

3 Pharmaceutical Sector - Recent Trends

3.1 Global Pharmaceutical Market Trends

The global pharmaceutical markets were estimated at US\$712bn in the year 2007 growing at 6.4 percent over 2006 (Refer table 5 & Chart 5). The global pharmaceutical industry has grown at a compounded annual growth rate (CAGR) of 10.7 percent for the period 2002-07.

Global Sales (US\$ bn./Year)	2000	2001	2002	2003	2004	2005	2006	2007
Total World market (current US\$)	365	392	428	499	560	605	649	712
Growth Over Previous year (constant US\$ Growth)	11.50%	11.80%	9.50%	10.30%	8.00%	7.30%	7.10%	6.40%

*Source: IMS Health Market Prognosis (includes IMS Audited and Unaudited markets)
All information current as of March 28, 2008*

The market size of USA is estimated at US\$295-305bn with an estimated growth rate of 4-5 percent. It is followed by Top 5 European countries (EU-5) with an estimated market size of US\$135-145bn growing at 4-5%, emerging markets VIZ., Brazil, China, India, Mexico, Russia, South Korea and Turkey with an estimated market size of US\$85-90bn. (growing at 12-13%) and Japan with an estimated market size of US\$64-68bn (growing at 1-2%). The pharmaceutical market size of the rest of the world (ROW) is estimated at US\$125-135bn which is estimated to grow at 7-8 percent in the coming years (refer table 6 & chart 6).

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

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The global data on pharmaceutical market sizes and growth rates suggest that while protected markets such as US and Japan, account for major chunk of the global market, these are growing at a slow rate of 4-5% or even stagnant as in the case of UK & Italy. Spain, Germany and Canada on the other hand are huge and are growing between 6-7 percent. Argentina, Australia and Brazil are amongst the high growth markets. The size & growth rate of various therapeutic segments are presented in table 8 & Chart 8 and major exporting countries of the world are presented in table 7 & chart 7 below.

Table 8: Global Pharmaceutical Exports by Major Countries (figs. in US\$ bn.) (2006)	
Germany	44
Belgium	38
Switzerland	31
USA	29
UK	26
India	7.2
<i>Source: WTO</i>	

Further, it can be noticed that the global pharmaceutical market is highly fragmented with top 22 companies accounting for only US\$50bn which is 7% of total pharmaceutical sales and is highly competitive (refer Table 8 & Chart 8 for various major global pharmaceutical companies and their total sales.).

Table 9: Selected Global Generics Players 2007E Total Sales (figs. in US\$ bn.)	
Company	US\$ bn
Teva	\$9.1
Sandoz	\$5.8
Mylan/Merck GX	\$4.6
Watson Andrx	\$2.7
Barr	\$2.5
Actavis	\$2.1
Ratiopharm	\$2.1
Stada	\$2.1
Ranbaxy	\$1.7
Perrigo	\$1.5
Dr. Reddy's	\$1.4
Apotex	\$1.1
Cipla	\$1.0
Krka	\$1.0
Abraxis	\$1.0
Gedeon Richter	\$0.9
Sun/Taro	\$0.9
Zentiva	\$0.9
PAR	\$0.8
<i>Source: Capital IQ, Evaluate Pharma & Deutsche bank Report</i>	

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Of late, due to market compulsions for price efficiencies through economies of scale, necessity for huge investments in R&D, high entry barriers as a result of high cost of product registrations in multiple countries, increasing patent protection, increasing disposable incomes, etc., pharmaceutical industry across the globe has witnessed high-levels of mergers & acquisitions. (Refer table 9 & chart 9)

Table 10: M&A Activity in the Worldwide Generic Market (figs. in US\$ mn.)	
Year	US\$ mn
2000	1,438
2001	1,025
2002	1,112
2003	3,083
2004	1,411
2005	20,056
2006	6,901

Source: Company fillings, Wall Street Research, UBS Investment Bank Report (includes only limited major activities)

3.2 Trends in Indian Pharmaceutical Industry

The Indian retail pharmaceutical market size is estimated at US\$7.8bn in the year 2008 (refer Table 10 & chart 10) and is expected to grow at a high CAGR of 9.9 percent till 2010 and thereafter at a CAGR of 9.5 till 2015.

