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India's Pharmaceutical Industry on Course for Globalization: A Review

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Abstract

Pharmaceutical consumption in India is expected to grow substantially over the next five years, driven by a rise in disposable income, an ageing population and improving medical infrastructure. These growth driver shave led to India becoming a major emerging location for global pharma companies, however ongoing problems such as frequent power cuts, an insufficient transport infrastructure and gaps in the new patent regime may slowdown the sector's development. The pharmaceutical industry in India is going through a major shift in its business model in the last few years in order to get ready for a product patent regime from 2005 onwards This shift in the model has become necessary due to the earlier process patent regime put in place since 1972 by the Government of India. This was done deliberately to promote and encourage the domestic health care industry in producing cheap and affordable drugs. As prior to this the Indian pharmaceutical sector was completely dominated by multinational companies (MNCs).

Keywords: Pharmaceutical, multinational companies, patent regime, medical infrastructure

Introduction

These firms imported most of the bulk drugs (the active pharmaceutical ingredients) from their parent companies abroad and sold the formulations (the end products in the form of tablets and capsules, syrups etc.) at prices unaffordable for a majority of the Indian population. This led to a revision of Government of India's (GOI) policy towards this industry in 1972 allowing Indian firms to reverse engineer the patented drugs and produce them using a different process that was not under patent. The entry of MNC's was also discouraged by restricting foreign equity to 40%. The licensing policy was also biased towards indigenous firms and firms with lesser foreign equity1. All these measures by GOI laid foundations to a strong manufacturing base for bulk drugs and formulations and accelerated the growth in the Indian Pharmaceutical Industry (IPI), which today consists of more than 20,000 players. As a result the Indian pharmaceutical industry today not only meets the domestic requirement but has started exporting bulk drugs as well as formulations to the international market. Currently the main activities of Indian pharmaceutical industry are broadly restricted to producing (i) bulk drugs and (ii) formulations with very few companies risking investing in primary research aimed at developing and patenting new drugs[1, 2].

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The bulk drug business is essentially a commodity business, where as the formulation business is primarily a market driven and brand oriented business. Multinational companies which have entered the Indian market have mostly restricted themselves to formulation segment till date. The domestic pharmaceutical industry (MNC's and Domestic) meets about 90% of the country's bulk drug requirement and almost the entire demand for formulations. The economics of bulk drug business and that of formulation business are quite different. Since a majority of the Indian companies are producing both bulk as well as formulations, these are considered together for the purpose of the present study.

Pharma industry in India is playing a vital role in the healthcare area of the nation. With the implementation of product patent from the year 2005, there will be a tough competition for the global market share. Pharma companies will have to focus more intensively on R&D activity to survive the competition. As we are moving towards globalization, there is a need for strategic planning to meet the challenges posed by the product patent era. In the present context with the available expertise, manpower and skill, the Indian Pharma Industry will fight successfully for the global market share[3].

The Indian pharmaceutical industry is the worlds 13th largest in terms of value and the 4th largest in terms of volume. With over 60,000 brands in over 60 therapeutic categories, the total market size is approximately USD 5bn. India has world class facilities and expertise in manufacturing with the largest number of US FDA approved manufacturing units in the world outside the US. Ancillary industries are well developed with support available locally. Quality bulk drugs at competitive prices are assured. In R&D, basic research and biology skills are weak, a legacy of the lax patent regime where basic research was neglected. But process chemistry skills – honed over decades of reverse-engineering – are strong. The Indian pharmaceutical industry accounts for at least 35% of bulk drug filings in the US. Post-TRIPS, the Indian pharmaceutical landscape is set to change permanently[4, 5]. Local pharmaceutical majors are moving up the international value chain, focusing on generics marketing in Europe and the US to complement their already-strong presence in bulk active pharmaceutical ingredient (API) supply and to capitalize on the record number of drugs set to go off-patent over the next five years. To leverage their experience in manufacturing, local companies are scouting for contract manufacturing opportunities. And to leverage their country-wide network of skilled marketing personnel they are actively seeking in-licensing and marketing opportunities.

