



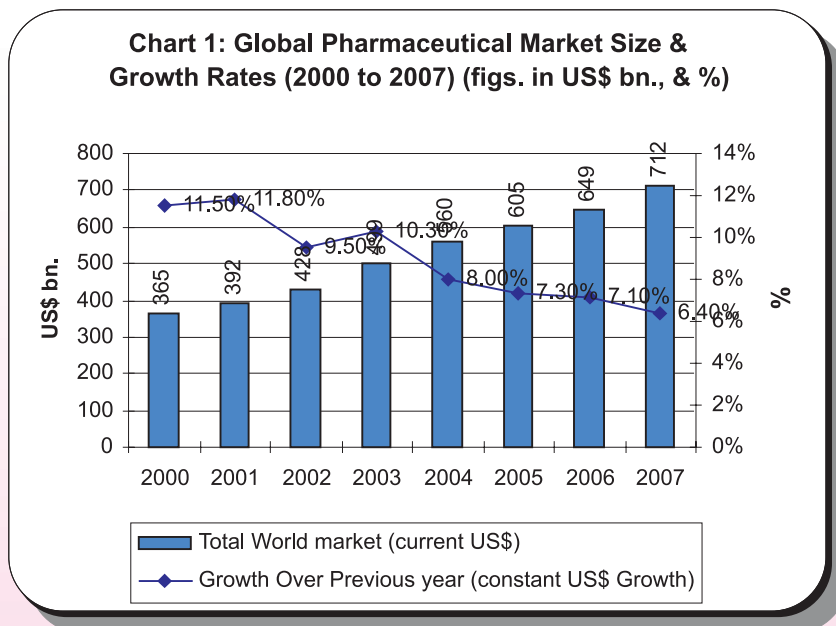
EXPORTS PERFORMANCE OF INDIAN PHARMACEUTICALS INDUSTRY

Introduction:

The total pharmaceutical market size of India, for the year 2008 stands at US\$11.32 billion growing at 8.4% over the previous year. This is approximately 16.5% of the total healthcare expenditure of the country estimated at US\$68.6 billion and 0.8% of the country's GDP. India still has one of the lowest per capita expenditure on pharmaceutical products in the world estimated at US\$10. Generic drugs occupy 70-80% of the total market.

Global Pharmaceutical Markets – An Overview

The global pharmaceutical markets are estimated at US\$712bn in the year 2007 growing at 6.4 percent over the 2006 and an estimated compounded annual growth rate (CAGR) of 10.7 percent for the period 2002-07. (Refer Chart 1).



Source: IMS Health

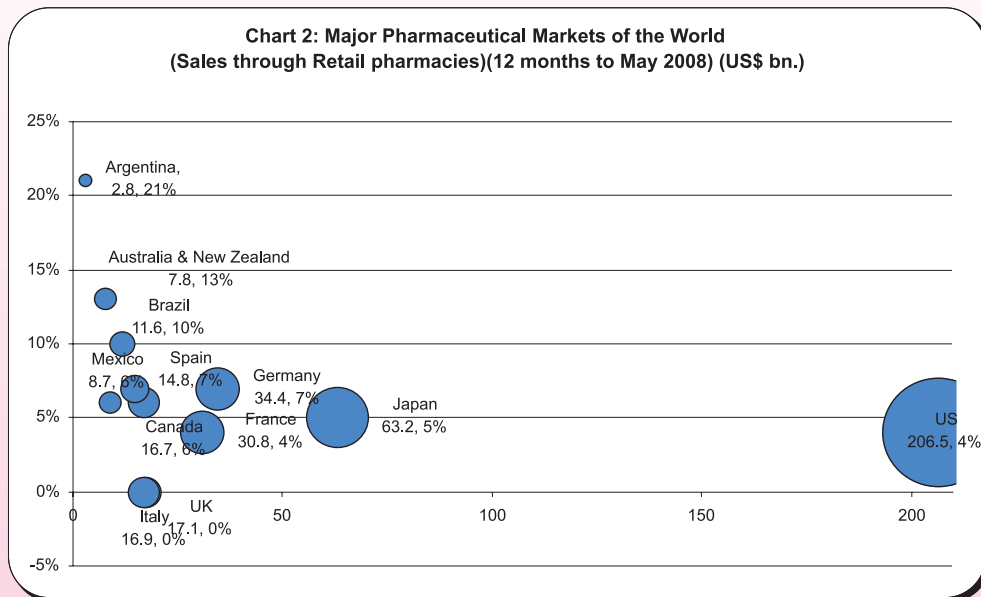
USA is the largest market with an estimated size of US\$295-305bn and growing at 4-5 percent during the last 12 months ended May 2008. It is followed by Top 5 European countries at US\$135-145bn (4-5%), emerging markets (Brazil, China, India, Mexico, Russia, South Korea and Turkey) at US\$85-90bn. (12-13%), Japan at US\$64-68bn (1-2%) and the rest of the world is estimated at US\$125-135bn for the same period which is expected to grow at 7-8 percent in the coming years (refer Table 1 & chart 2).

Table 1: Sales Through Retail Pharmacies

(Twelve months to May 2008*)

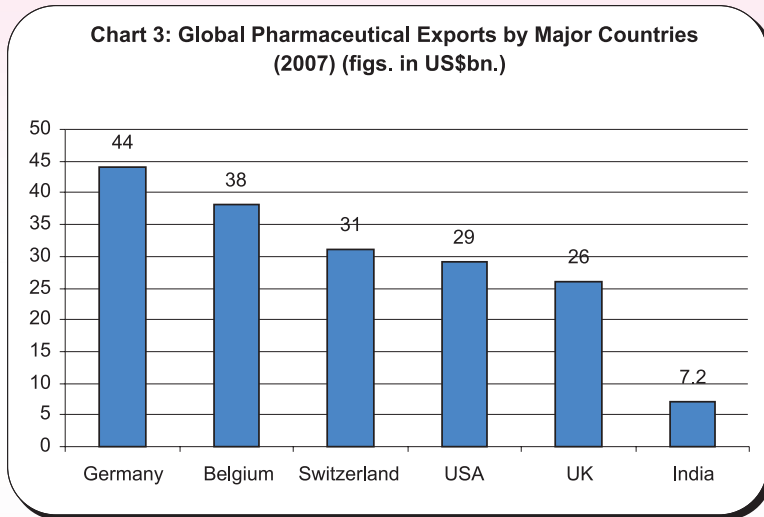
Sl. No.	Region/Country	Market Size US\$ bn.	Growth Rate
1.	NORTH AMERICA	223.3	2%
1a.	United States	206.5	4%
1b.	Canada	16.7	6%
2.	EUROPE (Top 5)	114.3	4%
2A.	Germany	34.4	7%
2b.	France	30.8	4%
2c.	United Kingdom	17.1	0%
2d.	Italy	16.9	0%
2e.	Spain	14.8	7%
3.	JAPAN (including hospitals)	63.2	5%
4.	LATIN AMERICA (Top 3)	23.2	9%
4a.	Brazil	11.6	10%
4b.	Mexico	8.7	6%
4c.	Argentina	2.8	21%
5.	AUSTRALIA/NEW ZEALAND	7.8	13%

