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Evolution of Pharmaceutical Industry: A global Indian & Gujarat perspective

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ABSTRACT:

Most of today's major pharmaceutical companies were founded in the late 19th and early 20th centuries. Key discoveries of the 1920s and 1930s, such as insulin and penicillin, became mass-manufactured and distributed. Global pharmaceutical market is highly dynamic and is characterized by greater levels of R&D expenditure and extensive regulation of its products. Global pharmaceutical sales are estimated to be US$ 643 billion in 2006, a growth of 7% over the previous year. All of these changes are ultimately good for the Indian pharmaceutical industry, which suffered in the past from inadequate regulation and large quantities of spurious drugs. They force the industry to reach a level necessary for global competitiveness. At the time of independence in 1947, India's pharmaceutical market was dominated by Western MNCs that controlled between 80 and 90 percent of the market primarily through importation. Approximately 99 percent of all pharmaceutical products under patent in India at the time were held by foreign companies and domestic Indian drug prices were among the highest in the world. According to industry estimates, a great chunk --almost 40 per cent --of machinery used in the pharmaceutical manufacturing in India is produced in Gujarat. This creates a very good local and global opportunity for Gujarat in the manufacturing of pharmaceutical machinery, given its strong and well established engineering sector, points out a recent study titled Gujarat Pharma-Industry-striding into the future, KPMG, India The strong growth prospects of the pharmaceutical exports segment and growing demand from the domestic market, will further fuel growth in the pharmaceutical machinery sector. However, Gujarat's engineering sector is highly fragmented, especially the pharma-machinery manufacturing segment. Due to the highly fragmented nature, there is a dearth of pricing power and critical scale. This in turn restricts the ability to produce the technology-driven products required for operating in global markets.

KEY WORDS: Global scenario, India Pharma industry, Industry in Gujarat

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INTRODUCTION:

Introduction of Pharmacy

The first known drugstore was opened by Arabian pharmacists in Baghdad in 754, and many more soon began operating throughout the medieval and eventually medieval Europe. By the 19th century, many of the drugstores in Europe and North America had eventually developed into larger pharmaceutical companies. Most of today's major pharmaceutical companies were founded in the late 19th and early 20th centuries. Key discoveries of the 1920s and 1930s, such as insulin and penicillin, became mass-manufactured and distributed. Switzerland, Germany and Italy had particularly strong industries, with the UK, US, Belgium and the Netherlands following suit. Legislation was enacted to test and approve drugs and to require appropriate labeling. Prescription and non-prescription drugs became legally distinguished from one another as the pharmaceutical industry matured. The industry got underway in earnest from the 1950s, due to the development of systematic scientific approaches, understanding of human biology (including DNA) and sophisticated manufacturing techniques. Numerous new drugs were developed during the 1950s and mass-produced and marketed through the 1960s. These included the first oral contraceptive, "The Pill", Cortisone, blood-pressure drugs and other heart medications. MAO Inhibitors, chlorpromazine (Thorazine), Haldol (Haloperidol) and the tranquilizers

ushered in the age of psychiatric medication. Valium (diazepam), discovered in 1960, was marketed from 1963 and rapidly became the most prescribed drug in history, prior to controversy over dependency and habituation. Attempts were made to increase regulation and to limit financial links between companies and prescribing physicians, including by the relatively new U.S. Food and Drug Administration (FDA). Such calls increased in the 1960s after the thalidomide tragedy came to light, in which the use of a new anti-emetic in pregnant women caused severe birth defects. In 1964, the World Medical Association issued its Declaration of Helsinki, which set standards for clinical research and demanded that subjects give their informed consent before enrolling in an experiment. Pharmaceutical companies became required to prove efficacy in clinical trials before marketing drugs. Cancer drugs were a feature of the 1970s. From 1978, India took over as the primary center of pharmaceutical production without patent protection.

The History of the Pharmaceutical Industry

As a result of introduction and success of penicillin in the early forties and the relative success of other innovative drugs, research and development (R&D) became a major thrust area of the pharmaceutical industry. The industry expanded rapidly in the sixties, benefiting from new discoveries. In the 1960s attempts were made by the U.S. Food and Drug Administration (FDA) to increase regulation of pharmaceutical industries and to limit financial links between companies and prescribing physicians. In 1964, after the thalidomide tragedy (in which the use of a new tranquilizer in pregnant women caused severe birth defects in the new born child), the World Medical Association set standards for clinical research. Pharmaceutical companies were required to prove efficacy and safety of the drug in clinical trials before marketing them. Tighter regulatory controls were introduced in the seventies. The new regulations revoked permanent patents and established fixed periods on patent protection for branded products. As a result industries flourished by producing generic products and they started earning huge profits, because generic manufacturers do not incur the cost of drug discovery.

Global scenario:

Global pharmaceutical market is highly dynamic and is characterized by greater levels of R&D expenditure and extensive regulation of its products. Global pharmaceutical sales are estimated to be US$ 643 billion in 2006, a growth of 7% over the previous year. Sales have grown from US$ 334 billion in 1999 to US$ 643 billion in 2006, witnessing a CAGR of 10%. North America is the major pharmaceutical market accounting for around 48% of global pharmaceutical sales, followed by Europe (30%), Japan (9%). Leading therapy classes in world-pharmaceutical market include lipid regulators (with a market share of 5.8%), oncologics (5.7%), respiratory agents (4%), acid pump inhibitors (4%), and anti-diabetics (3.5%) [1]

Figure-1.1: Market cap of Pharmaceutical companies has grown substantially over 25 years

The Pharmaceutical industry in India is the world's third-largest in terms of volume and stands 14th in terms of value. According to Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India's pharmaceuticals industry between 2008 and September 2009 was US$21.04 billion, while the domestic market was worth US$12.26 billion. Sale of all types of medicines in the country is expected to reach around US$19.22 billion by 2012. Exports of pharmaceuticals products from India increased from US$6.23 billion in 2006-07 to US$8.7 billion in 2008-09 a combined annual growth rate of 21.25%. According to PricewaterhouseCoopers (PWC) in 2010, India joined among the league of top 10 global pharmaceuticals markets in terms of sales by 2020 with value reaching US$50 billion. Some of the major pharmaceutical firms include Sun Pharmaceutical, Cadila Healthcare and Piramal Healthcare. [2]