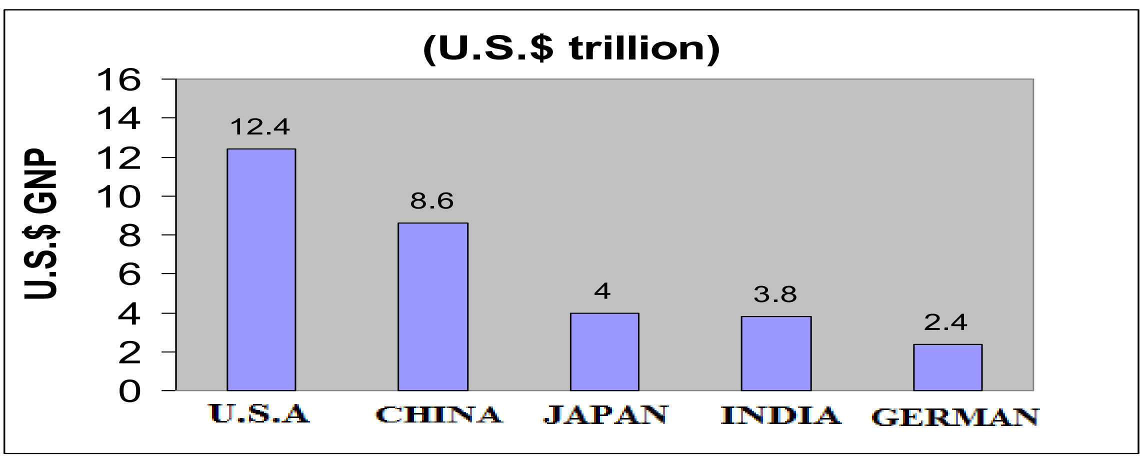

Figure1: India 4th Largest Economy

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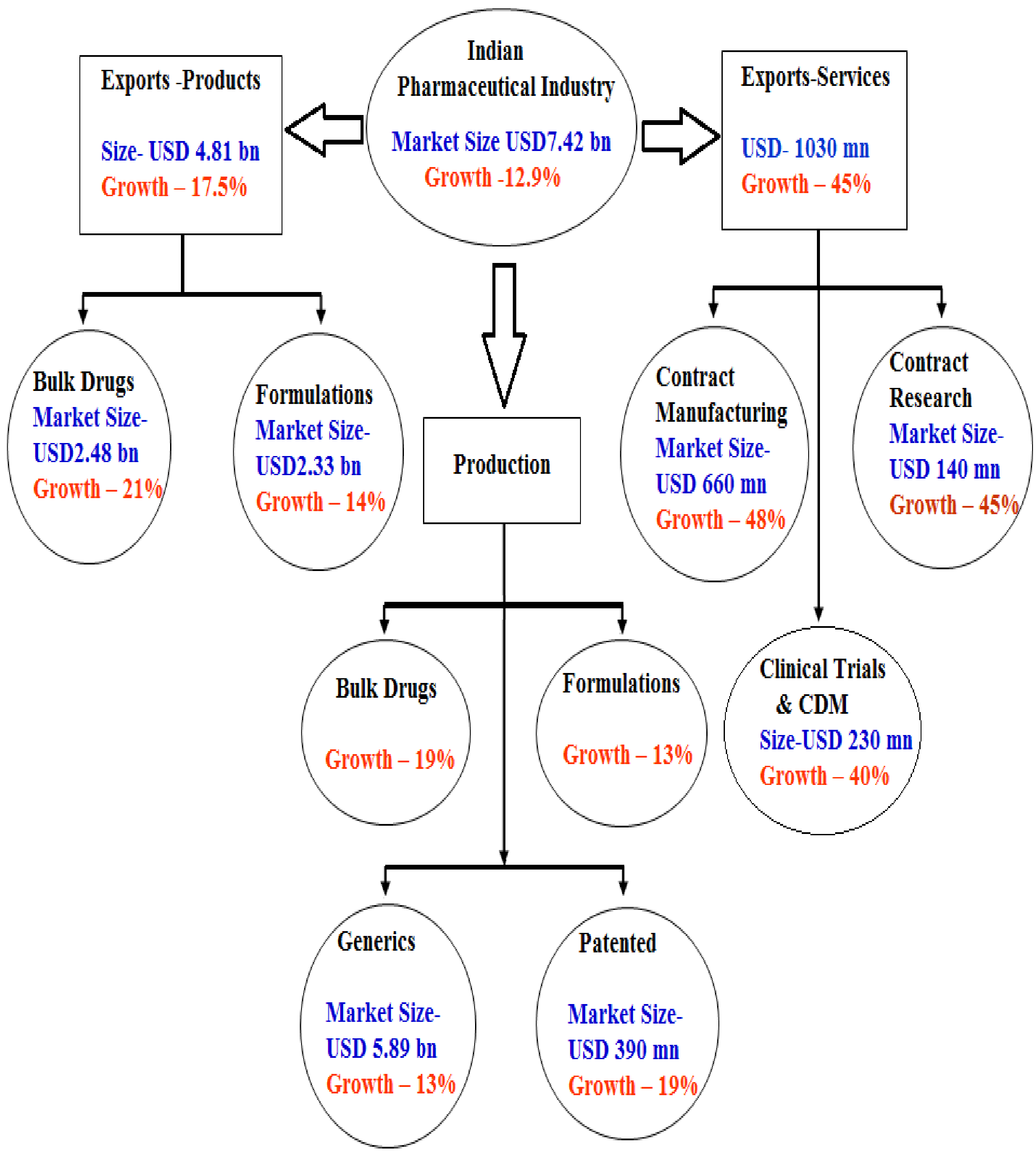