Source: IMS Health



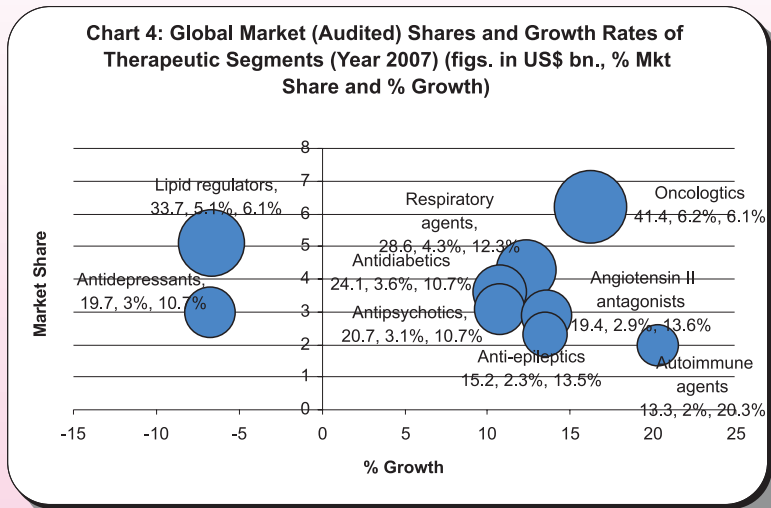
Source: IMS

Share of pharmaceutical products in world exports have grown from a level of 1.7% in 2000 to 2.6% in 2006. In the year 2006, world exports of pharmaceutical products amounted to US \$ 311 billion. The major exporting countries of pharmaceutical products in the world are given in Chart 3.



Source: ITC, Exim Bank

Leading therapy classes in world pharmaceutical sales in 2007 include oncologics (6.2%), lipid regulators (5.1%), respiratory agents (4.3%), acid pump inhibitors (4%) and anti-diabetics (24.1%) (refer chart 4).



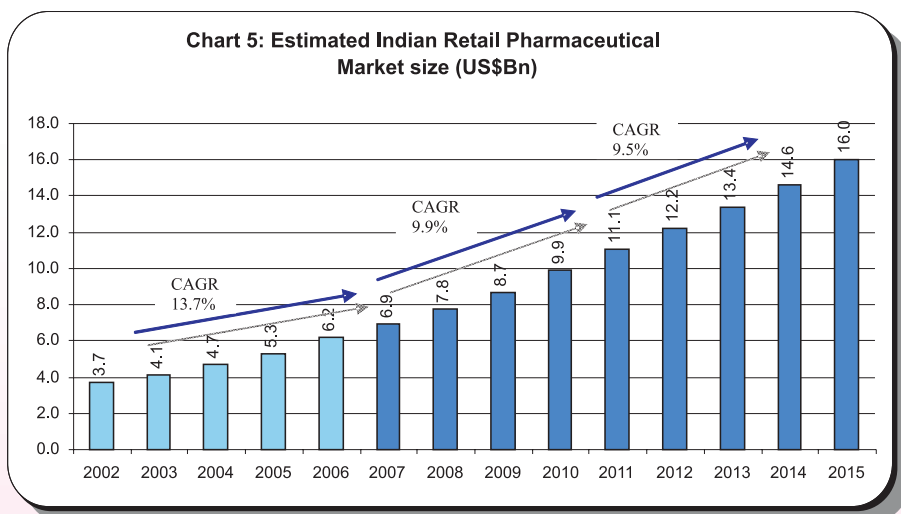
Source: IMS, *Excludes unaudited markets, and Russia, Ukraine and Belarus audited data. Sales cover direct and indirect pharmaceutical channel purchases in U.S. dollars from pharmaceutical wholesalers and manufacturers. The figures above include prescription and certain over-the-counter data and represent manufacturer prices. Totals may not add due to rounding.

The global pharmaceutical market is highly fragmented with top 22 companies accounting to only US\$50bn which is 7% of global pharmaceutical sales.

Indian Pharmaceutical Market

The Indian retail pharmaceutical market size is estimated at US\$7.8bn in the year 2008 and is expected to grow at a CAGR of 9.9 percent till 2010 and thereafter at a CAGR of 9.5 till 2015 (Refer Chart 5). The pharmaceutical sector is emerging as one of the major contributors to Indian exports with export earnings rising from a negligible amount in early 1990s to Rs.29,139.57 crores by 2007-08 growing by 16.83% over 2006-07. The total size of the industry is estimated at US\$14.2bn during that year.

India is seen not only as an API and formulation manufacturing base, but also as an emerging hub for biotechnology, bioinformatics, contract research, clinical data management and clinical trials.

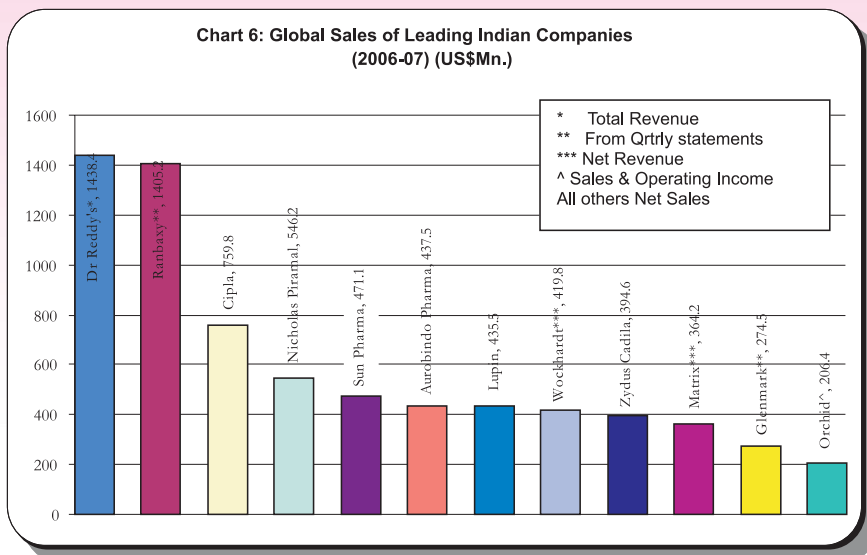


Source: EIU Report, Datamonitor, primary interviews, Deloitte Consulting LLP analysis

The domestic industry is fragmented with top 10 companies capturing 30 percent (refer chart 6) and the organized sector constituting over 400 companies.