Table 11: Estimated Indian Retail Pharmaceutical Market size (US\$ Bn)	
Year	US\$ bn.
2002	3.7
2003	4.1
2004	4.7
2005	5.3
2006	6.2
2007	6.9
2008	7.8
2009	8.7
2010	9.9
2011	11.1
2012	12.2
2013	13.4
2014	14.6
2015	16.0

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

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The domestic industry is fragmented with top 10 companies capturing 30 percent (refer table 11 & chart 11) and the organized sector constituting over 500 companies. The total size of the industry is estimated at US\$18bn at the end of the year 2007.

Table 12: Global Sales of Leading Indian Companies (2006-07) (US\$ mn.)	
Dr Reddy's*	1,438.4
Ranbaxy**	1,405.2
Cipla	759.8
Nicholas Piramal	546.2
Sun Pharma	471.1
Aurobindo Pharma	437.5
Lupin	435.5
Wockhardt***	419.8
Zydus Cadila	394.6
Matrix***	364.2
Glenmark**	274.5
Orchid^	206.4
<i>Source: Pharma Outlook, Espicom, 2008,</i>	
<i>* Total Revenue, ** From Qtrly statements, *** Net Revenue</i>	

3.3 India's Pharmaceutical Export Profile

Pharmaceutical industry has shown commendable export performance, the trade balance being positive through out the years. Over the period 2003-04 to 2008-09 the compounded annual growth rate (CAGR) of exports has been 17.8 percent. (Refer Tables & Chart s 13 & 14).

Table 13: India's Trade in Pharmaceutical Products (2003-04 to 2007-08) (figs in Rs. Crores & %)						
Commodity Name	Mar-04	Mar-05	Mar-06	Mar-07	Mar-08	CAGR (2003-04 to 2007-08)
Exports of Drugs, pharmaceuticals & fine chemicals	15,213.24	17,857.80	22,115.72	26,895.18	29,139.57	17.8
Imports of Medicinal & pharmaceutical products	2,958.04	3,169.35	4,550.87	5,851.64	6,679.87	18.4
Exports Growth Rate	18.61	17.38	23.84	21.61	8.34	
Imports Growth Rate	3.24	7.14	43.59	28.58	14.15	
<i>Source: DGCI&S</i>						

Table 14: India's Trade in Pharmaceutical Products (2003-04 to 2007-08) (figs in US\$ mn. & %)

Commodity Name	Mar-04	Mar-05	Mar-06	Mar-07	Mar-08	CAGR (2003-04 to 2007- 08)
Exports of Drugs, pharmaceuticals & fine chemicals	3,312.99	3,972.81	4,994.52	5,939.75	7,241.44	22.2
Imports of Medicinal & pharmaceutical products	644.17	705.08	1,027.75	1,292.32	1,660.01	22.9
Exports Growth Rate	24.76	19.92	25.72	18.93	21.91	
Imports Growth Rate	8.59	9.46	45.76	25.74	28.45	

Source: DGCI&S

The composition of Indian pharmaceutical exports during the years 2003-04 to 2006-07 are given in the table 15 & Chart 15:

Table 15: India's Exports of Bulk Drugs, Formulations, Ayurvedic, Unani, Homeo & Herbal Products (figs. In Rs. Crores)

