Case writing is a process that begins with the decision to use a case in a class room setting and ends with the use of the case in class. To derive maximum benefits of this methodology of teaching, the teachers themselves must write cases. There is no substitute and shortcut for this. It may be part of research and/or consulting undertaken by the Faculty.The research, consulting and case writing go hand in hand and are complementary to each other.

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Does the Government as an Actor Stimulate Innovation? A Case Study of Indian Pharmaceutical Industry

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Indian pharmaceutical industry is an important innovative industry and is the fastest growing pharmaceutical industry in the world. The pharmaceutical industry is a knowledge intensive industry which plays a vital role in driving the technology, R & D and innovation. Unlikely high tech industry, R & D is very crucial to the pharma industry which can be very costly and risky. The Indian Patent Act 1972 that has significantly changed the pharma industry removing the product patents and shortening the patent statutory term to seven years. Post TRIPs regime, Indian pharma companies have responded to the innovation gap through a variety of tactics, from increasing investment on internal R & D to horizontal industry consolidation and an increased dependence on in-licensing from the biotechnology sector (Hughes et al; 2007). So, the journey of Indian pharmaceutical industry is today termed as "reverse engineering to reverse innovation". This case studies the role of government and how its pro-innovation policies have shaped the India's most innovative sector to a new height. The debate is "has the government policy successful or does the pharma industry still needs government intervention?" The attempt has been made to look at answers to research questions, which is eloquently addressed, based on theoretical review complemented with empirical data analysis.

Keywords: Pharmaceutical, India, Innovation, Policy, R & D, Patent

Introduction

India's pharmaceutical industry is one of the highly innovative and growing industries of India. The Pharmaceutical industry which is fueled by export has grown from mere US$ 0.3 billion turnover in 1980 to about US$ 21.73 billion in 2009-10 (Reddy 2013). Today, the Indian pharmaceutical industry is one of the developing world's largest and most developed, ranking 3rd in the world in terms of production volume and 14th in domestic consumption value (Dept. of Pharmaceuticals 2010) and is mostly dominated by Indian companies with a share of 77.3% (Chaudhry; 2005).

The pharmaceutical industry is a knowledge intensive industry which plays a vital role in driving the technology, R & D and innovation. Unlikely high tech industry, R & D is very crucial to the pharma industry which can be very costly and risky. The Indian Patent Act 1972 that has significantly changed the pharma industry removing the product patents and shortening the patent statutory term to seven years. It started the era of reverse engineering where firms developed new products by changing their production processes. Reverse engineering is broadly defined as the process of extracting know-how or knowledge from a human-made artifact (James ,2012)). During the last three decades the large private Indian pharmaceutical firms focused their efforts on reverse engineering oriented process R&D (Wendt, 2000). Accumulating extensive knowledge in process R & D, Indian pharmaceutical pharma has developed innovative R & D which is a successful case of indigenous self-reliant development.

India accepted the Trade related Intellectual Property Rights (TRIPs) agreement in 1995 and amended its patent law "Indian Patents (Amendments) Act 2005" that re-instituted the product patents and put a stop on 36 years of protection for Indian companies and terminated legal reverse engineering, or copying of patented foreign pharmaceutical drugs (Greene; 2007). When India joined the WTO in 1995, its pharmaceutical exports were valued at less than $600 million. By 2005, its exports had grown to $3.7 billion and accounted for more than 61 percent of industry turnover (Greene; 2007). The TRIPS Agreement has not only increased the R&D expenditure of the Indian pharmaceutical industry but has also changed its R&D structure. (Kamiike & Sato, 2011). Post TRIPs regime, Indian pharma companies have responded to the innovation gap through a variety of tactics, from increasing investment on internal R & D to horizontal industry consolidation and an

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increased dependence on in-licensing from the biotechnology sector (Hughes et al; 2007). So, the journey of Indian pharmaceutical industry is today termed as "reverse engineering to reverse innovation".

The Evolution of the Pharma and Biotech Industry

Indian pharmaceutical industry is an important innovative industry and is the fastest growing pharmaceutical industry in the world. With a market value estimated worth US $12.26 billion the Indian pharma industry is expected to reach around US $ 19.22 billion by 2012 (Department of Pharmaceuticals). The Pharmaceutical industry of India is the world's 3rd largest in terms of volume and stands 14th in terms of value (Mahajan & Sharma, 2011)). So, Indian pharmaceutical market undoubtedly plays a major role not only domestically but also in the global market. With a consecutive domestic growth of 13.5% for the last five years (PwC, 2010) and composite CAGR at domestic level of 9.5% (IBEF, 2008), the Indian pharma market shows highly global strength in the world. In 2006-07, the domestic consumption was accounted 57% while the rest 43% was constituted by exports (IBEF 2008). Furthermore, according to IMS Health 2010, the emerging markets of Asia/Africa/Australia grew at a rate of 15.9% in 2009, as compared to much slower growth rates in North America (5.5%), Japan (7.6%) and Europe (4.8%) (PWC, 2011.

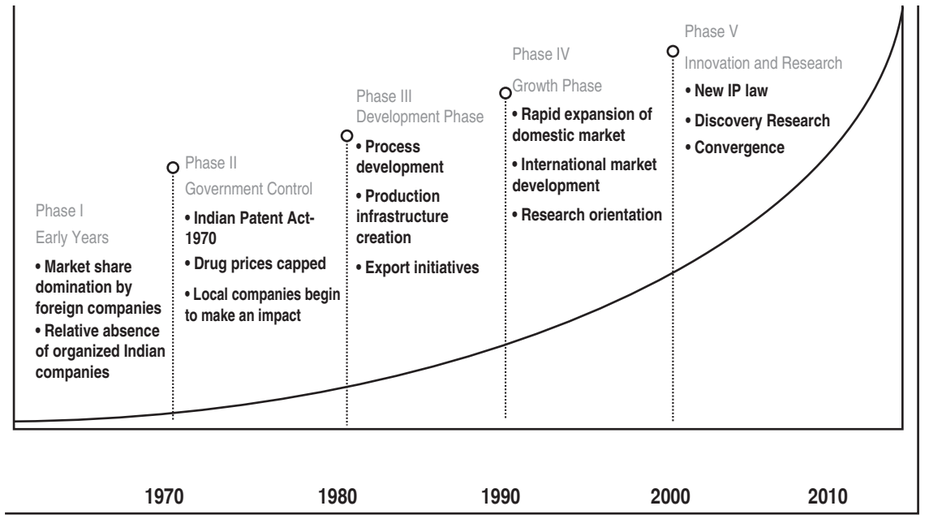
The evolution of today's billion dollar Indian pharmaceutical industry has come across a long way since 1970. The Pharmaceutical industry which is fueled by export has grown from mere US$ 0.3 billion turnover in 1980 to about US$ 21.73 billion in 2009-10 (Department of Pharmaceuticals). The Indian patent act 1970 played a significant role in driving the growth of Indian pharma industry giving power and protection of innovation to the pharma innovators in India.

