Research (OCR) as well as Contract Manufacturing and Research (CMR). There were 74 US FDA-approved manufacturing facilities in India, more than in any other country outside the US, and in 2005, almost 20% of all Abbreviated New Drug Applications (ANDA) to the FDA were filed by Indian companies.

The Pharmaceutical Industry is expected to increase to \$30 billion by 2020 (source: ORG-IMS). Going forward, the Indian Pharmaceutical industry is taking leaping strides in innovative drug discovery with clinical trials underway in 34 molecules. The market is growing at about 30% annually spurred by the high cost advantage of up to 50% for clinical trials as compared to those of developed countries⁴.

B. Bilateral Developments

India's exports of Pharmaceutical Products to the US increased from \$841.9 in 2007 to \$1.479 billion in 2008. The bulk of the increase was from medicaments for therapeutic etc. uses in dosage or retail sale form (HTS category 3004) which saw an increase of \$615 million. US imports from India in the first quarter of 2009 have declined.

⁴ IMS Health, Mckinsey, ABLE

The India-US Chamber of Commerce has taken the initiative to bring together senior executives from the Life Sciences Industry with the support of industry, industry groups and US and Indian government officials to form the Biotech, Pharmaceuticals and Medical Devices Council. Their mission is to provide a professional platform for senior management in these industries in the US and India to network, facilitate and promote business, investments, workforce activities, discuss critical issues, share best practices and experience working with their India initiative⁵.

In recent years India has also made progress in expanding their investment base in the US. Notable among these are Dr Reddy's Laboratories and Ranbaxy which have pharmaceutical manufacturing units in the US.

What is the situation?

- Indian investments in global companies grew at a 70% annual rate from 2002-07
- These investments have been mostly in Europe and have focused on generics and contract manufacturing (CMO), with almost none involving companies focused on R&D
- R&D deals are becoming easier for Indian companies
 - R&D divisions are maturing
 - Some are breaking out their R&D divisions (e.g., Glenmark, NPIL)
- The US is home to many subscale, small to mid-sized pharma companies
 - High quality but inefficient R&D
 - Significant SG&A
 - Clinical assets that demand high development investment

What is the business opportunity?

- Indian companies should consider acquisitions and investments in smaller, subscale US companies (generics and R&D-focused).
- Business case to make acquisitions value creative and rapidly accretive
 - Indian cost focus and investment prudence
 - Reduction of US companies' expensive G&A
 - Reduction of US companies' R&D costs by leveraging India R&D
 - Extraction of greater value from Indian R&D by leveraging US assets
 - Market expansion enabled by US talent and assets

The Pharmaceutical sector in India has been able to attract Foreign Direct Investment (FDI) amounting to \$1.4 billion in the period 2000-01 to 2008-09 (up to September 2008) of which, there has been an inflow of \$125.3 million during the first half of 2008-09. In 2007-08 FDI inflow was highest at \$334.09 million.

Most of the acquisitions involve Indian companies searching for ways to penetrate overseas markets and widen their global footprint. Indian companies without significant R&D capabilities for drug discoveries are also purchasing western drug discovery companies. In 2005-06 Indian companies spent

⁵ <http://www.usaindiachamber.org/bpmcouncil.shtm>

approximately \$1.6 billion to acquire generic drug manufacturing firms in the developed countries, notably the US companies. Nicholas Piramal acquired Dobutrex brand name (US) and Jubilant Organosys acquired Target Research Associates and Trinity Laboratories (both US).

Indian companies have also been acquired by US companies notable among which is the acquisition of Matrix, one of India's and world's leading producers of API's by Mylan of US in January 2007 for \$546 million. Mylan, one of the largest generic drug producers in the US, acquired Matrix to expand its manufacturing capabilities and gain a foothold in key markets and gain access to Matrix's technical and scientific expertise.

The large US MNC's have been active in India's pharmaceutical market mainly through subsidiaries. The re-introduction of product patents precipitated the return of the large MNC's which were also attracted by tax holidays, deduction of capital R&D expenditure and other financial incentives offered by the Indian Government. Pfizer accounts for 5.1% of the Over the Counter (OTC) market in India whereas Johnson & Johnson has 4.8% of the OTC market. Other US MNC's active in the Indian market include Eli Lilly, Bayer, Bristol Meyers Squibb and Abbott.

India has the resources and experience necessary to be a hub for pharma contract manufacturing

India has the highest number of FDA plants outside US

Country	Number of FDA Plants
India	75
Italy	55
China	25
Spain	22
Taiwan	12
Israel	10
Hungary	8

More than 50% of the Indian plants are API plants

Indian pharma contract manufacturers are well positioned to supply regulated markets

- Regulated market contract manufacturing in India is already ~ US \$0.6 billion
- Strong presence in custom synthesis, clinical supply and intermediates/API supply for on and off patient drugs
- Indian pharma contract manufacturers account for over 35% share in DMFs and 25% share in ANDA filings every year
- India is also TRIP compliant and thus offers a favorable IP environment