Relationship between pharmaceuticals and biotechnology:

Unlike in other countries, the difference between biotechnology and pharmaceuticals remains fairly defined in India. Bio-tech there still plays the role of pharma's little sister, but many outsiders have high expectations for the future. India accounted for 2% of the $41 billion global biotech market and in 2003 was ranked 3rd in the Asia-Pacific region and 11th in the world in number of biotechs. In 2004-5, the Indian biotech industry saw its revenues grow 37% to $1.1 billion. The Indian biotech market is dominated by biopharmaceuticals; 75% of 2004-5 revenues came from biopharmaceuticals, which saw 30% growth last year. Of the revenues from biopharmaceuticals, vaccines led the way, comprising 47% of sales.[1]

Comparison with the U.S.:

The Indian biotech sector parallels that of the U.S. in many ways. Both are filled with small start-ups while the majority of the market is controlled by a few powerful companies. Both are dependent upon government grants and venture capitalists for funding because neither will be commercially viable for years. Pharmaceutical companies in both countries have recognized the potential effect that biotechnology could have on their pipelines and have responded by either investing in existing start-ups or venturing into the field

themselves. In both India and the U.S., as well as in much of the globe, biotech is seen as a hot field with a lot of growth potential. [3]

Relationship with IT:

Many analysts have observed that the hype around the biotech sector mirrors that of the IT sector. Biotech colleges have been popping up around the country eager to service the pools of students that want to take advantage of a growing industry. The International Finance Commission, the private investment arm of the World Bank, called India the "centerpiece of IFC's global biotech strategy." Of the $110 million invested in 14 biotech projects investment globally, the IFC has given $43 million to 4 projects in India. According to Dr. Manju Sharma, former director of the Department of Biotechnology, the biotech industry could become the "single largest sector for employment of skilled human resource in the years to come." British Prime Minister Tony Blair was similarly impressed, citing the success of India's biotech industry as the reason for his own country's own biotech opportunities. Malaysia is also looking to India as an example for growing its own biotech industry. [3]

Innovation:

Several studies on the economics of technological change and technology gap approach to international trade (e.g., Fegerberg 1987, Verspagen 1991) have brought out that growth performance and competitive advantages of countries go together with their activities of technological innovation and imitation. They have shown that technological development measured by patent and R&D expenditures have significant impact on the trade performance of the countries. The pharmaceutical industry being one of the most technology-intensive industries, the extent and nature of innovation is crucial for countries to prolong their productivity growth and competitiveness in the long run. In broad terms the process of technological change can occur through improvements in the products, production process, raw material and intermediate inputs, and through enhancements in the efficiency of the management system.

Challenges:

All of these changes are ultimately good for the Indian pharmaceutical industry, which suffered in the past from inadequate regulation and large quantities of spurious drugs. They force the industry to reach a level necessary for global competitiveness. However, they have also exposed some of the inadequacies in the industry today. Its main weakness is an underdeveloped new molecule discovery program. Even after the increased investment, market leaders such as Ranbaxy and Dr. Reddy's Laboratories spent only 5-10% of their revenues on R&D, lagging behind Western pharmaceuticals like Pfizer, whose research budget last year was greater than the combined revenues of the entire Indian pharmaceutical industry. This disparity is too great to be explained by cost differentials, and it comes when advances in genomics have made research equipment more expensive than ever. The drug discovery process is further hindered by a dearth of qualified molecular biologists. Due to the disconnect between curriculum and industry, pharmas in India also lack the academic collaboration that is crucial to drug development in the West. [4]

Evolution of pharmaceutical industry in India

State of the economy:

Economic growth decelerated in 2008-09 to 6.7 per cent. This represented a decline of 2.1 per cent from the average growth rate of 8.8 per cent in the previous five years (2003-04 to 2007-08). The five years of high growth has raised the expectations of the people. Few remember that during slowdown from the average growth of 7.3 per cent per annum during the previous five years, it is the preceding five-year period from 1998-99 to 2002-03 average growth was only 5.4 per cent, while the highest growth rate achieved during the period was 6.7 per cent (in 1998-99). Per capita GDP growth, a proxy for per capita income, which broadly reflects the improvement in the income of the average person, grew by an estimated 4.6 per cent in 2008-09.Though this represents a substantial still significantly higher than the average 3.3 per cent per annum income growth during 1998-99 to 2002-03.[5]

Background analysis:

Introduction:

The Indian Pharmaceutical Industry has come a long way from being almost non-existent in the 1970's to being one of the largest and most advanced Pharmaceutical industries in the world. The domestic Pharmaceutical output has increased at a CAGR of 13.4.Currently the Indian Pharmaceutical Industry is valued at $ 8 billion (approx).Globally the industry ranks 4th in terms of volume and 13th in terms of value. It provides employment to millions and ensures that essential drugs are available to the vast population of India at affordable prices.

Relevance for growth:

India has the highest number of manufacturing plants approved by US FDA, which is next only to that in the US. More than 85% of the formulations produced in the country are sold in the domestic market. Over60% of India's bulk drug production is exported. India holds the lion's share of the world's contract research business as activity in the Pharmaceutical market continues to explode, over 15prominent contract research organizations (CROs) are now operating in India attracted by her ability to offer efficient R&D on a low cost basis. Thirty five per cent of business is in the field of new drug discovery and the rest 65 per cent of business is in the clinical trials arena. India offers a huge cost advantage in the clinical trials domain compared to Western countries. India got a major boost with the signing of Trade Related Intellectual Property Rights (TRIPS) under the General

Agreement on Tariffs and Trade (GATT) in January 2005 with which it began recognizing global patents.[6]

Export profile

Exports constitute a substantial part of the total production of Pharmaceutical in India. The formulations contribute nearly 55% of the total exports and the rest 45% comes from bulk drugs. Pharmaceutical exports clocked $7.2 billion in 2007-08, accounting for six per cent of the country's total exports. Indian companies export drugs to over 200 countries, but the top 25 markets, which includes the US, Germany, Russia, China and few European and African countries, account for about half of the total. Indian drug makers exported medicines worth Rs 31,608 crore during April 2008-January 2009 and exports shot up 30.7% as compared to last year due to a weak Indian currency and increased demand for low-cost generic medicines. US is the Largest importer of drugs followed by Russia and Germany.[7]