In the post-independence era, the Indian pharmaceutical industry has gone through four stages. In the first stage, the Indian pharmaceutical market was largely dominated by the foreign MNCs. The Indian pharma industry was infant and was incapable to meet its domestic requirement due lack of skills and technology.

The second growth stage of pharma industry took place in 1970s and the enactment of government policies such as Indian Patent Act (IPA) 1970 and the New Drug Policy (NDP) 1978 are the important milestones. Another important milestone is the implementation of the Foreign Exchange Regulation Act (FERA) 1973 that allows foreign ownership up to 74 per cent for firms producing high technology drugs.

In the third stage of pharma industry growth, the domestic pharma companies invested more on research and development and on large-scale reverse engineering and process innovation which achieved near self-sufficiency in the technology and

Figure 1: Evolution of Indian Pharmaceutical Industry



Source: Lal, Akshay (2006);

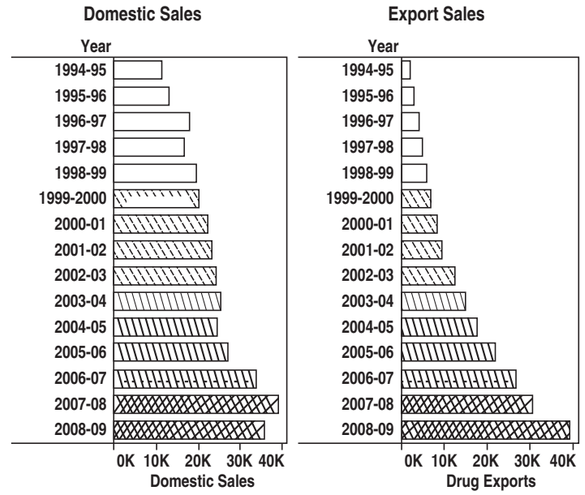
production of bulk drugs. The development of this growth stage was extremely important for the pharma industry. During this period in 1991 Indian firms dominated the domestic market with about 70 and 80 per cent in the case of bulk drugs and formulations respectively.

The fourth stage witnessed Indian pharma companies in a dominant position. This stages also witnessed further policy changes. The licensing requirement for drugs has been abolished, 100 per cent foreign investment is permitted under automatic route, and the scope of price control has been significantly reduced. India has amended three times in patent act 1970 three Amendments (March 1999, June 2002 and April 2005) in the Patent Act 1970 to bring Indian patent regime in harmony with the WTO agreement on the Trade Related Intellectual Property Rights (TRIPs). The Patents (Amendment) Act, 2005 came into force on 4th April 2005 and the patenting period has increased to a 20 year period. The changes in "the policy regime in the 1990s, thus, started a new chapter in the history of Indian pharmaceutical sector where free imports, foreign investment and technological superiority would determine the trade patterns and industrial performance" (Pradhan, 2006).

In the period of 2000, with international market development and research orientation, Indian pharma industry has gone through a see-saw changes which focused on rapid expansion of both domestic market and foreign export. In the phase -V in the period 2010, Indian pharma industry sets a huge competition at global market and focuses on domestic challenges with new IP law. Industry analyst Price Waterhouse Coopers (PWC) predicts that domestic market will grow to approx. US$ 50 billion - a Compounded Annual Growth Rate (CAGR) of 15%, with the potential to reach US$74 billion – a CAGR of 20% by 2020 and export will rise from US $ 8 billion in 2009 to approx. US $ 20 billion by 2020. (PWC 2010, pp.5 - 10).

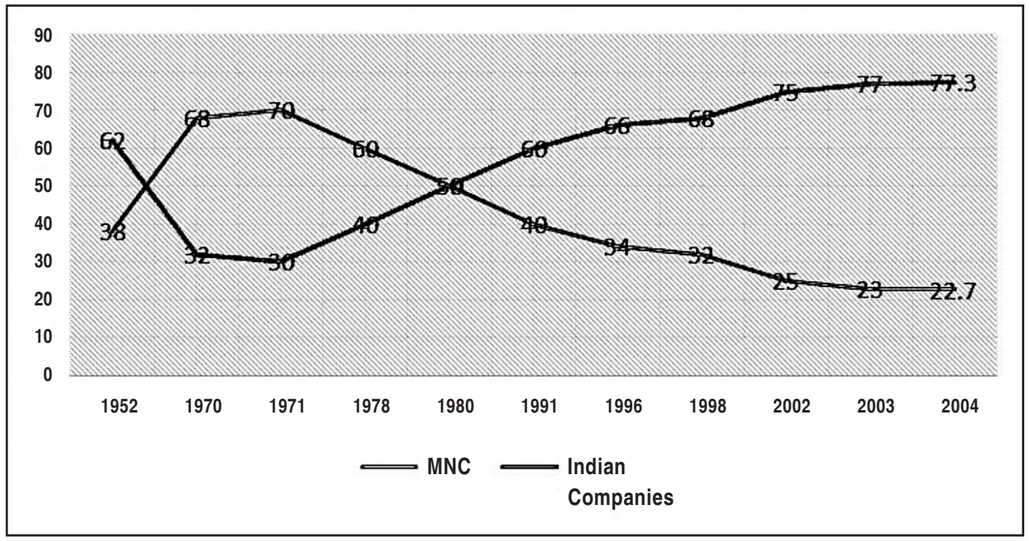
Figure 2 shows a radical shift of both domestic and export growth, which has boosted the Indian pharma industry. From a meager US $ 48 million in 1973-74, today the total pharmaceuticals export crossed over US $ 9 billion. Export as a percentage of total sales increased from 18% in 1994-95 to 52% in 2008-09 but it has been accompanied by MNCs, among the top 10 pharma companies in India, up to three from one in 1996-97. The total revenue generated by the top 10 firms accounted for 39% of total sales by all pharma companies of India (Taylor; 2010). Furthermore, with a rapid increase of export demand which was estimated with a CAGR of 41.6% in the regulated markets and CAGR of 25.6% in the semi-regulated markets and combined average CAGR of 32.1% for the period 2005-06 to 2010-11 (IBEF, 2008) and the sharp rise in the export revenue from US $6.23 billion in 2006-07 to US $8.7 billion in 2008-09 with a CAGR of 21.25%, the export market provides a platform to Indian pharma industry to play an eminent role in the global pharma market (Table 1). According to industry interview by PWC 2011, Indian pharma market is predominantly a branded generic market with 90% branded generic products and 10% accounted as other drugs.