Investment & R&D

The combined total investment (Gross Block) of 561 pharmaceutical companies listed on Bombay Stock Exchange as per the latest company filings available as per the latest data available at the end of June 2008 stood at Rs.40,461.7 crores (net fixed assets stood at Rs.29,325crores). Further, Rs.5,903.1 crores in some 550 projects under implementation and new investment projects announced in 637 new proposals of approx. Rs.5,861.8 crores as per Centre for Monitoring Indian Economy (CMIE) database Capex, resulted in the new investment of Rs.11,764.9 crores, which is an increase of 29 percent over the existing investment. Such investment of close to US\$ 3bn. is by global standards. Some of the major pharmaceutical Projects under implementation are given in table 2 below:



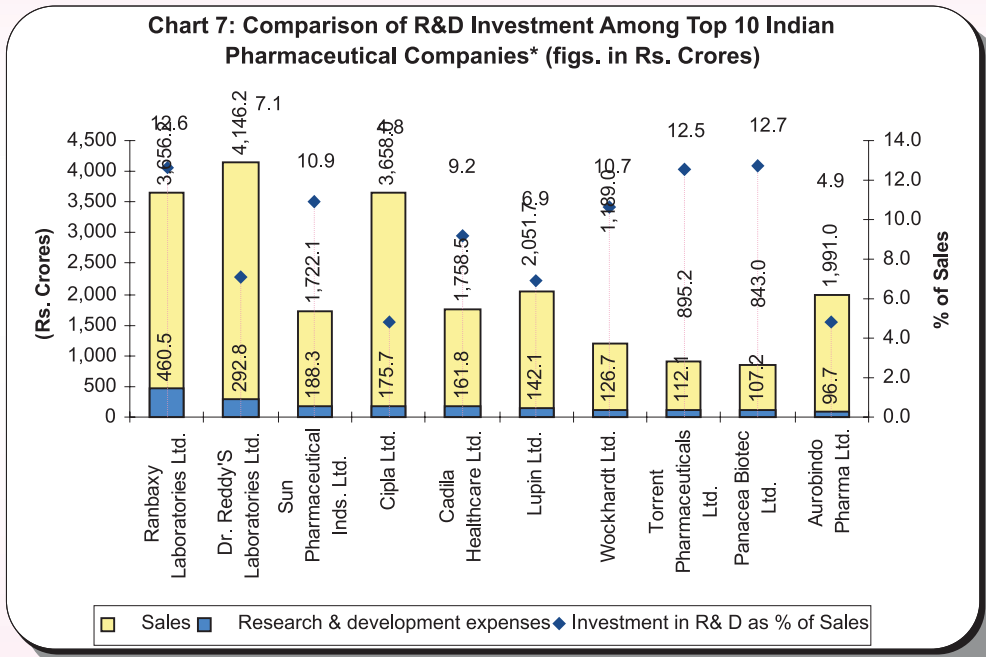
Source: Pharma Outlook, Espicom, 2008

Table 2: Top 15 Pharmaceutical Projects Under Implementation in India

Sl. No.	Company Name	Project Name	Project Status	Project Cost (Rs. Crore)
1	Zydus Infrastructure Ltd.	Pharma S E Z Project	Under Implementation	1,000
2	Biocon Ltd.	Biopharma (Insulin) Project	Announcement	700
3	Wockhardt Ltd.	Shendre Pharmaceuticals S E Z Project	Under Implementation	700
4	Meditab Specialties Pvt. Ltd.	Keri Pharma S E Z Project	Under Implementation	650
5	Dishman Infrastructure Ltd.	Pharma S E Z Project	Under Implementation	600
6	Biocon Ltd.	'Statin' Drug Capacity Expansion Project	Under Implementation	500
7	Eisai Pharmaceuticals India Pvt. Ltd.	Vizag Pharma (Api) - R & D Centre Project	Announcement	500
8	Tamilnadu Industrial Devp. Corpn. Ltd.	Biogenomics & Bioinformatics Project	Under Implementation	450
9	Andhra Pradesh Indl. Infrastructure Corpn. Ltd.	Indira Gandhi Centre For Advanced Research Centre	Announcement	400
10	Cipla Ltd.	On Livestock Project Goa Drug Formulation Expansion Project	Announcement	400
11	Government Of Andhra Pradesh	Jadcherla Vaccine Centre Project	Announcement	400

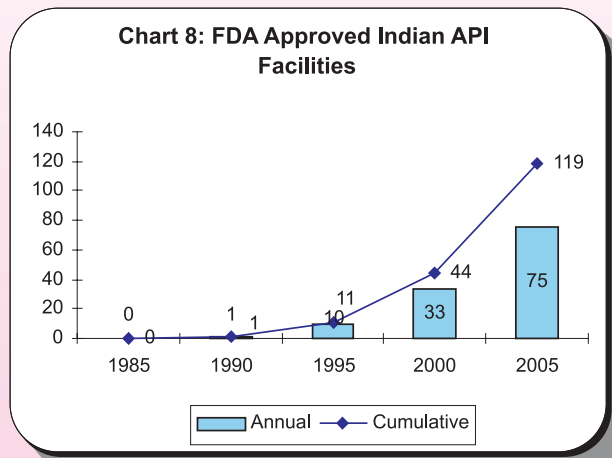
Source: CMIE database Capex (as on 30th June, 2008)

Data for 596 Indian pharmaceuticals companies, whose sales and R&D investment figures are available with CMIE database 'Prowess', reveals that a total of 151 companies (28.3%) companies invested in R&D activities as per latest data available till the end of June 2008 (Refer chart 14). The total investment in R&D by the pharmaceutical companies stood at Rs.2,973.2 crores which is 9.9 percent of the sales of these 151 companies. The average R&D expenditure for the leading Indian firms represented just 5.7 percent of their net sales in fiscal 2004 (Refer Chart 7)

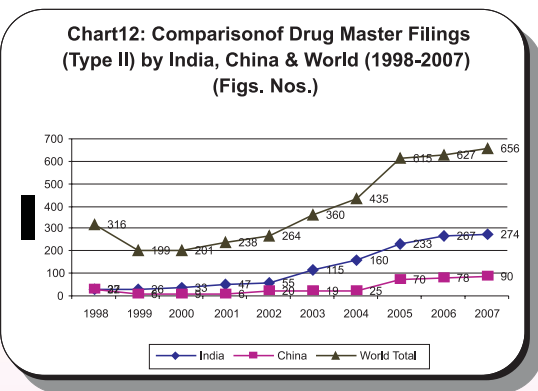
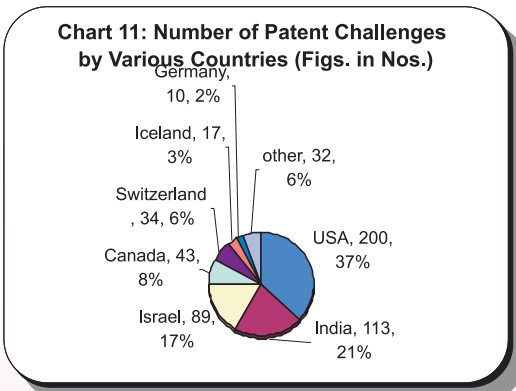
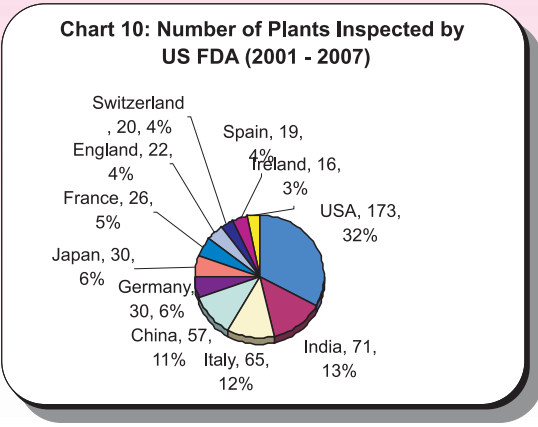
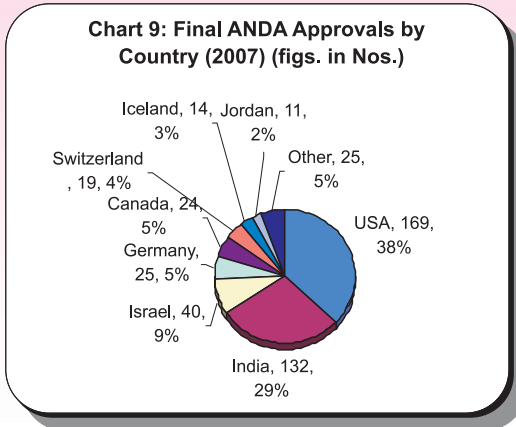