Figure 2: Pharmaceuticals Industry Value Chain

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Indian Pharmaceuticals Industry [6, 7]

- In 2006, R&D expenditure of 50 major companies totaled USD 495.19 m, growth of 26% over previous year.
- FDI in pharma industry was USD 172 m in 2006, growing at a CAGR of 62.6% during the last four years.
- Contract Research (including clinical trials &CDM) during 2006 is estimated to be USD 366 million, a growth of 45 % over previous year
- Contract manufacturing in 2006 was USD 659 million and growing at 48% over pervious year
- Bio Pharma market is valued USD 1.3 million. Vaccines are the largest segment of Biopharma accounting for 50% of the sectoral revenue.
- Indian pharmaceutical market – USD 7.42 billion in 2006 (Growth rate 12.9% over previous year).
- Domestic market contributed USD 2.61 billion and exports touched USD 4.81 billion (65% of the market).
- About 65% of bulk drugs and 6% of formulations are imported and balance requirements met from domestic manufacturing.
- Out of the total formulation sales, about 90% is accounted by generics, balance being patented drugs.
- Generics segment grew by 13% to USD 5.89 billion in 2006. Patented drugs sale was USD 389.36m in 2006 growing at a rate of 18.9% over the previous year.
- Bio Pharma market is valued USD 1.3 million in 2007.
- A vaccine is the largest segment of Biopharma accounting for 50% of the sectoral revenue.
- India is leader in global vaccine market (over 33% market as per E&Y 2007 report). India is the largest producer of recombinant Hepatitis B vaccine in the world
- Vaccines market in India in 2007 was USD 0.65 million registering a 40.26% growth over the previous year.
- Diagnostics contributed 19% with USD 0.25 million market size in 2007, over 50% growth over previous year.
- Therapeutics, 3rd largest contributed 14% of the total biopharma sales USD 0.18 million in revenues, growth of 28% in 2007.
- In 2007 Biopharma contributed USD 0.65 million worth exports.
- Serum Institute of India was the largest biopharma company recording revenue of USD 168 million in 2006. Major products include rubella, MMR and BCG vaccines[8].
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Table 1: **Indian Pharmaceutical Exports**

Country	Indian Pharmaceutical Exports (in Rs. Crores) (2004-2005)
United States	703
Russia	501
Germany	329
Hong Kong	331
Nigeria	244
United Kingdom	318
Singapore	294
Netherlands	300

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Iran	180
Brazil	174

Strong growth continues to India's pharmaceutical industry

Up until 2015, we expect pharmaceutical sales to rise by 8% p.a. to just under EUR 20 bn, compared with an increase of 6% in the world as a whole and 5% in Germany. But even then, India's share in the world pharmaceutical market would only come to slightly over 2% (Germany: 7%). In Asia, India looks set to lose market share, as other Asian countries are registering even stronger growth [9, 10].