Figure 2: Domestic and Export Sales of Indian Pharma Industry (1994-95 to 2008-09)



Source: Taylor (2010); Department of Industrial Policy and Promotion; Figures in Indian Rupees Crores. Note: 1 Indian crore equal to 10 million Indian Rupees.

Figure 3: Market Share (%) of MNCs and Indian Companies in the Pharmaceutical Industry in India (1952-2004)



Source: Chaudhry (2005)

Figure 3 suggests there has been a significant change in the market share of both domestic and MNCs since 1952. It provides a clear image that the decades of foreign companies dominance in the Indian market has finally come to an end in the year 1980 when both MNCs and Indian companies acquired equal share in Indian market. From 1980 onwards Indian pharma industry has a tremendous growth in terms of both market share and export activity.

Having a closer study on the growth of pharmaceutical sales over the last decade, there has been a substantial growth of sales. Dr. Reddy's sale was 244.99 in 1996-97 and it reached 4394.9 resulting a growth of as high as 1693.91% whereas pharma company Cipla has a growth of 963.93%. The average sales growth of the top 11 companies is 573.34% (Table 1).

With growing investment on R & D, Indian pharmaceutical industry "worked on the basis of reverse engineering and process innovation which achieved self-sufficiency in technology, and has been strengthening export orientation in the tide of economic liberalization since early1980s" (Kamiike and Sato 2011). Pro-innovation policy and government supports has further contributed to the growth of Indian pharma sector that has been resulted a positive trade balance since 1987. The increasing globalization and competitiveness

Table 1: Per Cent age of Sales growth in Indian Pharma Company (1996-97 to 2008-09)

Pharma Company	Sales	Pharma Company	Sales	Growth	%age growth
1996-97		2008-09			
Ranbaxy	1146	Ranbaxy	4755,76	3609,76	314,99
Glaxosmithkline	699,63	Glaxosmithkline	1668,08	968,45	138,42
Cipla	451,88	Cipla	4807,67	4355,79	963,93
Piramal	319,28	Piramal	1565,42	1246,14	390,30
Cadila	255,48	Cadila	1765,4	1509,92	591,01
Dr. Reddy's	244,99	Dr. Reddy's	4394,9	4149,91	1693,91
Aventis	382,69	Lupin	2934,25	N/A	N/A
Alembic	282,38	Aurobindo	2730,75	N/A	N/A
Torrent	258,85	Sun Pharma	2830,86	N/A	N/A
Ipca	251,15	Wockhardt	1448,87	N/A	N/A
Total	**4292,33**		**28901,96**	**24609,63**	**573,34**

Source: Taylor (2010), DIPP

provide incentive to the pharma industry. The export has been the driving force of the pharma industry growth over the last two decades. While the Indian pharmaceutical industry grows at a rate of about 10%, the export growth occurs about at 20% showing importance on export-led growth of the Indian pharmaceutical industry at the global market (Fig. 4).

Table 2: ANDA Approvals (2007)

Country	Numbers
USA	169
India	132
Israel	40
Germany	25
Canada	24
Switzerland	19
Iceland	14
Jordan	11
Other	25

Source: Thomson Scientific,

Table 3: Patent Challenges (as on March 2008)

Country	Numbers
USA	200
India	113
Israel	89
Canada	43
Switzerland	34
Iceland	17
Germany	10
Other	32

Source: Thomson Scientific,

India has achieved a respected position in the global pharma industry. India's innovation in the pharmaceutical products has been an outstanding success that challenges countries like Germany, China, and Canada etc. Indian pharma companies today are able to achieve a challenging second position in patent challenges and Abbreviated New Drug Application approvals (Table 2 and 3). In a comparative study of drug master filings, India is ahead of China from 1998 to 2007 which demonstrates India's innovation capabilities in pharmaceutical products (Table 4).

Table 4: Comparison of Drug Master Filings (Type II) by India, China & World (1998-2007)

Year	India	China	World Total
1998	32	27	316
1999	26	6	199
2000	33	9	201
2001	47	6	238
2002	55	20	264
2003	115	19	360
2004	160	25	435
2005	233	70	615
2006	267	78	627
2007	274	90	656

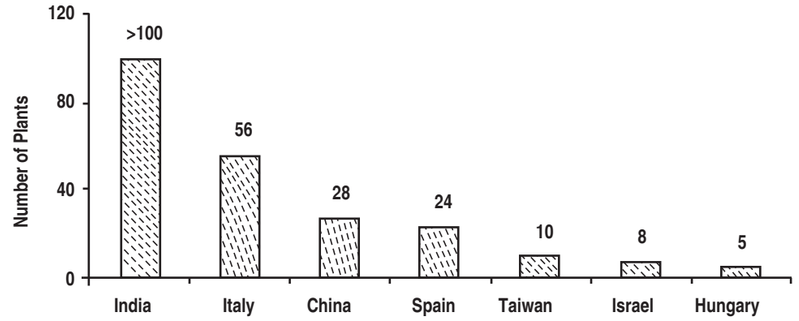
Source : Thomson Scientific

Leading Domestic Players: A Comparative Study

India's leading pharma companies play a tremendous role in driving the growth of pharma industry both in India and abroad. India's global pharma industry gives a solid boost in global competition with as low as 50% low cost production compared to the Western nations. India keeps a significantly low overall R&D costs about one-eighth and clinical trial expenses around one-tenth of Western levels (KPMG, 2006). With India's long-established manufacturing base and large pool of English-speaking workforce with 700,000 scientists and engineers graduating every year, including 122,000 chemists and chemical engineers, with 1,500 PhDs gives a clear signal that the Indian pharma industry is strengthening its global market share (KPMG, 2006 pp.7). PWC 2010 (pp.18) estimates the cost of conducting a trial cost as low as 50% than in the United States. With lower operational cost, the costs of pharmaceutical innovation in India are estimated as low as one-seventh of their levels in Europe, Indian prices for essential drugs are already the lowest in the world and (KPMG, 2006).