Source: CMIE database 'Prowess'

The largest number of US FDA approved facilities outside US are in India. India files over one third of drug master files in USA. Thirty percent of the approved ANDAs in US are from India, ranking India number 2 next to USA, needless to mention scores of approvals by UK MHRA and various other agencies. Even in patent challenges, India ranks next to USA with a share of 21 percent of patent challenges (Refer Chart- 8, 9, 10, 11 & 12).



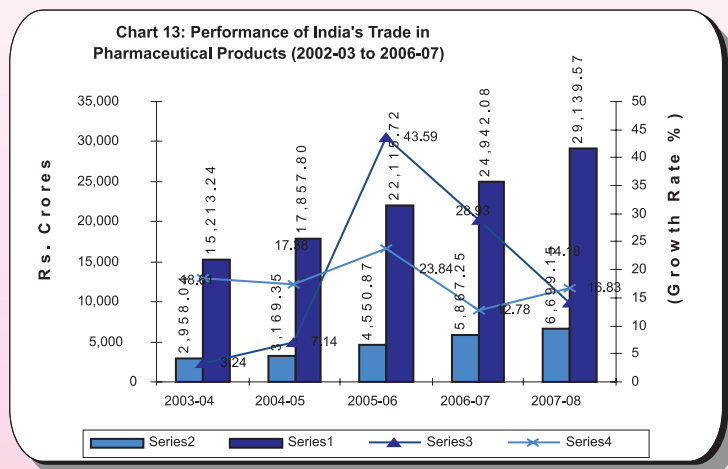
Source: Wall Street Research, Deutsche Bank



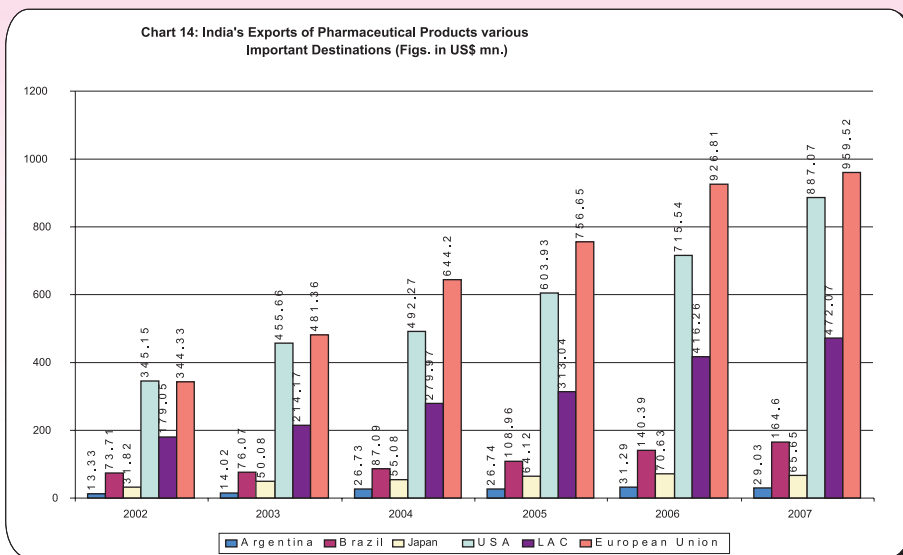
Source: Thomson Scientific, New Port Horizon Global

Export Performance of Indian Pharmaceutical Industry

Pharmaceutical industry has shown commendable export performance, the trade balance being positive. Over the period 2002-03 to 2007-08 the compounded annual growth rate (CAGR) of exports has been 18.5 percent. (refer Chart 13 & 14).



Source: CMIE trade database 'India Trades'



Source : CMIE database 'IndiaTrades'

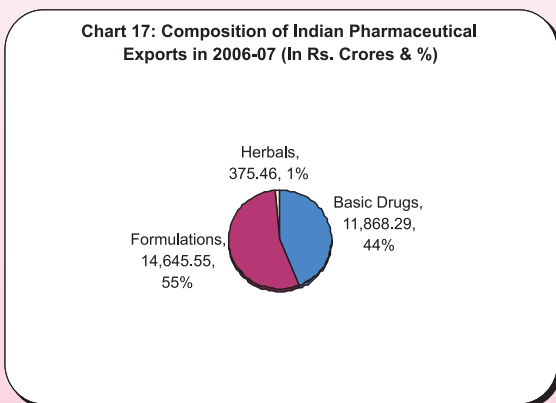
As of 2006-07 the largest markets for Indian pharmaceutical exports are presented in the chart 15 below:

Apart from these, some of the fast emerging markets (2005-06) are presented in table 3:

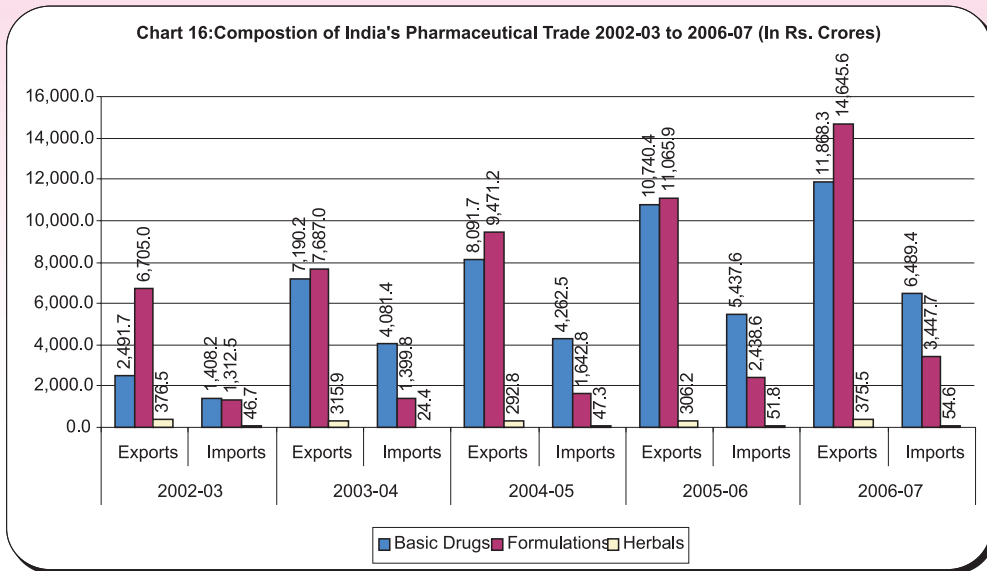
The composition of Exports & imports of India's pharmaceutical products in terms of Basic Drugs, Formulations & Herbals and region-wise exports have been presented in chart 16, 17 & 18 below.