Foreign participation

Drugs and Pharmaceuticals ranks 8th in India's top 10 FDI-attracting sectors. The government of India has allowed foreign direct investment up to 100% through the automatic route in the drugs and Pharmaceuticals industry of the country, on the condition, that the activity should not fall into the categories that require licensing. Pharmaceutical industry accounts for about 2.91% of total FDI into the country. The FDI in Pharmaceutical sector is estimated to have touched US$172 million, thereby showing a compounded annual growth rate of about 62. The Industry has received almost Rs 2141 crore investment from 36 countries through FDI between April 2007 to April 2009 with most of the fund infusion directed to healthcare and biotech ventures. [7]

Detailed analysis of the pharmaceutical sector pharmaceutical growth:

The Indian Pharmaceutical industry has grown from a mere Rs. 1,500 crore turnover in 1980 to over Rs. 78,000crore in 2008 with about 10 per cent of share volume of global production. High growth has been achieved through; the creation of required infrastructure, capacity building in complex manufacturing technologies of active production ingredients(APIs) and formulations, entering into drug discovery through original and contract research and manufacturing (CRAM) and clinical trials and product specific strategies of acquisition and mergers. The domestic sector had a production turnover of Rs. 47,241 crore from about 10,000 small-scale and 300 large and medium manufacturing units in 2008. [7]

Evolution of industry:

In India, modern system of medicine is a 20th century phenomena, though the traditional system of medicine has been in practice for many centuries. Therefore, in discussing the evolution of the IPI, three points of time are very relevant. These are: 1900-1970, 1970-1990 and the decade of 1990sThe period 1900-1970 signifies the dominance of the multinationals in this field that were basically importing bulk drugs and formulations from abroad. Most domestic manufacturers were engaged in repacking the formulations produced by the multinationals and production was concentrated in the hands of the multinationals. Production of modern medicine by indigenous units started with the setting up of Bengal Chemical and Pharmaceutical works in 1892, which was followed by the establishment of Alembic Chemical, works in1907 and Bengal Immunity in 1919. At this point in time, the Patents Act of 1911 was in practice, which facilitated patenting all the known and possible processes of manufacturing of the said drug besides patenting the drug itself. Hence, the indigenous firms were legally prevented from manufacturing most of the new drugs during the life of the patent secured by the latter, i e, for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not been sufficiently remunerative to the patentee. This gave them the monopoly power initially. The domestic firms were also forbidden from processing a patented drug into formulations or importing it. However, the Second World War and the introduction of sulpha drugs and penicillin gave on impetus to the pharmaceutical industry.

India's Pharmaceutical industry in 2005:

- Share of global sales: Value 1%, Volume 8%
- Global ranking: 4th in volume, 13th in value
- Domestic market: $5.3 billion
- Exports: $3.7 billion
- Imports: $985 million
- Bulk drug production: $2.1 billion
- Employment: 5 million direct, 24 million indirect.
- Capital investment: $1.2 billion
- Production costs: Among the lowest in the
- World, estimated to be 70% less than the West

India's Pharmaceutical industry: independence to 2005:

At the time of independence in 1947, India's pharmaceutical market was dominated by Western MNCs that controlled between 80 and 90 percent of the market primarily through importation. Approximately 99 percent of all pharmaceutical products under patent in India at the time were held by foreign companies and domestic Indian drug prices were among the highest in the world. The Indian pharmaceutical market remained import-dependent through the 1960s until the government initiated policies stressing self-reliance through local production.5 At that time, 8 of India's top 10 pharmaceutical firms, based on sales, were subsidiaries of MNCs. [8]

Table 1.1 Top 20 Publicly Listed Life Science companies in India, as of 2010

Rank	Company	Revenue 2011(USD millions)
1	Cipla	1348.51
2	Ranbaxy	1327.56
3	Dr. Reddy's Laboratories	1178
4	Lupin Ltd	929.84
5	Aurobindo Pharma	865.19
6	Dabur	700.3
7	Sun Pharmaceutical	673.99
8	Cadila Healthcare	629.45
9	Jubilant Lifesciences	561.03
10	Piramal Healthcare	480.26
11	GlaxoSmithKline Pharmaceuticals Ltd	475.8
12	Ipca Laboratories	390
13	Wockhardt	381.23
14	Torrent Pharmaceuticals	380.2
15	Sterling Bio	358.1
16	Biocon	340.38
17	Orchid Chemicals & Pharmaceuticals Limited	320.62
18	Alembic	270.62
19	Aventis Pharma	263.75
20	Glenmark Pharmaceuticals	260.14

Research and development (R & D)

Both the Indian central and state governments have recognized R&D as an important driver in the growth of their pharma businesses and conferred tax deductions for expenses related to research and development. They have granted other concessions as well, such as reduced interest rates for export financing and a cut in the number of drugs under price control. Government support is not the only thing in Indian pharma's favor, though; companies also have access to a highly developed IT industry that can partner with them in new molecule discovery in R&D. [9]

The role of Indian generic drugs in the U.S. market:

The United States is the world's largest single market for pharmaceutical products accounting for nearly 50 percent of the value of the total world market. According to the Generic Pharmaceutical Association, U.S. retail drug sales for 2006 totaled $221 billion and generic pharmaceutical sales totaled $54.1 billion.61 U.S. pharmaceutical sales grew by 73 percent from $128.1 France is next spending $457 per capita 62 followed by Japan at $339. Economist Intelligence Unit. "Express Scripts Study Shows Substantial Savings Opportunity for Consumers, states, Health Care Purchasers with Generics, says GPhA," Generic Pharmaceutical Association, Press release, Aug. 16, 2005.*2006 Chain Pharmacy Industry Profile*, The National Association of Chain Drug Stores. *Pharmaceuticals in the United States*, Industry Profile. [10]