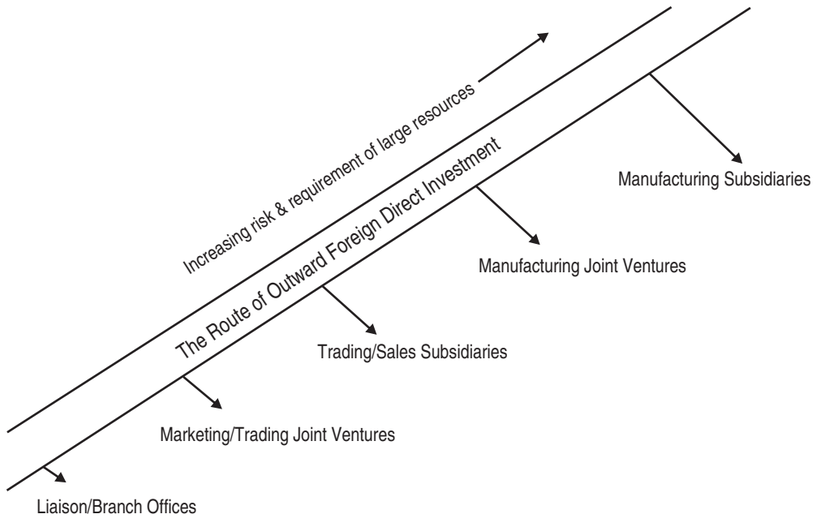
Research and development segment in pharma industry poses a critical task to the pharma companies. Companies are encouraged to involve in the New Drug Discovery Research (NDDR) with an "emerging pattern of diseases as well as responses in managing existing diseases" (Dept. of Pharmaceuticals). The Department of Pharmaceuticals further reported that "most of these companies have increased their R&D spending to over 5 per cent of their respective sales turnovers" and PwC 2010 studies show the top 10 drug firms spent US$480 million on R&D in 2008. With low operating cost India has been the most favourable outsourcing destination compared to its western counterparts.

Figure 4: India has more US FDA-approved manufacturing plants than any country except the US



Source: Pwc 2010, pp. 12

Figure 5: Different Options for Indian Pharmaceutical SMEs in OFDI



Source: Pradhan and Sahu (2008, p.56)

Considering international support and infrastructure facilities, India has the highest number of US FDA approved manufacturing plants (Figure 5) and Many Indian companies are standardizing their plants to CGMP (Current Goods Manufacturing Practices) compliant. Furthermore, according to the Department of Pharmaceuticals, "Indian companies are proving to be better at developing Active Pharmaceutical Ingredients (APIs) than their competitors from target markets and that too with non-infringing processes" which shows why Indian pharma industry is consecutively growing at above average consistently and provides a stiff competition to the other leading players at the global market.

The market dominance of Indian domestic pharmaceutical companies provides a clear boost of innovation in Indian pharma industry and Indian favorable policy. India's domestic leading players such as Cipla, Ranbaxy, Dr. Reddy's, Lupin, and Sun Pharma provide a platform for other domestic industry in pharmaceutical innovation, outsourcing and contract manufacturing.

PwC study says that there is a high level of market fragmentation and as of 2009, there were more than 10,000 firms in the market, of which, around 200 of them collectively controlled about 70% of the market share. As the figure depicts, 9 out of the top 10 players in the market had growth rates of over 18% except Ranbaxy which did not manage to keep

the growth rate of 18% instead it had 15.5% for the 12 months ending July 2010. The study further said Cipla continued to have the largest market share of 5.2%, followed by Ranbaxy with a 4.7% share. Cipla is the number one domestic pharma company and growing at faster rate. In 2008, it has a market share of 5.38% with 924 products. Ranbaxy acquired the second position followed by GSK pharma.

Government Policies and Supports

The Government of India has introduced policies on drugs and pharmaceuticals from time to time to facilitate and to create market for companies to innovate in pharmaceutical products as well as for the welfare of its citizen in terms of supplying cost-effective pharmaceutical products.

a. **Drug Order (Price Control) 1979:** The special feature of "the order has exempted new bulk drugs which are developed through research originally made in India and are not produced anywhere else. With regard to other bulk drugs, every importer has to obtain previous approval from the Government. The order was "likely to safeguard the interests of the indigenous manufacturers" and after proper inquiry and supervision, the government was exercising "in fixing of the maximum price of the indigenous drugs".

b. **National Drug Policy 1986:** The Government of India introduced National Drug Policy 1986 on 17 March 1986 to implement The Narcotic Drugs and Psychotropic Substances (NDPS) Act 1985 to prevent illicit trafficking, rational use of drugs, quality control, pricing, licensing, duty rationalization and proper coordination between health and industry ministry.

   The policy had a significant impact on pharmaceutical companies – on the one side it provides a platform of facilitation of quality and cost-effective production, on the other side it prevents illegal and misuse of drug consumption and pricing control.

c. **Drug Order (Price Control) 1995:** The Government of India introduced an updated version of previous price control order 1979 in 1995 with more execution power that enable government to power to recover overcharged amount, display of price of non-scheduled products, maintenance of records and production etc. The overall objective of this order is to curb the price of essential medicines for the welfare of the common man.

d. **National Institute of Pharmaceutical Education and Research (NIPER) Act 1998 & 2007** NPIER was set up in terms of provisions of NIPER Act, 1998 to nurture and promote phrmacutical education & research at Post Graduate level. The NIPER Act, 1998 was subsequently amended by The National Institute of Pharmaceutical Education & Research (Amendment) Act, 2007. The Amendment Act, 2007 inter-alia empowered the Central Government to establish similar institutes in different parts of the country.

e. **Essential Commodity Act 1995:** The EC Act, 1955 gives powers to control production, supply, distribution etc. of essential commodities for maintaining or increasing supplies and for securing their equitable distribution and availability at fair prices. Using the powers under the Act, various Ministries/Departments of the Central Government have issued Control Orders for regulating production/distribution/quality aspects/movement etc. pertaining to the commodities which are essential and administered by them. An exemption was made to food-grains, edible oilseeds or edible oils and sugar.

f. **Drugs and Cosmetic Act 1995:** The Drugs and Cosmetic Act 1940 was revised further "to regulate the import, manufacture, distribution and sale of drugs [and cosmetics]". Under this act, the government constituted The Drugs Technical Advisory Board ") to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act". Above all, the act gave government enormous power to supervise drugs productions and activities of the life science companies.

g. **National Pharmaceutical Policy 2002:** Emphasizing as one of the most important knowledge based industries in which India has a comparative advantage, the Prime Minister's Advisory Council on Trade and Industry has recommended several guidelines in National Pharmaceutical policy 2002. The objective of this policy is to strengthen the pharmaceutical industry to be able to face the new challenges of liberalization of Indian economy.

   The policy emphasizes on industrial licensing, foreign investment up to 100%, automatic

approval for Foreign Technology Agreements, imports as per export- import (EXIM) policy and centralized system of registration, encouragement of research and development through "the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board (DDPB) on the lines of the Technology Development Board to administer the utilization of the PRDSF". Furthermore, the policy provides appropriate fiscal incentives to encourage "the generation of intellectual property and facilitating indigenous endeavours in pharma R&D". Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs produced using DNA technology and foreign investment was raised to 100% through automatic route.

h. **National Pharmaceutical Policy, 2006:** The main objectives of National Pharmaceutical policy 2006 are:

(a) To ensure availability at reasonable prices of good quality medicines within the country

(b) To improve accessibility of essential medicines for common man particularly the poorer sections of the population

(c) To facilitate higher investment for increased production of good quality medicines

(d) To promote greater research and development in the pharmaceuticals sector by providing suitable incentives in this regard.