Table 3: Countries of High Import Growth Rates in Pharmaceutical Products from India (2005-06) (figs. In Rs.Crores)

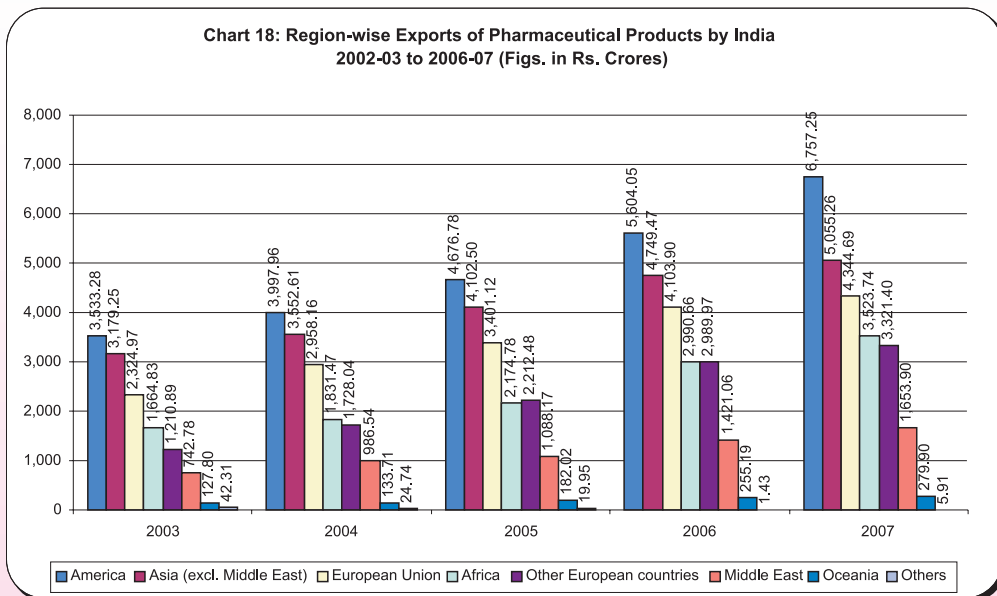
Country	Export Value	Growth%
South Africa	442.18	104.0
Israel	310.33	84.2
Turkey	426.22	78.5
Kenya	227.74	78.3
Singapore	378.50	58.5
UK	820.63	40.0
China	762.55	40.0
Russia	1,051.12	35.8
Italy	411.98	35.4
Vietnam	400.69	31.3



Source: CMIE, India Trades



Source: CMIE, India Trades



Source: CMIE, India Trades

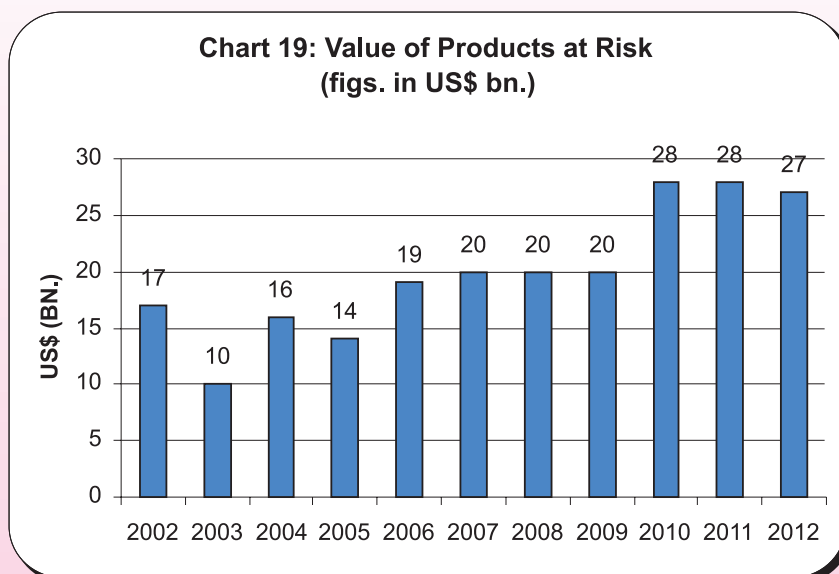
The export figures of Indian pharmaceutical products to Top 10 importing countries are given in Table 4. USA remains the most important export destination with a share of 24.5% in the country's exports. The exports to USA experienced 79.7% growth during the quarter ended Dec.07 over the previous quarter Oct.07. Germany, Russia, UK & Brazil were the other top importing countries.

Table 4: Quarterly Analysis of Exports of India's Pharmaceutical Products to Top 10 Destinations (Figs. in Rs. Crores)

Sl. No.	Importing Country	Sep-06	Dec-06	Mar-07	Jun-07	Sep-07	Dec-07	% Share
1	USA	1,023.87	1,286.56	1,188.66	1,160.81	1,022.84	1,838.43	24.5
2	Germany	356.77	298.50	347.30	317.38	312.88	308.83	4.1
3	Russia	314.01	353.10	354.99	231.53	290.84	295.76	3.9
4	UK	233.88	223.91	233.59	225.92	284.63	277.33	3.7
5	Brazil	219.06	209.74	165.22	169.60	187.76	190.86	2.5
6	Canada	160.53	137.77	121.67	168.17	153.54	182.75	2.4
7	South Africa	123.17	100.13	164.24	129.10	147.56	178.32	2.4
8	China	149.91	157.17	182.89	162.88	243.77	175.00	2.3
9	Nigeria	183.95	183.59	137.76	133.34	175.47	171.18	2.3
10	Turkey	114.00	108.77	111.16	93.40	105.15	141.89	1.9