Several Indian contract manufacturers provide APIs and dry products

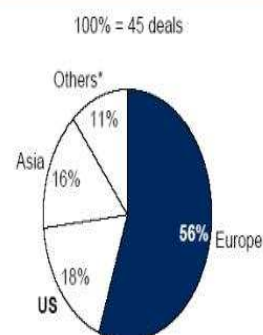
Company	Market cap US \$ billion	Comment
Zydus	2.3	Supplies API and custom chemical synthesis to Mylan, Merck, Abbott, GSK and ~15 other top 25 innovator pharma
Cadila	1.8	5-year contract (\$10MM-15 MM) with Allergan for APIs. 5 year contract (\$15 MM-20 MM) with AMO for formulations
Zydus Cadila	0.9	Supplies intermediates to Altana since 1998 and currently servicing 80% of Altana's global sales. Also JV with Mayne for cytotoxic injectables
Dishman	0.6	Supplies bulk and intermediates to European market, likely to supply US market once USFDA approval is obtained
Emcure Private*		Pioneered chiral technology in India. Mfg relationships with Ivax, Pfizer, Glaxo, BMS, Gilead

Facing lagging sales of patented drugs by MNC's in their home markets, declining R&D revenues and rising costs, many MNC's have turned to Contract Manufacturing and Research Services (CRAMS), co-marketing alliances, outsourcing of research and clinical trials to

reduce costs, increase development capacity and trim the "time to market" for new drugs. India has emerged as the principal destination for global pharmaceutical companies. Nicholas Piramal signed a 5 year \$350 million agreement with Pfizer for 12 products. The agreement made Nicholas Piramal Pfizer's largest manufacturing partner⁶.

① US pharma contract manufacturers have lagged behind their European counterparts in out-licensing to India

Geographic breakdown of publicly announced pharmaceutical out-licensing deals to India 2002-08



Other notable alliances, joint ventures with US companies are Nicholas Piramal with Genzyme, Eli Lilly, Biogen Idec, Minrad, Gilead Sciences and Allergan (all US), Ranbaxy with IPCA Labs, Cephalon, Gilead Sciences (all US), Cadila with Geneva and Mallinckrodt (all US) and Glenmark with forest Labs, Lehigh Valley Technology and Apotex (all US).

C. Recent Events

Mr Ashok Kumar, Secretary, Department of Pharmaceuticals (DOP) attended the 45th Drug Information Association (DIA) annual meeting held in San Diego, California from 21st to 26th June, 2009. This was a meeting of leaders and academia and CEO's/senior functionaries of US based pharmaceutical companies. The Secretary (DOP) also proceeded to New York in connection with the India Pharma Summit 2009.

On 14th May, 2009, US-India BioPharma & Healthcare Summit 2009 was held at Cambridge, MA, USA. This is an annual high

⁶ The Economic Times, July 25, 2006

profile summit of among others Pharmaceutical companies from India and US, Venture Capitalists, Investment Bankers, Policy Makers and Academia.

The Pharmaceuticals Export Promotion Council (PHARMEXCIL), set up by Ministry of Commerce & Industry, Government of India, held a Patents Awareness Programme on 20th March, 2009 at Mumbai, India present the current positions on Patent Law in India and provide an insight into the various aspects and rationale of the patent law.

PHARMEXCIL also organized an interactive session with exporters on 27th June, 2009 at Chennai, India titled “Meeting Global Market Challenges”. This interaction focused mainly on:

- Export potential of Indian Pharmaceuticals in the global market place
- Regulatory issues and product registrations
- Export Credit
- Pre-shipment Inspection related issues.

Seminar on Environmental Issues Pertaining to the Pharmaceutical Industries was held on 12th February, 2009 at New Delhi, India organized by The Department of Pharmaceuticals (DOP), Ministry of Chemicals and Fertilizers, Government of India, Federation of Indian Chambers of Commerce and Industry(FICCI) and National Institute of Pharmaceutical Education and Research(NIPER).

The seminar was organized to identify the Environmental issues that are being faced by the bulk drug industry in particular and the pharmaceutical industry in general and to identify areas where the newly established environment cell under the Department of Pharmaceuticals can facilitate the process of environmental compliance for such industries to ensure environmental sustainability.

D. Upcoming Events

A. Pharmaceutical Outsourcing Congress India 2009, India’s most important pharmaceutical outsourcing event is to be held at Mumbai from 28-29 July, 2009. This event will bring together key industry and regulatory experts to debate the future of pharma outsourcing in India.

B. The 2nd Molecular Diagnostics World Congress together with the Microarray World Congress and Lab-on-a-Chip World Congress is to be held at South San Francisco from 6-7 August, 2009.

C. The CPhI India Trade Show is being held during 01-03 December, 2009 to be held at Mumbai. This show will include ICSE-India Show, P-MEC India Show and BioPh India Show at the same time. Each show covers the different aspects of modern day pharmaceuticals covering manufacturing companies, service companies, universities, bioregions and start ups. It will be an opportunity to meet with key pharmaceutical professionals from many countries such as US, UK, China, Spain and India. Latest innovations, technologies and trends and developments will be on show.

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