(e) To enable domestic pharma companies to become internationally competitive by implementing CGMP, GLP, GCP and other established international guidelines

(f) To facilitate higher growth in exports of APIs and formulations by reducing the barriers to international trade in pharmaceuticals sector

i. **National Pharmaceuticals Pricing Policy was 2011:** The main aim of this pricing policy to regulate the prices of formulations through Market Based Pricing (MBP). The earlier Drug policy of 1994 was based on Cost Based Pricing (CBP). The essential basis of the pricing policy are:

(1) Essentiality of Drugs
(2) Market Based Pricing
(3) Control of Formulations prices only

This policy proposal aims to bring 348 essential drugs under price control, so it will bring 60% of total market under price control which is currently only 10%. Though this policy will reduce profit and but benefits the people.

This policy (national pharmaceuticals pricing policy 2011) is yet to execute into law. The Supreme Court of India has asked the government to finalize it by september 27 and government may execute an interim policy.

Policy Mechanism, Fiscal Incentives and Pharmaceutical Innovation

Policy shapes business culture, facilitates innovation, creates market and develops future research and development. Through fiscal incentives mechanism, government attempts to encourage firms to carry out research and development and develops platform through infrastructure development which is the basis of innovation. The Government of India has introduced various policy and fiscal incentives from time and time for pharmaceutical innovation.

Through policy mechanism, the Government of India has facilitated various fiscal incentives and infrastructure development. The major initiatives are:

Fiscal Incentives

Fiscal incentives benefit pharma companies in R & D, skills improvement, export activities, contract and joint manufacturing and infrastructure development which are the basis for innovation to challenge the stiff competition. Besides, fiscal incentives provides concessional import duty on capital goods imported under the Export Promotion Capital Goods (EPCG) Scheme, reimbursement of customs and central excise duties, export production free of customs duty under the Duty Exemption Scheme. Tax incentives play a major relief to pharma companies to engage themselves in export and import and R & D activities. Moreover, it further benefits companies to take advantages of being located in the Special Economic Zones (SEZ) and being an Export Oriented Units (EOU)

(Pradhan and Sahu, 2008, p.64).

Further, Government provides 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. There is exemption from VAT and other fees, financial assistance with patents and subsidies on everything ranging from investment to land to utilities as support from government (Saxena, 2008).

Foreign Direct investment

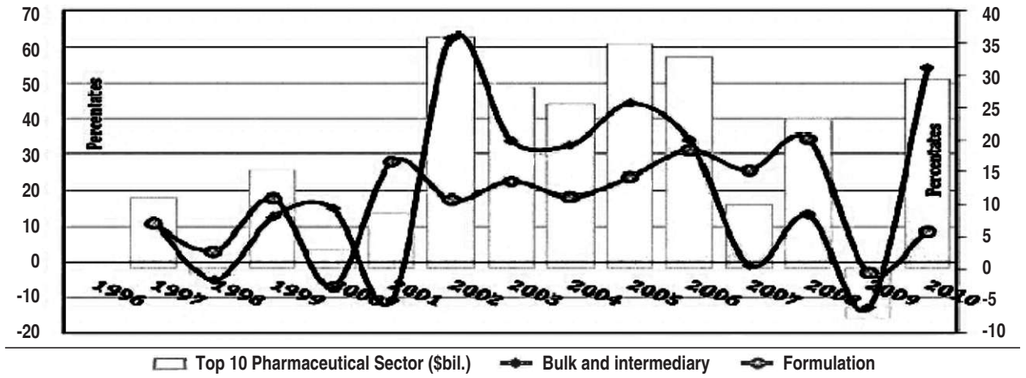
The Government has facilitated 100% Foreign Direct Investment (FDI) without seeking compulsory licensing from the government authority. The direct FDI policy certainly helps firms to overcome financial constraints. Besides, the government has approved Outward Foreign Direct Investment (OFDI) that pharmaceutical SMEs can compete in international market by investing overseas (Figure 6).

Export Dynamics, Destinations and Products

Export has been the keystone of Indian pharmaceutical sector that has driven the growth of pharmaceutical products and established the industry one of the most innovative industries of India. The fabulous achievement by the pharma industry is highly concentrated and export dynamics is highly organized and coordinated by other institutions.

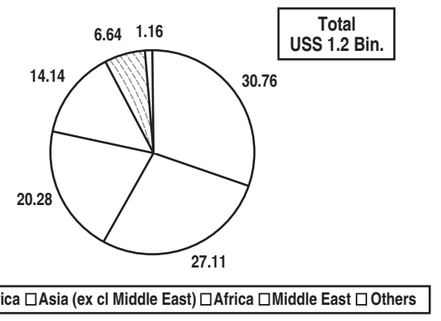
The export dynamics of top ten products contributes a larger share to the pharma industry in terms of growth and market size. Although the top ten products has been accounted for less than 2 percent of all pharmaceutical products in terms of numbers, but their market share in India's total pharmaceutical was on average 60 percent during 1996 to 2010. So, this suggests a high concentration of India's pharmaceutical exports in a few products. (Kallummal & Bugalya, 2012)

Figure 6: Segregated Annual Growth Trends of Top Ten Products of the Pharmaceutical Sector



Source: Kallummal & Bugalya, 2012, p26

Figure 7:
Region wise destination of India's Export of Drugs and Pharmaceuticals (2006-07)



Source : Directorate General of Commercial Intelligence and Statistics

Source: Export Import Bank of India (2007)

It is necessary to keep the track of top 10 products that contributes 60% of total revenue. Studying the annual growth trends, Figure 7 suggests that there is a little impact of growth in formulation on the total export growth of the pharmaceutical industry and bulk and intermediary products has a higher impact.

Indian pharmaceutical products have gone global and India is exporting its pharmaceutical products across the globe. US is the major country of India's pharmaceutical products followed by Germany and Russia. UK and Brazil are in 4th and 5th positions respectively in the year 2006-07. In region wise product destination study, Europe is the top importer of Indian pharmaceutical products with 30.76% followed by America with 27.11% and Middle-East is the least importer with a 6.64% of total India's pharmaceutical exports in the period of 2006-07 (Figure 8).

There is shift in product destination in the year 2011. Although US continues to be the number one spot for the India's pharmaceutical products, but the UK has acquired 2nd spot from the 4th position in the year 2006-07. China and Canada are no longer the top ten product destinations and Netherlands and Turkey are the 9th and 10th position respectively in the year 2011. It is clear from the both table 10 and 11 that India's export is increasing through there is a geographical shift in the product destination.