Commodity Name	Mar-03	Mar-04	Mar-05	Mar-06	Mar-07	Mar-08
Exports of Formulations	5,952.93	7,481.45	9,066.94	10,829.55	14,382.55	16,647.36
Exports of Basic Drugs, Fine Chemicals & Intermediates	2,493.36	7,207.79	8,091.69	10,740.51	11,868.29	13,299.33
Exports of Herbals	390.79	318.44	293.63	307.48	377.02	470.73
Medicants & Medicaments of Ayurvedic System	743.88	192.75	399.82	233.07	259.54	321.44
Medicants & Medicaments of Homeopathic System	8.19	10.30	2.11	1.87	2.74	3.05
Medicants & Medicaments of Unani System	0.00	2.08	1.89	1.13	0.70	1.13
Medicants & Medicaments of Siddha System	0.00	0.42	0.47	0.30	0.02	0.42

Source: DGCI&S

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3.3.1 Major Importing Countries from India

As of 2007-08 the large markets for Indian pharmaceutical exports & suppliers of pharmaceutical products to India are presented in the tables 16, 17 & charts 16 & 17 below:

Table 16: Top Importing Countries of Drugs, Pharmaceuticals & Fine Chemicals (2007-08) (figs. in Rs. Crores)			
Rank	Importing Country	Rs. Crores	% Share in India's Exports
1	USA	5,534.68	19.1
2	Germany	1,357.72	4.7
3	Russia	1,199.02	4.1
4	UK	1,077.72	3.7
5	China	818.46	2.8
6	Brazil	752.62	2.6
7	Canada	738.03	2.5
8	South Africa	650.35	2.2
9	Nigeria	644.08	2.2
10	Netherlands	504.17	1.7
11	Spain	485.88	1.7
12	Turkey	485.47	1.7
13	Ukraine	475.88	1.6
14	Viet Nam	466.07	1.6
15	Israel	430.83	1.5
16	Italy	428.16	1.5
17	Mexico	426.28	1.5
18	UAE	412.13	1.4
19	Singapore	401.23	1.4
20	Iran	366.21	1.3

3.3.2 Major Exporting Countries to India

As of 2007-08 the source countries for Indian pharmaceutical imports of India are presented in the tables 17, 18 & charts 17 & 18 below:

Table 17: Top Exporting Countries of Medicinal & Pharmaceutical Products to India (figs. in Rs. Crores & %)			
Rank	Exporting Country	Rs. Crores	% Share in India's Exports
1	China	2,760.90	40.7
2	Switzerland	912.13	13.4
3	USA	658.14	9.7
4	Germany	391.66	5.8
5	Denmark	287.03	4.2
6	Italy	208.25	3.1
7	France	194.82	2.9
8	UK	160.79	2.4
9	Belgium	124.59	1.8
10	Spain	117.44	1.7
11	India	102.37	1.5
12	Ireland	93.36	1.4
13	Japan	83.09	1.2
14	Korea Republic (South)	72.11	1.1
15	Netherlands	68.18	1.0
16	Austria	47.80	0.7
17	Indonesia	43.47	0.6
18	Poland	34.20	0.5
19	Mexico	31.03	0.5
20	Thailand	26.41	0.4

Source: DGCI&S

Apart from these, some of the fast emerging markets (2005-06) are presented in table 18:

Table 18: 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: WTO

3.4 SWOT Analysis of the Pharmaceutical Industry

Preceding sections make an effort to place Indian Pharmaceutical industry in the global perspective, followed by an examination of the trends in growth of industry both in terms of the emerging markets and products; and also the trends in global competition. It may be useful now to present a SWOT analysis of Indian Pharmaceutical Industry⁴:

3.4.1 Strengths

1. India is regarded as having an edge over China in terms of qualified, English-speaking manpower and fair protection of intellectual property rights supported by well-developed judicial system. (Appendix IV gives more information on IPR status in India).
2. India has skilled scientists/technicians/management personnel at affordable cost leading to low cost of innovation/ manufacturing/capex costs/ expenditure to run cGMP compliance facilities and high quality documentation and process understanding.
3. The country has well developed chemistry, R & D and manufacturing infrastructure with proven track record in advanced chemistry capabilities, design of high tech manufacturing facilities and regulatory compliance.
4. The healthy domestic market with rising per capita expenditure is another significant strength enabling achievement of economies of scale. The country also has a strong marketing & distribution network.
5. India is considered a desirable destination for off shoring of data management functions for clinical trials and also due to its rich biodiversity and strength in Chemistry which are essential for drug discovery.
6. The country has significant ability to circumvent API Patents. India has filed a number of non-infringing process patents. The country has a recent success track record in circumventing formulation patents. Proven Legal skills to evaluate IP and commercial strategies are available at least in select top companies.