Labour force

India's greatest strengths lie in its people. India also boasts of well-educated, English-speaking labor force that is the base of its competitive advantage. Although molecular biologists are in short supply, there are a number of talented chemists who are equally as important in the discovery process. In addition, there has been a reverse brain drain effect in which scientists are returning from abroad to accept positions at lower salaries at Indian companies.[11]

Table 1.2: India's pharmaceutical firms, by size, sales, function, exports, and R&D capabilities

Size of Indian pharmaceutical industry *vis-à-vis* selected countries, 1980–2000, PPP $

Year	*Pharmaceutical Value Added (In PPP $ million)*						*As a % of Global Pharmaceutical Value Added*					
	1980	*1985*	*1990*	*1991*	*1995*	*2000*	*1980*	*1985*	*1990*	*1991*	*1995*	*2000*
Austria	174 (15)	260 (16)	523 (15)	595 (15)	752 (16)	1129 (16)	0.58	0.53	0.66	0.67	0.65	0.70
Belgium	482 (11)	677 (13)	1005 (12)	1110 (12)	1805 (12)	2819 (11)	1.61	1.37	1.28	1.24	1.55	1.74
Canada	409 (12)	964 (11)	1695 (11)	1751 (11)	2043 (11)	2338 (13)	1.36	1.95	2.15	1.96	1.76	1.44
Denmark	132 (16)	286 (15)	481 (16)	566 (16)	877 (15)	1611 (15)	0.44	0.58	0.61	0.63	0.75	1.00
Finland	93 (17)	159 (17)	197 (17)	221 (17)	240 (17)	269 (18)	0.31	0.32	0.25	0.25	0.21	0.17
France	2170 (4)	3408 (4)	4809 (5)	5333 (6)	7189 (4)	9679 (4)	7.24	6.89	6.11	5.97	6.18	5.98
Germany	1648 (6)	2250 (6)	3243 (6)	6304 (3)	7408 (3)	9514 (5)	5.49	4.55	4.12	7.05	6.37	5.88
India	1136 (8)	1786 (7)	3061 (7)	3731 (7)	6420 (6)	11508 (3)	3.79	3.61	3.89	4.18	5.52	7.11
Italy	2757 (3)	4151 (3)	6119 (3)	6073 (4)	6055 (7)	9043 (6)	9.19	8.39	7.77	6.80	5.21	5.59
Japan	6718 (2)	10334 (2)	15612 (2)	16166 (2)	19236 (2)	21511 (2)	22.40	20.89	19.83	18.09	16.54	13.29
Korea	779 (10)	1492 (9)	2775 (8)	3030 (8)	4520 (8)	6235 (8)	2.60	3.02	3.53	3.39	3.89	3.85
Mexico	798 (9)	1283 (10)	2182 (10)	2159 (10)	3433 (9)	5512 (9)	2.66	2.59	2.77	2.42	2.95	3.41
Netherlands	319 (13)	733 (12)	585 (14)	705 (14)	1304 (14)	1682 (14)	1.06	1.48	0.74	0.79	1.12	1.04

Table 1.3: Growth of pharmaceutical R & D, PP

Growth of Pharmaceutical R&D, PPP $

Country	*Growth of Pharmaceutical R&D (%)*			*Relative R&D Expenditure (USA=100)*			
	1987–91	*1992–96*	*1997–2001*	*1987*	*1990*	*1995*	*2000*
Australia	19	48	24	1.4	1.3	1.9	1.9
Belgium		42	36	4.5		3.6	5.6
Canada	76	41	23	2.0	3.1	3.6	4.2
Czech Republic		49	74			0.2	0.3
Denmark	51	41		1.9	2.1	2.5	
Finland	17	25	94	0.8	0.7	0.7	1.2
France	31	18	13	18.3	16.9	19.8	19.7
Germany			17			11.9	17.7
India	17	26	83	3.2	2.4	2.9	4.8
Ireland	107	30		0.3	0.4	0.9	
Italy		-15	13			5.8	4.9
Japan	35	10	20	44.2	42.0	37.0	37.1
Korea			70			1.3	1.5
Netherlands	15	26	23	3.7	3.3	2.3	3.3
Norway	48	-7		0.6	0.7	0.5	
Poland			22			0.3	0.3
Spain	47	18	16	2.7	2.9	2.5	2.4
Sweden	48	41	38	4.7	5.4	6.3	9.2
UK	32	11	23	29.4	31.8	27.1	34.1
USA	36	13	5	100	100	100	100

Patents

As it expands its core business, the industry is being forced to adapt its business model to recent changes in the operating environment. The first and most significant change was the January 1, 2005 enactment of an amendment to India's patent law that reinstated product patents for the first time since 1972. The legislation took effect on the deadline set by the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated patent protection on both products and processes for a period of 20 years. Under this new law, India will be forced to recognize not only new patents but also any patents filed after January 1, 1995. Indian companies achieved their status in the domestic market by breaking these product patents, and it is estimated that within the next few years, they will lose $650 million of the local generics market to patent-holders. **(Slater et al.)**[13]

In the domestic market, this new patent legislation has resulted in fairly clear segmentation. The multinationals narrowed their focus onto high-end patients who make up only 12% of the market, taking advantage of their newly bestowed patent protection. Meanwhile, Indian firms have chosen to take their existing product portfolios and target semi-urban and rural populations.[12]

Product development

Indian companies are also starting to adapt their product development processes to the new environment. For years, firms have made their ways into the global market by researching generic competitors to patented drugs and following up with litigation to challenge the patent. This approach remains untouched by the new patent regime and looks to increase in the future. However, those that can afford it have set their sights on an even higher goal: new molecule discovery. Although the initial investment is huge, companies are lured by the promise of hefty profit margins and thus a legitimate competitor in the global industry. [12]

Role of Government

The Indian government has been very supportive. It established the Department of Biotechnology in 1986 under the Ministry of Science and Technology. Since then, there have been a number of dispensations offered by both the central government and various states to encourage the growth of the industry. India's science minister launched a program that provides tax incentives and grants for biotech start-ups and firms seeking to expand and establishes the Biotechnology Parks Society of India to support ten biotech parks by 2010.