Generic Drugs

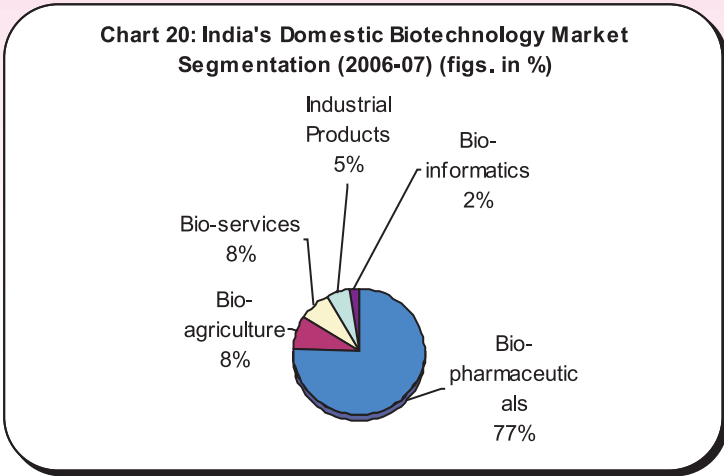
The generic pharmaceutical sales in the world are estimated to be over 12% of world pharmaceutical sales. This translates into a market size valued US \$ 85 billion in 2007. Some estimates have put the ethical generic sales to have a share of 95% of total generic market, and the rest being the generic OTC (over the counter) market. Besides this, a number of leading drugs go off patent every year and the generic pharmaceuticals penetration is increasing in all the countries of the world further rising the opportunity for exports in this segment. Approximately US\$123 billion of generic products are at risk of losing patents by 2012 (refer Chart 19). Even at a conservative estimate of 15% opportunity this translates into US\$31.2 billion opportunity for India.



Source: IMS Health Market Prognosis Sep. 2007

Indian Biotechnology Industry

With 200 companies, India's biotechnology sector is growing fast and is in the early stages of development with initial emphasis on vaccines and bioservices. The break-up of Indian domestic biotechnology market is given chart 20. This industry grew by 37 percent in the year 2006-07. Biopharmaceuticals, the largest segment exceeded US\$1 billion.

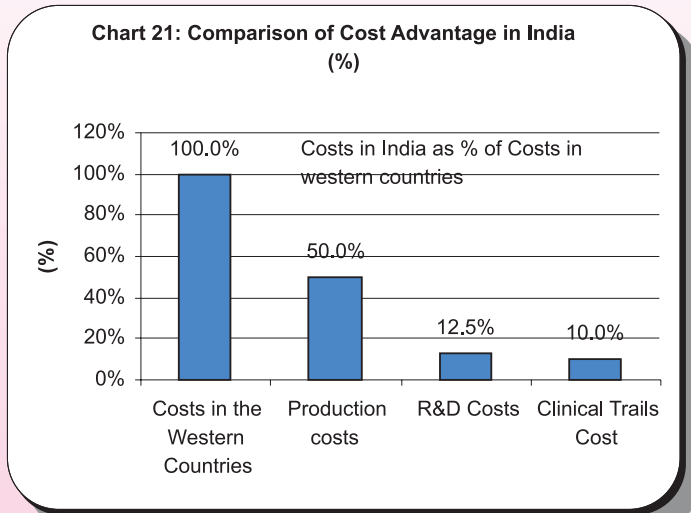


Total biotechnology exports stood at US\$763 million during 2006-07 with 75 percent of it coming from biopharmaceuticals. The country ranks first in clinical research valued at US\$100-120mn and growing at 20-25% per year.

IMS Health estimates that biotechnology products accounted for over 10 percent of global pharmaceutical sales. A significant portion of new drugs in the recent years are from biopharmaceuticals arena. The revival of this once strong sector has begun. Serum Institute, Biocon, Panacea Biotech, Venkateswara Hatcheries, Wockhardt, Shanta Biotech and Bharat Biotech are some of the emerging players.

Contract Manufacturing

The global market for contract manufacturing of prescription drugs is estimated to increase from a value of \$26.2 billion to \$43.9 billion, although the over-the-counter medicines and nutritional products sector will show the fastest growth. Asia has recently been challenging North America & Europe's traditional domination of the global pharmaceutical contract manufacturing market. India



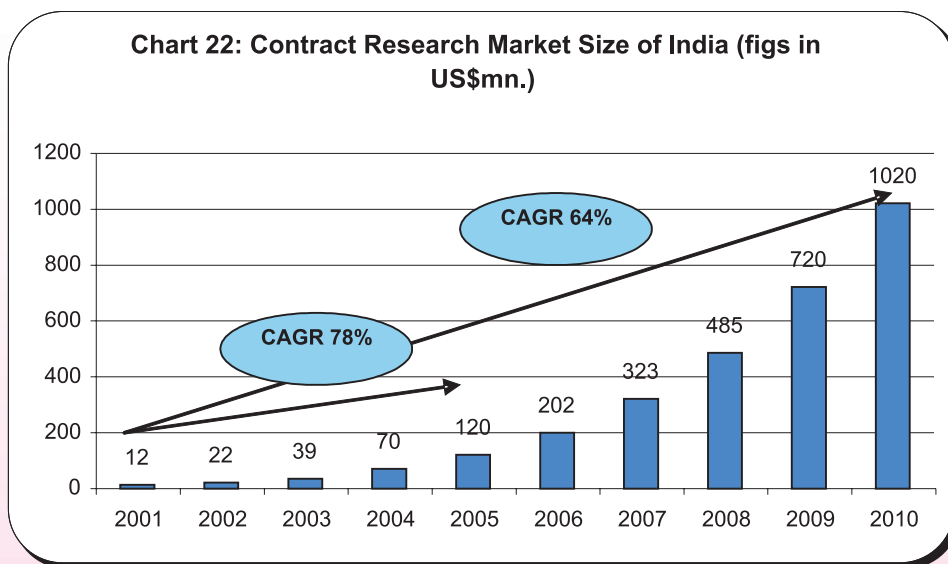
Source: Pharmexcil

and China could potentially account for 35 percent to 40 percent of the outsourced market share for active pharmaceutical ingredients, finished dosage formulations and intermediates. A comparison of India's cost advantage vis-à-vis Europe & North America are presented in Chart 21 below.

India's entrepreneurial pharmaceutical manufacturers are now beginning to leverage benefits from the introduction of the nation's product patent system. The scientific, technical and manufacturing skills, developed under the country's 35-year process patent system, perfectly matches the requirements of global drug manufacturers who are increasingly seeking to offshore many manufacturing activities previously performed in-house.

Contract Research

Contract research in generic pharmaceuticals is also a significant opportunity (refer chart 22). Established generic companies would like to outsource or buy services in formulation development, bioequivalence testing, stability studies centers, etc.



Source: zinnov Analysis

Various surveys indicate that India has quite a number of resourceful firms in the field of Chemistry providing high quality output in timely schedules, allowing more leads to pursue. India is significantly ahead in chemistry services such as analog preparation, analytical chemistry, focus library, combinatorial chemistry, structural chemistry, structural drug design, computer aided drug design, high throughput screening and assay development.

New Technologies

Biocatalysts, Organocatalysts, Nanotechnology are some of the new technologies that will have significant influence on the industry. Developing micro organisms which act as enzyme catalysts accelerating certain chemical reactions which otherwise take multiple steps or cause lot of environmental issues is an essential technology.