⁴ on the basis of statistics and perceptions founded on empirical evidence

Strategy for Increasing Exports of Pharmaceutical Products

7. The present domestic regulatory environment though in need of further improvement has been conducive to the growth of an emerging pharmaceutical industry.

3.4.2 Weaknesses

1. Low investments in innovative R&D continue to be a major weakness of Indian pharmaceutical industry.
2. Diffused nature of the Indian pharmaceutical industry means that only about 20 to 30 companies are large enough to bear the transactions costs associated with sustained exports to and compliance with entry regulations of the developed markets.
3. Majority of companies lack the ability to compete with MNCs for New Drug Discovery, Research and commercialization of molecules on a worldwide basis due to lack of resources.
4. Strong linkages between industry and academia which are essential for growth of the industry is lacking in India.
5. Comparatively small domestic market size due to low medical and healthcare expenditure in the country.
6. The country has at times shown inadequate regulatory framework or compliance and enforcement regime, reflected in occurrences such a production of spurious or low quality drugs.
7. Competency in API/Formulation, intellectual property creation, facility design and maintenance, global regulatory affairs, legal intricacies, and managing international work force is limited to a few players among the big players.
8. Rapidly increasing costs of skilled manpower such as scientists/ regulatory compliance personnel / pharmaceutical lawyers/ international business development personnel is pushing up the cost of innovation. Ability to evaluate contracts/alliances etc., is available only in top companies. Significant lacuna in this area exists and companies are falling into traps created by the competitors.. Institutionalisation of learning in the following areas is restricted:
 - Regulatory affairs knowledge for different countries and continents
 - Process and product patents procedures knowledge for different countries and continents.
9. Sales and marketing knowledge is inadequate due to lack of understanding of international Pharmaceutical marketing/pricing practices and market environment in various countries.
10. Inadequate manufacturing practices in comparison to those accepted in developed world such as change of API source, change of manufacturing locations, equipment, etc., with out proven stability/ bioequivalence may be creating inadequate technical work force for exports. The

Strategy for Increasing Exports of Pharmaceutical Products

national drug regulatory system though evolved substantially, has been in the need of strengthening its manpower and systems requirements.

11. Inadequate emphasis on Biosciences in education system leading to slower development in areas related to Biology giving away advantage to China.

3.4.3 Opportunities

1. India is faced with significant export opportunities , such as,
 - i. US\$40 billion worth of drugs in the U.S.A and US\$25 billion worth of drugs in Europe are expected to go off patent soon. Assocham estimates that Indian manufacturers may capture 30 percent of that market. This translates to an opportunity of US\$19.5bn which is significant considering the country's current exports of approx. US\$7.25bn. However the figures need to be appropriately deflated since Indian opportunity will lie in generics equivalent of branded or patented drugs, which would be cheaper.
 - ii. Generic launches by Indian manufacturers have increased in the United States from 93 in 2003 to 250 by 2008.
 - iii. Compulsory licensing provisions negotiated in the Doha Round, allows for countries to import cheaper generic versions of patented drugs in the interests of public health. Thailand and South Africa have already started such initiatives from which Indian firms have benefited.
2. Due to the cost advantage in contract manufacturing & Research multi-national companies find it compelling to shift their production bases to countries offering such cost advantage. Typical of the industry which requires approval of manufacturing facilities by various drug regulatory agencies of the world involving a very high cost, once such business finds base in India it would continue with it for at least one & half to two decades.
3. Licensing deals with MNCs for NCEs (New Chemical Entities) and NDDS (New Drug Delivery Systems) offer new opportunities for Indian manufacturers.
4. Marketing alliances for MNC products in domestic and international market is another emerging opportunity.
5. Contract manufacturing arrangements with MNCs is estimated at 10% of patented markets estimated at US\$450bn which is approx. US\$45bn.
6. India has a very high potential for developing as a centre for international clinical trials due to its rich diversity.