Pharmaceutical industry today

The number of purely Indian pharma companies is fairly low. Indian pharma industry is mainly operated as well as controlled by dominant foreign companies having subsidiaries in India due to availability of cheap labour in India due to availability of cheap labour in India at lowest cost. In 2002, over 20,000 registered drug manufacturers in India sold $9 billion worth of formulations and bulk drugs. 85% of these formulations were sold in India while over 60% of the bulk drugs were exported, mostly to the United States and Russia. Most of the players in the market are small-to-medium enterprises; 250 of the largest companies control 70% of the Indian market. Thanks to the 1970 Patent Act, multinationals represent only 35% of the market, down from 70% thirty years ago.

Biotechnology Statistics

Table 1.4 Top 20 Biopharmaceutical & Biotechnology companies in India, as of 2011

Rank	Company	Revenue 2011(Rs crore)
1	Biocon	1483
2	Serum Institute of India	1041
3	Panacea Biotec	928.41
4	Nuziveedu Seeds Private Limited	610
5	Reliance Life Sciences	490
6	Quintiles	476.25
7	Novo Nordisk	462
8	Rasi Seeds	371.88
9	Mahyco	364.9
10	Trans Asia	350
11	Ankur Seeds	325
12	Syngene International	318
13	Bharat Biotech International	298.34
14	Indian Immunologicals Limited	283
15	Krishidhan Seeds	276.13

Challenges

The biotech sector faces some major challenges in its quest for growth. Chief among them is a lack of funding, particularly for firms that are just starting out. The most likely sources of funds are government grants and venture capital, which is a relatively young industry in India. Government grants are difficult to secure, and due to the expensive and uncertain nature of biotech research, venture capitalists are reluctant to invest in firms that have not yet developed a commercially viable product. As previously mentioned, India hopes to solve its funding problem by attracting overseas investors and partners. Before these potential saviors will invest significant sums in the industry, however, there needs to be better scientific and financial accountability. [13]

Regulatory environment

To end the dominance of foreign drug companies, the Indian government enacted a series of policies designed to foster self-sufficiency in the production of basic drugs. Because these measures lowered barriers to entry, thousands of medium and small Indian pharmaceutical companies entered the market challenging the MNCs for control. These actions laid the foundation for today's highly competitive domestic industry that is capable of offering some of the lowest drug prices in the world. [14]

The Patent Act, 1970

The Act's stated objective was to foster the development of an indigenous Indian pharmaceutical industry and to guarantee that the Indian public had access to low-cost drugs. The Act replaced intellectual property rights laws left over from the British colonial era and ended India's recognition of Western-style "product" patent protection for pharmaceuticals, agricultural products, and atomic energy. Product-specific patents were disregarded in favor of manufacturing "process" patents that allowed Indian companies' to reverse engineer or copy foreign patented drugs without paying a licensing fee.[13]

Drug Price Control Order, 1970 (DPCO)

The order was introduced when most of India's drugs were under strict price controls. Since its introduction, the number of bulk drugs under price controls gradually declined from 347 in 1987 to 163 in 1994 to 74 in 1995.8 In 2005, the government capped prices on 74 bulk drugs and 260 formulations that account for approximately 25 percent of India's retail pharmaceutical market (attachment).9 Trade margins for these drugs were capped at 8 percent for retailers and 16 percent for wholesalers. The National Pharmaceutical Pricing Authority, founded in 1997, is responsible for monitoring prices using the DPCO to fix ceiling prices on drugs and ensure that no Indian company in a monopoly position takes advantages of its monopolistic position by profiteering. In June 2006, the National Pharmaceutical Policy 2006 (Part A) proposed to add price controls on 354 specific drugs listed as essential medicines. [13]

Industry production

Thirty-five years of protection has enabled the Indian pharmaceutical industry to perfect its scientific and manufacturing capabilities, allowing many of its leading companies to move up the value added chain. India's pharmaceutical industry consists of large, medium, and small companies and is one of the world's most price competitive. It is also highly fragmented with more than 20,000 domestic production units. Because of low barriers to entry and low capital requirements, the number of domestic pharmaceutical firms engaged in the formal and informal sectors expanded dramatically from 2,257 in 1970 to more than 20,000 in 2005.

Industry structure

Mergers, acquisitions, and other alliances: The last 3 years have seen a significant rise in the number of consolidations, mergers & acquisitions, and other types of alliances and tie-ins in the Indian pharmaceutical industry. Most of the acquisitions involve Indian companies searching for ways to penetrate overseas markets and widen their global footprint, diversify and enhance their product portfolios, offer their customers a 'nearshore-offshore' option, improve their custom manufacturing, packing, and R&D capabilities, acquire existing brands, and gain access to the highly regulated markets. [15]

Contract research and manufacturing, outsourcing, and other services: The passage of the Patents (Amendment) Act 2005 has significant implications for both Indian and multinational companies competing in the Indian market. Leading Indian companies are moving away from a reliance on the domestic market to the development new drugs, exports to regulated markets, and cooperative agreements with MNCs. Facing lagging sales of patented drugs by MNCs in their home markets, declining R&D revenues, and rising costs, many MNCs 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. [14]

EVOLUTION OF PHARMACEUTICAL INDUSTRY IN GUJARAT

There is no stopping the pharmaceutical and biotechnology industry in Gujarat, which from its glorious past is racing ahead by meeting the needs of era of outsourcing that has of late infused new life into the pharma and biotech industry world over. The pharma industry in Gujarat, which took off in 1907 with Alembic setting up its facility, is now a major contract research and manufacturing services (CRAMS) provider in India contributing significantly (more than $400 million as per various industry analysts) to the country's US $1.21 billion CRAMS market in 2007. The latest distinction as the favorite locale for outsourcing follows its stint as the major exporter of pharmaceuticals and producer of active pharmaceutical ingredients (APIs) in the country.