Europe, US and other key countries are focusing on biocatalysts for significant gains in food processing, environment management, etc. Companies working in biocatalysts have succeeded significantly, licensing the technology/ biocatalysts with out incurring huge capital expenditures in setting up production units. Technologies based on biocatalysts helped European and US firms to cut several steps in chemical process and compete comfortably with low cost countries.

Being one of the largest producers of APIs, the country is poised to develop biocatalysts either to reduce load on environment as also to reduce cost of manufacturing.

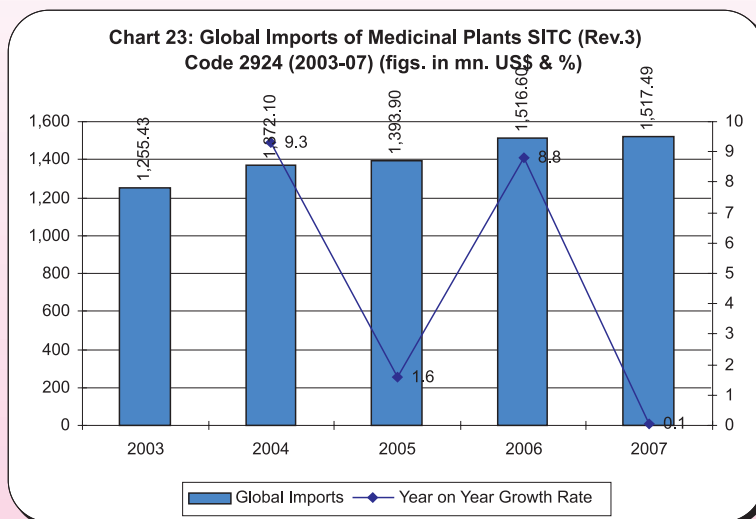
Medical Tourism

The medical tourism market in India was estimated at US\$333 million in 2004, growing by about 25 percent and this is predicted to become a US\$2 billion-a-year business opportunity by 2012. India is witnessing a surge of patients from developed countries as well as from Africa, South & West Asia because while the cost of comparable treatment in India is about 1/8th to 1/5th of the cost in the Western countries, the quality of Indian healthcare delivery (in certain institutions) is world class.

Exports of Herbal, Ayurvedic, Siddha, Unani & Homeopathic Products

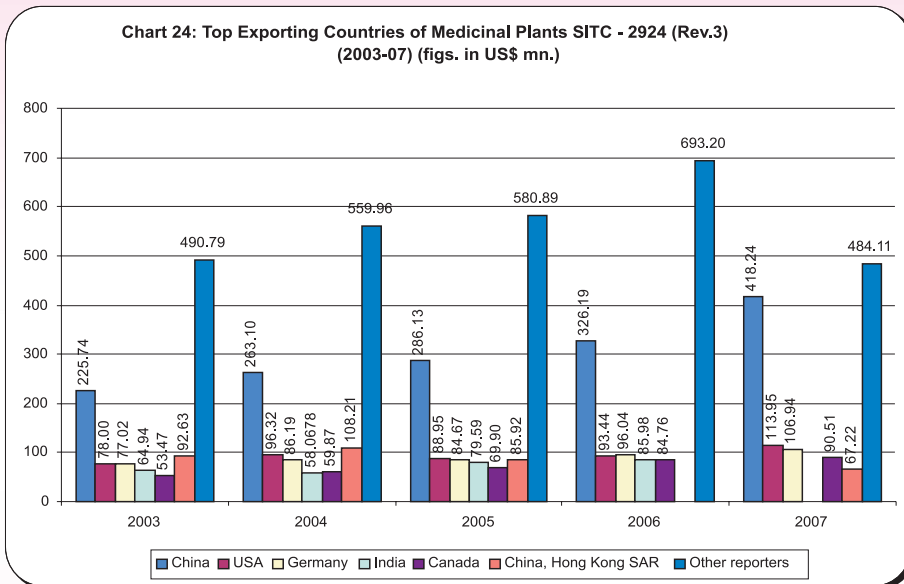
The global imports of Medicinal plants as per United Nations statistical division (SITC Code No. 2924) stood at US\$1.57 billion during the year 2007 growing at a compounded annual growth rate of 4.85% during the years 2003-07 (refer chart 23).

China along with Hong Kong with exports at US\$485.45mn is the



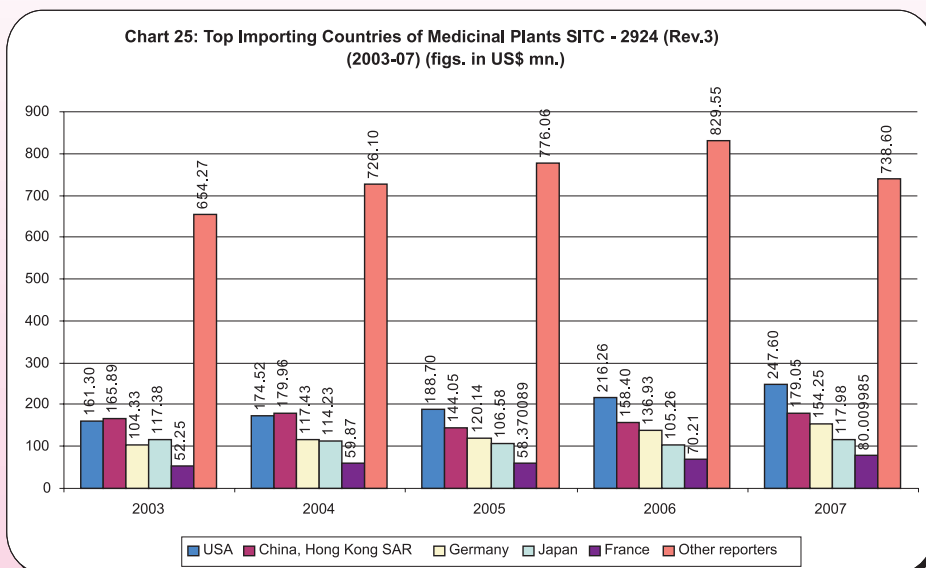
Source: Comtrade, United Nations Statistics Division

largest exporting country. It is followed by USA (US\$113.95mn) and Germany (US\$106.94) in the year 2007. India with its exports of US\$85.98mn is considered as the major source exporting country for Herbal medicines (refer chart 24).