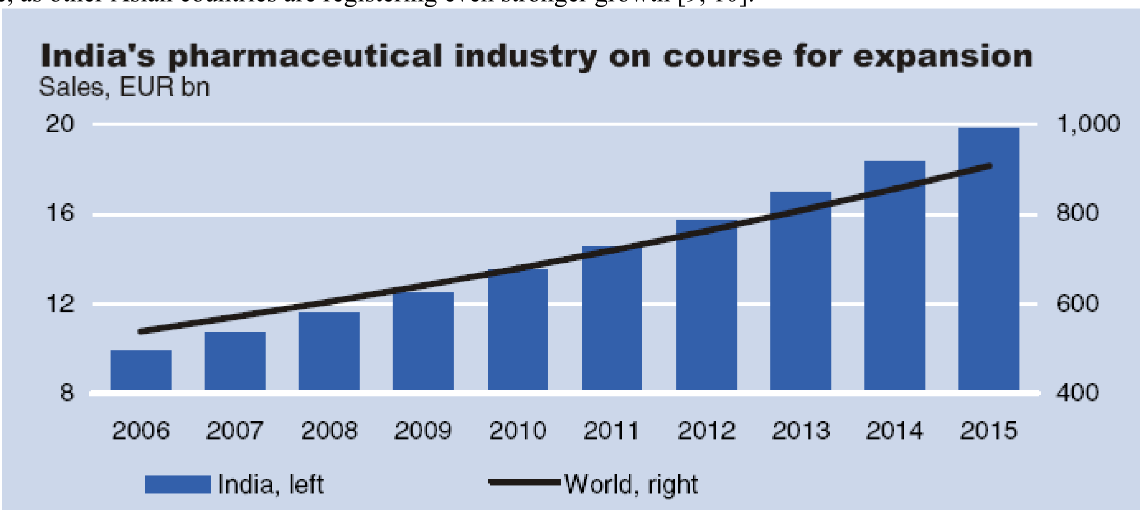

Figure3: Growth Rat of Indian Pharma Industry

The top 10 pharma Companies in India

India's top ten pharmaceutical companies have reported a record of 24.57% growth in their net profits during 2007-08 where as their bottom-line grew by 14.68% over 2006-07. The top ten listed companies based on consolidated net sales include Ranbaxy Laboratories, Dr Reddy's Laboratories Cipla, Sun Pharma Piramal health care, Lupin, Wockhardt, Jubilant Organosys, Aurobindo Pharma,Cadila Healthcare; posted strong growth during 2007-08.The consolidated sales of the top ten companies rose to Rs 349.01 bn in 2007-08 from Rs 304.34 bn reported in the previous year where as the net profit was Rs 54.87 bn in 2007-08 as compared to Rs 44.05 bn in 2006-07. Ranbaxy occupied the first place with Rs 69.82 bn followed by Dr Reddy with Rs 49.14 billion [11-14].

Table 2. List of The top 10 Pharma Company in India

S.No.	Companies	Net sales (Rs bn)		% Change	Turn Over (US $ Mill)	Turn Over (Rs crore)
		2007-08	2006-07			
1	Ranbaxy Laboratories Ltd.	69.82	61.32	13.90	987.00	4243.00

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2	Cipla Ltd	42.27	35.71	18.40	478.00	2055.00
3	Dr. Reddy'S Laboratories Ltd	49.14	64.35	-23.60	428.00	1839.00
4	Nicholas Piramal India Ltd.	28.73	24.72	16.20	335.00	1440.00
5	Aurobindo Pharma Ltd.	24.35	22.50	8.22	321.00	1341.00
6	Glaxosmithkline Pharmaceuticals Ltd	24.89	18.10	37.50	289.00	1242.00
7	.Lupin Ltd.	27.06	20.14	34.40	287.00	1233.00
8	Cadila Healthcare Ltd	22.66	17.86	26.90	273.00	1172.00
9	Sun Pharmaceutical Inds. Ltd.	33.56	22.37	50.02	218.00	936.00
10	Wockhardt Ltd.	26.53	17.19	53.40	178.00	767.00

bn= billion

Growth drivers (Mergers & Acquisitions) [15-18]