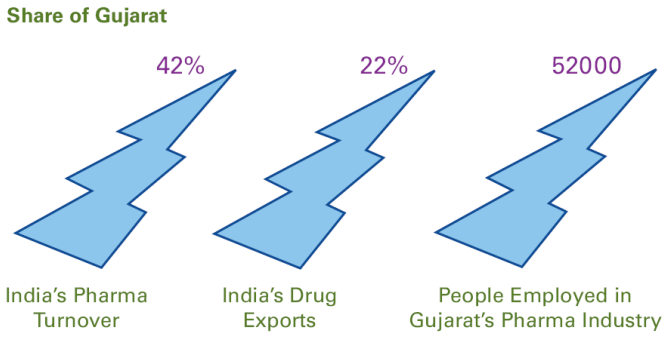

Figure-2.1 Share of Gujarat in Indian Pharmaceutical Industry

From the days that saw pharma and biotech industry making its path in the country, Gujarat has used its available resources to the best of its ability to propel the industry and in course of time came to be known as the pharma capital of India. In the process, Gujarat, the jewel of the West, became the first state in India to manufacture active pharmaceutical ingredients (APIs), finished dosage forms and pharmaceutical machineries. Also, as pharma and biotech industry slowly gained ground in the country, this jewel of the West earned the distinction of becoming the first state in the country to embark on preclinical safety and toxicology studies.[16]

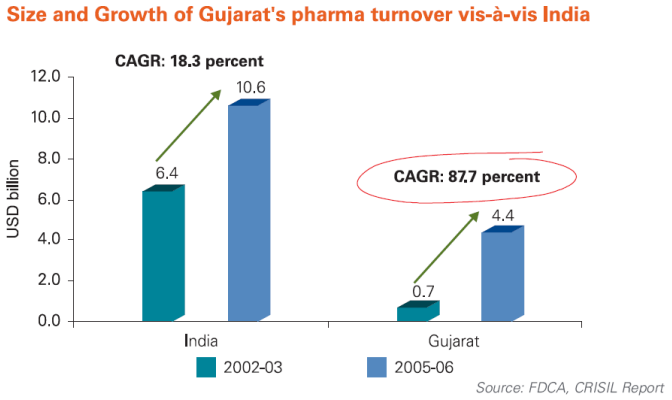

Figure-2.2 Turnover of Pharma industry in Gujarat

Now that pharma and biotech industry in India has established itself on the global market and multinational and foreign pharma companies are looking at the country for possible synergies. In tandem with the country's envious growth in this sector, Gujarat has also made its mark as global pharma hub, readying itself to live up to the expectations of the foreign and multinational pharma companies to vie as an outsourcing partner of choice, at a time when pharma industry is going through a sticky patch due to expiration of patents, lackluster drug pipelines and spiraling costs of research and development, manufacturing and marketing.

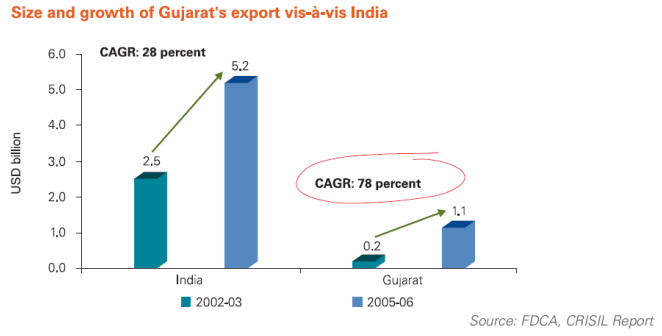

Figure-2.3 Size and growth of export of Pharmaceutical industry in Gujarat

When contacted industry sources, they pointed out that like many other segments of pharma business, in outsourcing to the state has got certain milestones to boast of. "The Gujarat pharmaceutical industry has carved out a special place for itself over a period of time. In fact, one of the early deals in the area of global contract manufacturing, the recent buzzword in the pharma industry, was accomplished in Gujarat way back in 1996. Hence, Gujarat is emerging a pioneer in this area too," said a leading pharma and biotech player in the state requesting anonymity due to certain technical reasons.

Comparison with other states

"Gujarat is home to approximately 40 per cent of contract research organizations (CROs) in the country. The state has witnessed action on outsourcing of clinical research activities and drug discovery related services. Globally, contract research is a high growth segment led by increasing outsourcing activities of multinational pharma companies. Gujarat is increasingly emerging as one of the most globally preferred outsourcing/off shoring destinations for pharma. This trend can be largely attributed to Gujarat's inherent competencies in terms of low manufacturing cost, vast talent pool having excellent chemistry skills, strong support from ancillary industries and a favorable regulatory environment," added by one of the prominent industry player. Agreeing that Gujarat has already emerged as an ideal pharma outsourcing destination, Hitesh Gajaria, sector head, pharmaceuticals, KPMG, said, "The state has a lot to offer in lines with the industry's requirement that includes good manufacturing infrastructure, skilled workforce and cost competitive advantages, apart from the regulatory support. Also, the existence of various pharma manufacturing clusters like the ones in Ahmedabad, Vadodara, Bharuch, Ankleshwar and Vapi / Valsad would further fuel the state's growth as an outsourcing destination."