Strategy for Increasing Exports of Pharmaceutical Products

7. India can become a niche player in global pharmaceutical R&D and possibilities exist for expansion of biotechnology generics (also known as bio-similars) and biopharmaceuticals.
8. There is a possibility of greater returns from an Indian entry into mature and more remunerative markets like Brazil, Japan, CIS, Russia, etc.
9. The Work Programme for the European Medicines Agency 2007 identifies greater co-operation with India - especially in the field of traditional and herbal medicines and remedies. Emerging preference for traditional medicines and herbs in the developed markets including lifestyle products and food supplements also presents an opportunity for the country in traditional medicinal systems & Herbal based products.
10. A rise in life expectancy generally, and increase in the population of the old, particularly in the developed world is causing higher expenditure from respective national health budgets compelling them to move to cheaper APIs and formulations which are India's forte.
11. Unleashing of a plethora of preferential trading arrangements, both bilateral and regional, offers opportunities for India to negotiate preferential access to partner markets for Indian pharmaceuticals in the long term and in a sustainable manner.

3.4.4 Threats

1. Product patent regime poses serious challenge to domestic industry unless it invests in research and development.
2. R&D efforts of Indian pharmaceutical companies are hampered by lack of enabling regulatory requirement.
3. Drug Price Control Order puts unrealistic ceilings on product prices and profitability.
4. Export effort is hampered by procedural hurdles in India as well as non-tariff barriers imposed abroad. For example:
 - i. Indian manufacturers are prevented from bidding for government contracts as US permits bidders only from countries that are signatories to WTO Agreement on Government Procurement.
 - ii. Indian manufacturers have to submit separate state level applications for marketing drugs in the United States as there is no nation-wide system of application even where FDA approval has been received.
5. Lowering of tariff protection has increased competition in domestic markets resulting in erosion of profitability.

6. Mergers and acquisitions by foreign companies particularly multinational corporations of a few Indian generic leaders may completely change the direction of India's pharmaceutical movement neutralising its thrust on generics and cost competitiveness.
7. The generics market in developed countries may be affected by a number of factors:
 - i. The release of authorized generics by major drug manufacturers.
 - ii. New mid sized players, establishing themselves in the generics market.
 - iii. Increased competition due to newer Chinese and East European manufacturers. (E.g. there has been massive state level investment by China in the biotechnology sector – though at present India still has the edge due to IP laws.)
 - iv. TA's entered into by the United States of America with third countries (e.g. the Morocco-U.S.A FTA) may be harmful to Indian pharmaceutical exports because of provisions for increases in patent terms, etc. The United States enters into a number of FTA's with different countries and while the exact text of these agreements differ from country to country, each of these agreements contains provisions which can be damaging to Indian exporters of pharmaceuticals partly also because of their provisions on patents. These FTA's contain a large number of provisions which increase patent terms for pharmaceuticals by allowing for patentability of new uses of discovered inventions and by increasing patent terms by taking into account the time taken to process claims (evergreening). These provisions go beyond TRIPS and hence it may not be possible to challenge these under the WTO Dispute Resolution process. However, the compatibility of these provisions with Article XXIV of the GATT needs to be examined.
8. Specific non-tariff and para-tariff barriers being increasingly adopted by other countries such as long transaction time taken for registration of drugs, insistence on completing long process for registration when the drug may actually have gone through the most rigorous process of registration such as the USFDA; insistence on allowing imports of only those drugs which are registered in some developed countries, etc.