Table 3: Major Deals Announced/Completed By Indian Companies in 2007

Bidder / Merger Partner	Country	Target / Merger	Country	Value (US $ m)
Sun pharmaceutical industry	India	Taro Pharmaceuticals	Israel	454
Wockhardt	India	Negma Lebs	France	265
MNS Group	India	Armour Pharmaceuticals	India	45
Dishman Pharma & chemicals	India	Solvay's Fine chemicals	Netherlands	Undisclosed
Avesthagen	India	Renaissance Herbs Inc	US	11
Granules India	India	ISP Invest co	US	Undisclosed

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Ranbaxy	India	Be-Tabs pharmaceuticals	South Africa	70
Ranbaxy	India	BMS (13 dermatology products marketing rights)	US	26
Cadila Healthcare	India	Nikkho	Brazil	26
Lupin Limited	India	Kyowa Pharma	Japan	60

The year 2006-07 saw only a few outbound acquisitions and instead of bigwigs like Ranbaxy, mid-size firms like Sun Pharma and oncology drug maker Dabur Pharma hogged the limelight. Sun Pharma acquired Israel's Taro Pharmaceutical Industries, a multinational generic manufacturer for about INR18 billion in the year's biggest in the sector. Sun Pharma, Jubilant Organosys, Ranbaxy and Zydus Cadila are the major firms that came out with high valued acquisitions [19].

- Sun Pharma acquired Israel's generic manufacturer Taro Pharma for USD 454 m (approximately INR18, 370m). This is the second largest overseas acquisition by an Indian drug company after Betapharm acquisition by Dr Reddy's for USD 572 m.
- Jubilant Organosys Ltd acquired the US-based Hollister-Stier Laboratories for USD 122.5 m. The acquisition would provide Jubilant with fast growing contract injectables manufacturing business and also a stable and profitable allergy business.
- Ranbaxy has acquired Be-Tabs for USD 70 m, which will make it the fifth-largest generic pharma company in South Africa. Ranbaxy acquired 14.9% stake in Jupiter Biosciences, a Hyderabad-based company.
- Zydus Cadila bought Brazilian company, Quimica e Farmaceutica Nikkho do Brasil Ltd (Nikkho), which is purely into the market of 'branded generics', for USD 26 m after signing an agreement to acquire 100% stake. With this acquisition, the companies will basket generic products across various therapeutic segments such as general medicine, pediatrics, gynecology, neurology, gastroenterology, otolaryngology, dermatology and others. Zydus Cadila will strengthen its base in Japan and be accessible to the USD3 billion Japan's generics market from its acquired Nippon Universal Pharmaceuticals Ltd.
- Ranbaxy Laboratories Inc, the wholly-owned US subsidiary of the Indian pharma major, acquired the rights to 13 dermatology products from Bristol-Myers Squibb (BMS) for a value of USD 26 m (INR 1,050 m). These 13 products totaled USD 15 m (INR 600 m) in 2006 and are used in the treatment of dermatitis, psoriasis, fungal infections, scabies and acne. This acquisition will strengthen Ranbaxy's franchise in dermatology arena [20].
- Lupin Limited acquired a majority stake in Japanese generic drug maker Kyowa Pharmaceutical Industry Co Ltd. Lupin Limited acquired Rubamin Laboratories Ltd (RLL), part of the Baroda-based Rubamin group, for an undisclosed amount. The pharmaceutical business of the Rubamin group, RLL focuses largely on advanced intermediates for active pharmaceutical ingredients under the contract research and manufacturing model.
- The year 2007 witnessed only 25 M&A’s with 15 cross border transactions with an estimated value of about USD 600-700 m in the Indian pharmaceutical sector. The industry restricted itself to consolidation on the domestic turf rather than looking for acquisitions abroad [21].

Conclusion

This report on the Global Pharmaceutical Market looks at the entire pharmaceutical industry, covering its segments, the technologies making waves, leading players taking the industry forward, and much more. An analysis of the key markets boosts the report from an investor’s point of view, and the general basic knowledge about the pharmaceutical industry is beneficial to anyone in the industry.

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