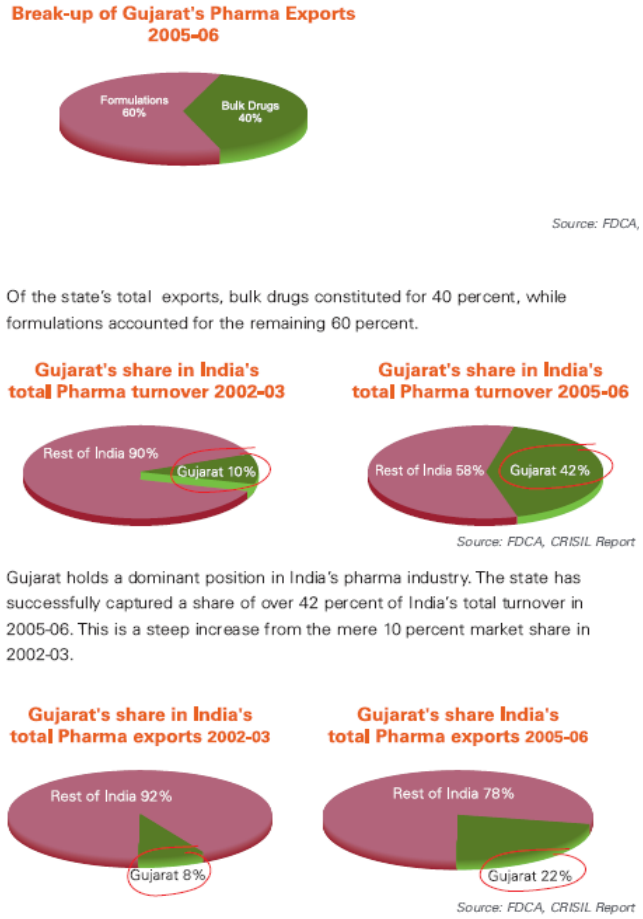

Figure-2.4 Share of export of Pharmaceutical industry in Gujarat

He also indicated that Gujarat's established academic and research institutes and pharma manufacturing, packaging and chemical industries, coupled with factors such as backward linkages, large number of CROs, and enhanced level of investment in R&D by local industry and IT capabilities would

give it an edge as a preferred sourcing partner over other states in the country. During its growth as a sourcing centre through CRAMS business, Gujarat has also developed its own strengths in different segments of pharma business. Referring to the competencies that Gujarat pharma industry hold in this outsourcing regime, I. A. Modi, chairman, Cadila Pharmaceuticals Ltd, said, "In the field of outsourcing, Gujarat has a great potentiality in tackling and development of problems in research and development (R&D).[16]

SWOT Analysis

Figure-2.5 Gujarat Pharma-A SWOT analysis

Export & R&D

However, the strides that the Gujarat pharma industry, which was worth around US $4.4 billion in 2005-06, is making is not limited to contract research and manufacturing services. The state is still batting as a major exporter of pharmaceuticals in the country with recent expert estimates putting the state's export growth rate at 20 to 25 per cent, at a time when the overall national export growth rate stands at 35 to 40 per cent. Available figures indicate that the state's pharma export is worth Rs 5,000 crore, while its total production stands at between Rs 12,000 and Rs 14,000 crore. Gujarat manufactures and exports different dosage forms, including tablets, capsules, dry syrups, external application preparations, and cytotoxic drugs, hormones, vaccines, small and large volume parental, APIs and biopharma products. The pharma industry in Gujarat houses more than 3,000 registered manufacturers and the stringent implementation of current good manufacturing practices (cGMP) has enabled these players to meet the international parameters and the much needed fillip to the export business.

Rich opportunities

Though the pharmaceutical industry in this jewel of the West is faring well adopting to new and emerging business conditions and opportunities, all is not well with the industry. There are certain issues to be addressed. "The pharmaceutical industry has shown its strength in R&D at all levels, but unfortunately it is facing crisis for the enough funds for R&D activities due to redundant drug price control order (DPCO). In India, the market forces keep prices at the lowest and therefore I feel DPCO neither helps the consumer nor the industry. Hope the government becomes practical so that the funds are available for research activities," said, I A Modi. [17]

Grooming bioindustry

Backed by the proactive government policies, the biotech industry is expected to attain new heights in Gujarat. According to Hitesh Gajaria of KPMG, Gujarat with its rich bio-resource, strong reservoir of medical and marine resources, strong pharma and health care base is also well poised to grow in the biotechnology front. "Biotech industry in Gujarat today consists of more than 50 biotech companies and 66 support organisations. The present annual turnover in biotechnology in the state has been around US $150 to $175 million," he noted. The thrust areas of Gujarat biotech industry include healthcare, pharmaceuticals, agriculture biotechnology, industrial enzymes, bioinformatics, contract research and marine and environmental biotechnology. The Gujarat government has proposed the development of various biotech zones that would act as enablers for the growth of this industry in Gujarat. Gujarat is again a recombinant deoxyribonucleic acid (rDNA) hub with the presence of world class centres in companies like Zydus Cadila.

Gujarat - A leader in pharma machines

According to industry estimates, a great chunk --almost 40 per cent --of machinery used in the pharmaceutical manufacturing in India is produced in Gujarat. This creates a very good local and global opportunity for Gujarat in the manufacturing of pharmaceutical machinery, given its strong and well established engineering sector, points out a recent study titled Gujarat Pharma Industry-striding into the Future, KPMG, India The strong growth prospects of the pharmaceutical exports segment and growing demand from the domestic market, will further fuel growth in the pharmaceutical machinery sector. However, Gujarat's engineering sector is highly fragmented, especially the pharma machinery manufacturing segment. Due to the highly fragmented nature, there is a dearth of pricing power and critical scale. This in turn restricts the ability to produce the technology-driven products required for operating in global markets. The pharma machinery manufacturing industry in Gujarat needs to consolidate and synergise the skills and complementarities available in the broader engineering sector (like the CNC machine tools industry) to be able to create world-class players with the scale and resources required, to tap the global as well as local demand. Gujarat's dominant position in India's pharmaceutical sector is well known. [18]

Brief idea about different pharma industries of Gujarat origin

Sun pharmaceuticals Ltd.

Sun Pharma began in 1983 with just 5 products to treat psychiatry ailments. Sales were initially limited to two states in

Location	Existing products	Export Potential	Market- based / Resource-based / Infrastructure-based	Degree of Competition with large units	Potential Future Products
Ahmedabad	API, Finished Dosages, Contract Manufacturing Biological Manufacturing	High	Market and Infrastructure	High	Biological manufacturing, Medical Devices
Vadodara	Finished Dosages, Biogenerics	High	Market and Infrastructure	High	API, CRAMS, Biological Manufacturing
Ankleshwar	APIs, Formulations, Vaccines	Medium	Resource	Medium	APIs for global companies
Bharuch and Vapi / Valsad	APIs, Finished Dosages	Medium	Resource	Medium	Intermediate and Finished Dosages

Figure-2.6 Characteristics of Pharma clusters in Gujarat

Eastern India. Sales were rolled out natiowide in 1985. Products for cardiology were introduced in 1987, and Monotrate, one of the first products launched then, countinues to be sold even today. Important products in Cardiology were later added; several of these introduced for the first time in India, and these brought patients the latest treatments at a sensible cost, a belief we've always lived by.