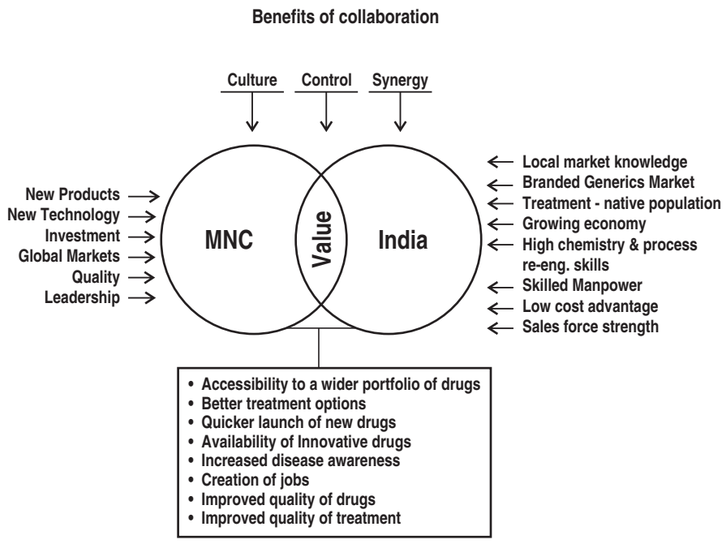
Pharmaceutical Export Promotion Council of India (Pharmexcil)

The government has set up Pharmexcil in May 2004, the only authorized agency of the government of India for promotion of pharmaceutical exports from India. Various pharmaceutical products, namely, bulk drugs, formulations, Biotech Products, Indian Systems of medicines, herbal products, diagnostics, clinical research, etc. are covered under its purview. Pharmexcil takes up several external trade promotion activities by organizing trade delegations outside India, arranging buyer-seller meetings, international seminars, etc. The Indian pharmaceutical industry has become the third largest producer in the world and is poised to grow into an industry of $ 20 billion in 2015 from the current turnover of $ 12 billion (Pharmaceutical Industry of India, 2012).

Tax and Capital Subsidy

Tax subsidy provides a big relief to the pharma industry and encourages them for the enormous activities to supply cost-effective quality product. For example, 150 per cent tax deductions for R&D expenses encourages firms to do research and development.115 scientific research and development expenses related to the business will continue to enjoy a deduction against business profits. Assets used in scientific research (other than land) would be permitted 100% depreciation. An

Figure 8:



Source: Pwc-CII (2011)

approved in-house R&D Facility will continue to enjoy 200% deduction of scientific research expenditure (other than expenditure on land and building) on scientific research under the DTC. The Department of Chemicals and Petrochemicals proposals to extend 5% interest subsidy to pharma small scale units for technology up-gradation on the basis of Schedule 'M' of Drugs and Cosmetic Rules, 1945 (Dept. of Science & Technology). The Central Sales Tax (CST) have reduced from 4% to 2%, it still continues to be a cost for the dealers, having inter-State transactions. PWC 2011,pp.40 The new tax code proposes a reduction in the corporate tax rate from the current 30% to 25% and an unlimited carry forward of business losses. pp27 Further, recently, a new provision has been added to provide 125% weighted deduction for expenditure incurred towards outsourcing of R&D activities. Income tax exemption on export profits in the first five years of operation, 50% exemption for the next five years, and 50% exemption on the reinvested export profits in the following five years (PwC2; 2010, p.27).

Foreign Collaboration and Partnership

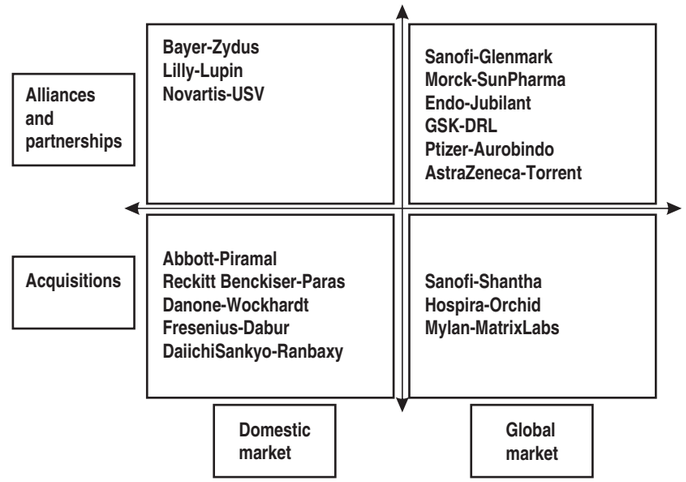
Foreign collaboration and partnership is vital for new product & market initiative, growth and sustainability. Today, despite robust demand and continuous growth of Indian pharmaceutical industry, challenges have been very complex and unexampled. India needs new technology to drive its R & D, to monitor its progress and to meet market demand. Improving of R & D productivity, reducing of costs and managing outcomes are not easy tasks at all unless there is a sustainable and cost-effective approach, so foreign collaboration, joint production and partnership have been vital to the modern pharma industry in India.

Governmental Norms in Foreign Direct Investment

Government has facilitated FDI and currently 100% FDI is permitted via the automatic route. To prevent the monopoly approach of MNCs in the domestic market, Government of India has set up a high-level committee to look into the following:

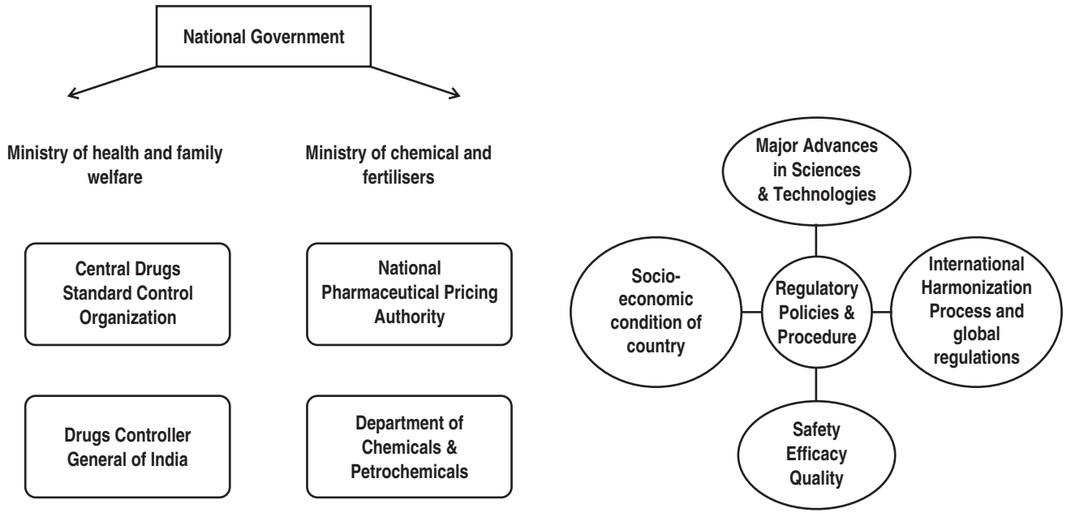
- 100 % FDI through the automatic route would be allowed for Greenfield projects.
- 100% FDI through the FIPB approval route for Brownfield investments in the pharma sector for a period of six months.
- During these six months, necessary enabling regulations will be put in place by the Competition Commission of India (CCI) for effective threshold limits on mergers and acquisitions to ensure that there is a balance between public health concerns and attracting FDI in the pharma sector.
- After six months the oversight will be done by the CCI entirely in accordance with the competition laws of the country (FIPB nod will not be required).