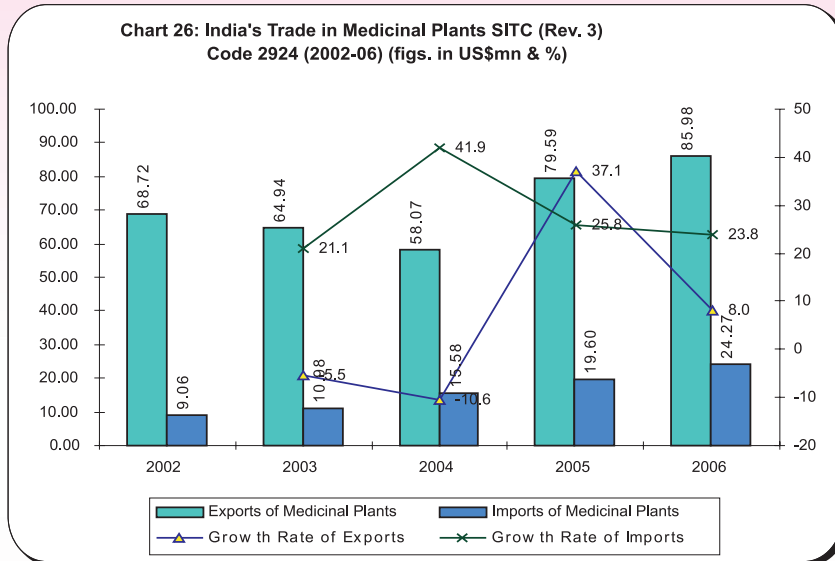
Source: Comtrade, United Nations Statistics Division

USA is the largest market for Medicinal plants with imports at US\$247.6mn, followed by Hong Kong (US\$179), Germany (US\$154.25mn), Japan (US\$117.98) and France (US\$80mn) (refer chart 25).



Source: Comtrade, United Nations Statistics Division

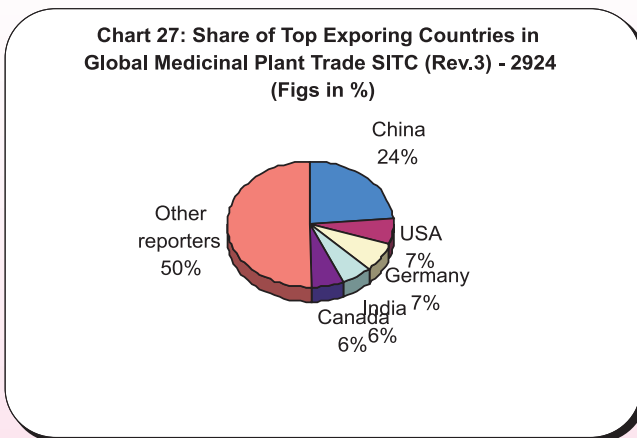
Indian exports of medicinal plants grew at 8% during 2006 over 2005. However, its imports of medicinal plants grew at 23.8% during the same period (refer chart 26).



Source: Comtrade, United Nations Statistics Division

China occupies a lion's share of 24% of global medicinal plant trade followed by USA (7%), Germany (7%), India (6%) and Canada (6%) (refer chart 27).

As per CMIE trade database 'Indiatrades', India's exports of 'Herbal plants' identified by 28 commodities by their HS Codes stood at Rs.375.46 crores during 2006-07 growing by 5.3% over the previous year. However, for the 4 year period between 2003-04 to 2006-07 the exports showed a decline with a negative compounded annual growth rate (CAGR) of -0.1% (refer chart 28).



Source: Comtrade, United Nations Statistics Division

The total exports of the 152 commodities belonging to ASU, Homeopathic & Herbal products reveals that the trade exports of these products stood at Rs.3,223.78 crores in the year 2006-07 growing at a compounded annual growth rate (CAGR) of 5.3% during four year period 2003-04 to 2006-07. Imports stood at Rs.933.58 crores with a CAGR of 4.1% during the same period (refer chart 29).

Chart 28: India's Foreign Trade in Herbal Products (2002-03 to 2006-07) (figs in Rs. Crores & %)

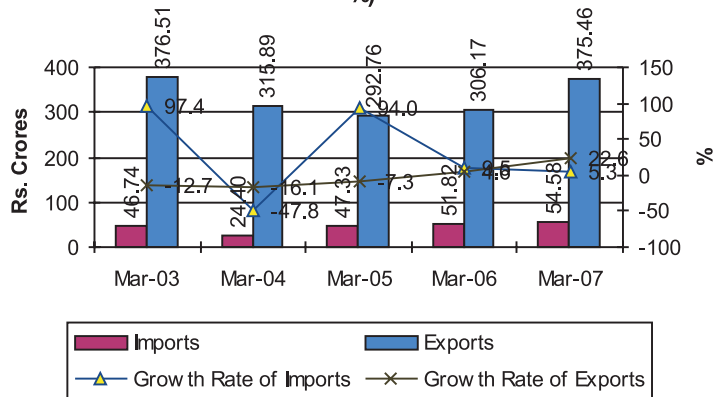
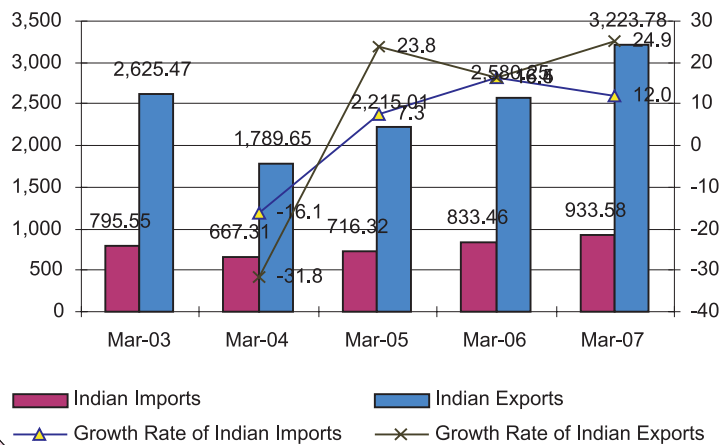


Chart 29: India's Exports & Imports of ASU, Homeopathy & Herbals Products (2002-03 - 2006-07) (figs. in Rs. Crores)



Source: CMIE, India Trades



Conclusion

After the introduction of TRIPs compliant IPR regime in India, pharmaceutical industry is undergone a paradigm shift. The sector has evolved from being dominated by multinational companies in the 1950's to some imports and indigenous manufacturing in the 1970's and then protected by the legislative provisions of the older Patents Act – to significant indigenous production and subsequent exports. Leading Indian companies have established marketing and manufacturing activities in a large number of countries including USA and countries of Western Europe as well as have been indulging in mergers and acquisitions in these countries in the past few years.

The new patent regime has also led to the return of the pharmaceutical multinationals, many of which had left India during the 1970s. Now they are back and are looking at India not only for its traditional strengths in contract manufacturing but also as a highly attractive location for research and development (R&D), particularly in the conduct of clinical trials and other services.

The country is therefore poised to become global manufacturing hub for pharmaceutical industry. However, to remain competitive, Indian companies will have to achieve economies of scale in their production. Large capacities would also attract contract manufacturing in a major way in the years to come. Further, India still has to consolidate/ acquire distribution chains in India and abroad which would be a major challenge in the coming years. If the country has to provide healthcare at reasonable price, it has to acquire strengths in biopharmaceuticals and new drug discovery which would be the foremost priority of the country. Further, India's pharmaceutical quality regulation would require strengthening.