Realizing the fact that research is a critical growth driver, we established our first research center, SPARC, in 1993 and this created the base for strong product and process development that enabled growth in the subsequent years.

Sun Pharma was listed on the main stock exchanges in India in 1994; and the Rs. 55 crore issue of a Rs. 10 face value equity share offered at a premium of Rs. 140/-, was oversubscribed 55 times. The minimum 25% that was required under the regulations then for listing was offered to the public, the founder's family continues to hold a majority stake in Sun Pharma. We used this money to build a greenfield site for API manufacture, as well as for acquisitions. For allowed acquisitions, typically companies or assets that allowed us entry into a new market or therapy area, assets that could be turned around and brought on track were identified.

Torrent Pharmaceuticals Ltd.

These words sum up the efforts of the Torrent group, which integrates people, processes and potential towards the betterment of mankind. It all began with the toil of one enterprising individual, Shri. U N Mehta, when he ventured on his own to create history in the Indian pharmaceutical industry by implementing successfully the concept of niche marketing. His journey, characterized by ups and downs, reached a milestone in 1970, with the launch of Trinicalm Plus, an effective tranquilizer in the niche segment, central nervous system (CNS). The foundations for Torrent were laid when 'Trinity Laboratories' began operations under the able guidance of Shri Mehta whose efforts are worthy of emulation. 'Trinity' was renamed 'Torrent' and with this not only did the company get a new name, it also focused on establishing its own manufacturing facilities in the early 80s. Torrent augmented its efforts with the expansion of its manufacturing capacity, emphasis on marketing and creating business opportunities through focus on exports. Torrent Pharmaceuticals Limited recorded a quantum leap in the year 1994. It has also been rated India's ninth best company among capital intensive companies in terms of ROCE in a study by ETIG-BCG in 2001. In recognition of the consistent performance Torrent Pharmaceuticals Limited has been receiving accolades from various quarters, such as the President's award for highest pharmaceuticals exports of Rs. 1570 million in 1991-92. The Company that had a humble beginning has now grown to become one of the leading players in pharmaceuticals. It has ambitious plans for the years ahead. The emphasis is on Post-2005 opportunities with greater focus on the international market, in particular the lucrative North American market. [19]

Dishman Pharmaceuticals and Chemicals Limited.

Dishman is the global outsourcing partner for the pharmaceutical industry offering a portfolio of development, scale-up and manufacturing services.
The products and services offered span customers' needs from chemical development to commercial manufacture and supply of active pharmaceutical ingredients. Dishman has a relationship driven business model that improves its customers businesses by providing a range of solutions at locations in Europe, China and India. Our offer delivers the best of both worlds: western expertise in speed, flexibility, innovation and rapid material provision new world expertise in process optimisation, robust large scale processes and secure economic commercial supply. Our commitment is to deliver cost-competitive technical excellence and to be a reliable partner to our customers, protecting their interests as if they were our own. Dishman is headquartered in Ahmedabad, India and is listed on the Bombay Stock Exchange (BSE). In 2008/09, Dishman had sales of over US$230m.[20]

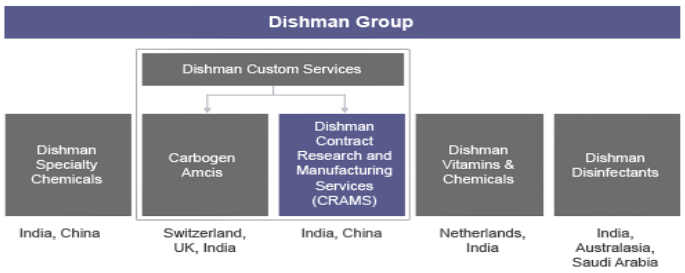

Figure-2.7 Business unit of Dishman Group

Zydus cadila healthcare Ltd.

An Integrated Global Healthcare Company
Zydus Cadila is an innovative global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare products. The group's operations range from API to formulations, animal health products and cosmeceuticals. Headquartered in the city of Ahmedabad in India, the group has global operations in four continents spread across USA, Europe, Japan, Brazil, South Africa and 25 other emerging markets. In its mission to create healthier communities globally, Zydus Cadila delivers wide ranging healthcare solutions and value to its customers. With over

13,000 employees worldwide, a world-class research and development centre dedicated to discovery research and eight state-of-the-art manufacturing plants, the group is dedicated to improving people's lives.

Formulations Business – India

With three multi-therapy divisions and eight specialty divisions, Zydus Cadila is one of the leading player in the Indian healthcare industry. It is the leading player in the cardiovascular, gastrointestinal and women's healthcare segments. The group has strong presence in respiratory, pain management, CNS, anti-infectives, oncology, neurosciences, dermatology and nephrology segments. It has been able to maintain overall position and market share through faster growing chronic / lifestyle segments. With several new product introductions and pillar brands such as Aten, Ocid, Deriphyllin, Pantodac, Atorva, Nucoxia, Mifegest to name a few, Zydus Cadila is considered a tour-de-force in therapy management and brand management. one of the strongest distribution channels in the industry, the group reaches out to 1,00,000 chemists and serves 2,00,000 doctors including physicians, specialists and super specialists.[21]

Alembic Pharmaceuticals

Established in 1907, Alembic Pharmaceuticals Limited is a leading pharmaceutical company in India. The Company is vertically integrated with the ability to develop, manufacture and market pharmaceutical products, pharmaceutical substances and Intermediates. Alembic is the market leader in the Macrolides segment of anti-infective drugs in India. Alembic's manufacturing facilities are located in Vadodara and Baddi in Himachal Pradesh. The plant at Vadodara has the largest fermentation capacity in India. The Panelav facility houses the API and formulation manufacturing (both US FDA approved) plants. The plant at Baddi, Himachal Pradesh manufactures formulations for the domestic and non-regulated export market. The company has a state of the art Research Centre at Vadodara. Alembic Pharmaceuticals Limited understands that only making profit should not be the sole purpose of any enterprise. Therefore we are not only involved in manufacturing and making the medicines available to the masses but also making a difference to society at large and rural areas in particular through various initiatives. [22]

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