Figure 9:



Source: Pwc-CII, 2011

Figure 10: Regulatory Bodies in India and What Decides the Regulatory Policies



Source: Sarda Rohit R et al. (2012)

Table 5: Recent M&A for addressing the Indian market

Year	Indian player	MNC	Nature of deal
2011	Wockhardt	Danone	Acquisition for US$ 350 million
2010	Paras Pharma	Reckitt Benckiser	Acquisition for US$ 726 million
2010	Piramal Healthcare	Abbott	Acquisition of domestic formulations business for US$ 3.7 billion
2008	Dabur (*)	Fresenius	Acquisition of 73.3% stake for Euro 139 million
2008	Ranbaxy (*)	Daiichi Sankyo	Acquisition for US$ 4.6 billion

Source : Industry reports,PwC analysis
(*) While these deals were Predominantly aimed at giving access to the domestic market, they also provided a platform for the acquirers to target global market

Indian pharmaceutical market has come across of alliances and partnerships with foreign companies for merger and acquisition to address the scarcity of assets and valuation of sectors that help the industry to bring into new technology, new process of production and new market expansion. A recent study by PwC shows the progress of MNCs companies in M & A of Indian firms aimed at gaining access to the domestic market and to provide a platform to target global market.

Foreign collaboration has not only limited to domestic market access, but also to look into the global opportunities. Table 5 shows the merger and acquisitions that aim to address the global opportunities and foreign market. Foreign partnership plays an important role when it comes to joint R & D and contract manufacturing. Skills, capital techniques and labor can be more productive with joint research to find the skill gap and to address the problems with collaboration, co-operation and joint co-ordination. Indian pharma industry has made tremendous achievement and success in building partnership for product outsourcing. The main advantage of this type of deal is to facilitate high quality product at low cost that will earn more profits to both partner companies. This type collaboration mainly happens between developed and developing countries companies – where the developed country firms can supply advanced technology and skilled personnel and the developing country firms can use its cheap labor and get advantage of its low cost production capabilities.

The Role of Government

The government plays a major role in driving growth of the pharma industry whether it is licensing or export promotion. Some of the major activities of government are as follow:

- Cooperating pharmaceutical innovation and coordinating joint public and private research
- Providing universal access to health and sanitation to create an environment of sustainable development
- Assisting firms to increase firms' competitive capabilities such as R & D, skills and productivity
- Supporting pharmaceutical clusters, training facilities and information facilitation
- Facilitates infrastructure development such as transportation, power, internet connection facilities, banking
- Ensure adequate and low cost finance and upgradation of technology
- Increasing public expenditure on healthcare to create a healthy market and job creation

The Indian Regulatory System in the Pharmaceutical Policy

The Indian pharmaceutical institutional structure is divided between centre and state authorities. While national government has higher authority in the implementation of policy, but state governmental authorities also play a major role executing them according to the cultural and environmental necessities.

The principal national authority is Central Drug Standards Control Organization (CDSCO) which is controlled by Drugs Controller General of India (DCGI). On the other hand, National Pharmaceutical Pricing Authority is controlled by Department of Chemicals and Petrochemicals set up by the Ministry of Chemicals and Fertilisers. In the state-level, there are 35 state-level Food and Drug Administrations that control, coordinate and monitor the drug and pharmaceutical policies in the respective states and union territories. While the ministry formulates policies, DCGI has been responsible in approval of preclinical and clinical trials, new drug applications and the importation of new drugs from abroad. CDSCO works both at state and central level with different institutions and is responsible for the safety and quality of drug supply to the respective regions (Figure 10). Figure 10 suggests about import factors that must be taken into consideration while formulating policy, whereas figure 11 suggest about the regulatory control of pharmaceutical sector.

Recent Government Initiatives and its impact on Pharmaceutical Industry

The government has been continuously backing the pharma industry with various policy and price reforms. It has been investing on major medial infrastructure and facilitating the rural healthcare system.

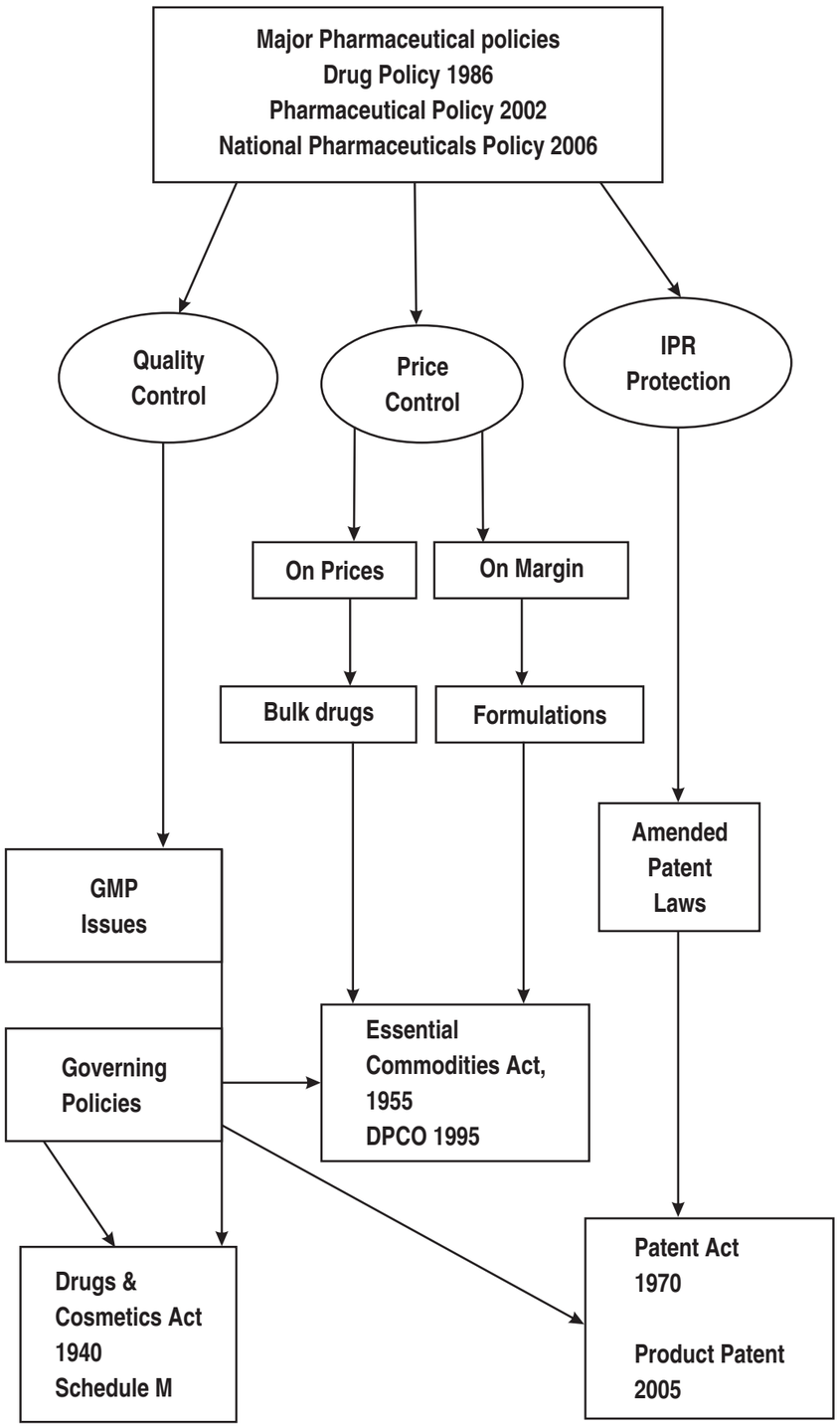
- 100 per cent FDI is permitted for health and medical services under the automatic route.
- The National Rural Health Mission (NHRM) had allocated US$ 10.15 billion for the upgradation and capacity enhancement of healthcare facilities.
- To meet revised cost of construction, in March 2010 the Government allocated an additional US$ 1.23 billion for six upcoming All India Institute of Medical Science (AIIMS)-like institutes and upgradation of 13 existing Government Medical Colleges.

With the policy reform and facilitation of FDI raised as much as US $ 1.1 billion in the period of April 2000 to November 2011 (DIPP). FDI inflow further facilitated medical and surgical appliances worth of US $ 472.6 million in the same period and the drugs and pharmaceuticals sector has attracted FDI worth US$ 5.0 billion between April 2000 and November 2011.

Budget Measure: In the Budget 2012-13, the government has increased the budgetary allocation for healthcare spending. The weighted deduction on in-house R & D expenditure was increased to 200% for a period of five years, which provides incentives and encourages firms to invest more on R & D.

Policy Measure: In policy measures, the DCGI has made compulsory registration of clinical trials which was voluntary before June 15, 2009. The government of India now provides licences for narcotic drugs and psychotropic substances to be

Figure 11: Regulatory Control of Pharmaceutical Sector



Source: Iyer (2008) adopted from Dun & Bradstreet, 2007

issued by Central Licensing Approval Authority (CLAA) which were previously issued by state licensing authorities. And DCGI has discontinued the issuance of WHO-GMP certificate for both pharmaceutical products and plant audits (India Budget, 2010).

Major Challenges

In spite of rapid expansion of pharmaceutical market, the Indian pharma industry is facing some perennial major problems, they are as follow:

1. **Price Controls:** Price control is one of the major challenges that the Indian pharma industry is continuously facing. India being one of the most price-controlled markets, Drugs Price Control Order (DPCO) is continuously monitoring both price and margin of product sales. The new draft of the National Pharmaceutical Pricing Policy (NPPP) 2011 aims to bring 60% total market under price control. Companies are likely to lose 1500 crore (approx. US $ 272 million) worth revenue and the stockists and traders are likely to lose 2500 crore (approx. US $ 453 million) worth revenue, if the policy executed (Neha, B. 2012).

2. **Poor Infrastructures:** Poor infrastructure is a major barrier to the growth of pharmaceutical industry. The major infrastructural problems are insufficient energy and inadequate transport infrastructures, though they are continuously improving, but are incapable to meet global challenges and competition both at domestic and international market.

3. **Counterfeiting Products in the market:** Counterfeiting product is another major problem that challenges the brand and goodwill of pharma industry. Counterfeiting products are sold at a lower cost than the market price and is putting pressure on incumbent firms on both sales and reputation. PwC 2010 report found that t only 0.046% of all medicines sold contained evidence of being spurious. International Pharmaceutical Federation financed by WHO said in a report that 3.1% of all drugs sold in India were spurious.

4. **Skilled Labor Shortage:** A PwC 2010 study suggests that India is facing shortage of skilled labor in the pharmaceutical industry due to demand and supply imbalance which has led to an increase in wage rate and so is the cost of labor.

5. **Intellectual Property:** Intellectual property is another major issue the Indian pharma industry is facing. India accepted the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995. India made a policy reform of the Patent (Amendment) Act 2005 to make it accordance with the TRIPS policy. India has been currently facing continuous amendment in patents which is a problem for the enforcement of legal system which is too overburdened for the improvement. Various committees are suggesting government to improve its policy on intellectual property that it should focus on pro-patent policy and data protection (The Satwant Reddy Committee), patenting for incremental innovation, drugs at affordable price and prevention of frivolous patents and evergreening patents (The Mashelkar Report). PwC 2010

Conclusion

This research based case study looked at answers to research questions, which is eloquently addressed, based on theoretical review complemented with empirical data analysis. On one hand, it confirms the pro-innovation policy by the government that is increasingly focused on pharmaceutical export output, market position both at domestic and international market, revolutionary growth of industry from mere US$ 0.3 billion turnover in 1980 to about US$ 21.73 billion in 2009-10. Moreover, the increasing investment of R & D both by public and private collaboration and set up of CGMP (Current Goods Manufacturing Practices) as well as progressive standardization of manufacturing plants and international recognition such as US FDA approved manufacturing plants are sign of rapid progress of innovation in the pharmaceutical industry.

On the other hand, fiscal incentives such as tax subsidy, capital subsidy, facilitation both outward and inward FDI into the pharma industry, initiation of Export Promotion Capital Goods (EPCG) Scheme and allotment into the Special Economic Zone (SEZ) and setting up the Pharmaceutical Export Promotion Council of India (Pharmexcil) has boosted the pharma industry into multifold growth and is one of the most innovative industries of the country. Though domestic firms are dominating the Indian market and are continuously increasing exports, but the major challenges the Industry is facing are the difficult paths to go through. Without government measure, these challenges will be the

major barriers to the growth of the Indian pharmaceutical Industry.

In the end, it is vital to mention here that pharmaceutical industry is reliant on multidisciplinary factors and government is one of the most important factors that coordinate, collaborate, facilitate and implement policy that shapes both the industry and its innovation activities.

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