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Reality and the Impact of the Government Policy towards Entertaining the Pharmaceutical Sector through Foreign Direct Investments In India

KEYWORDS Pharmaceutical sectors growth, Government initiative, Vision 2020.

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ABSTRACT The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, as per a report by Equity Master. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume. Of late, consolidation has become an important characteristic of the Indian pharmaceutical market as the industry is highly fragmented. India enjoys an important position in the global pharmaceuticals sector. The country also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level. Presently, over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome) are supplied by Indian pharmaceutical firms. The Indian pharmaceutical industry is one of the most attractive investment destinations in the world. With ever increasing returns, lowering risks and anticipated multifold growth, investors are more interested in this industry than ever before. Since 2000, the drugs and pharma sector has attracted one of the highest foreign direct investment (FDI) inflows of approximately $12,689 million (April 2000 to September 2014). In current scenario our government should take initiative decisions of increasing the more investments from other host countries. Following in the Indian policy maximum counties come and invest the Indian firm.

Foreign Direct Investments in India

FDI is one of the most interesting topics in the area of international business and trade. FDI assumes a lot of importance because it can influence many micro and macro economic variables of a host country. It has its impact on employment, exports, imports, prices, BOPs economic growth, competition, production investment etc. FDI represent one of the most important instrument through which a national economy can encourage production, know-how imports, increase in employment, infrastructure development, poverty reduction etc. the benefits achieved through the increase in FDIs have created strong competition in the global market free capital, all with the aim to attract as many and as diverse FDIs as possible.

The general trend in the global FDI market is the erasure of geographic borders between developing countries and developed ones as in the past years, developing countries have not only represented a growing FDI market, but have also been aimed at attracting capital intensive investments as well as R&D investments. FDI is now widely perceived as an important resource for expediting the industrial development of developing countries, especially India because of the fact that it flows as a bundle of capital, technology, skills and sometimes even market access. Therefore, most of the developing countries offer a welcoming attitude to MNCs that are usually associated with FDI.

India's case is a typical in this context because after following a somewhat restrictive policy towards international investment, India liberalized her FDI policy regime considerably since 1991. And this liberalization has been accompanied by changes in the sectoral composition, entry modes and sources. Although, conflicting view have been expressed by proponents and opponents of FDI with regard to attracting FDI. But, as a matter of fact, FDI is considered the boom of the globalization. In the present era of LPG, no individual country can conceive the Idea of all-round development without the judicious mix of foreign capital particularly FDI.

Market Size

The Indian pharma industry, which is expected to grow over 15 per cent per annum between 2015 and 2020, will outperform the global pharma industry, which is set to grow at an annual rate of 5 per cent between the same periods. The market is expected to grow to US$ 55 billion by 2020, thereby emerging as the sixth largest pharmaceutical market globally by absolute size, as stated by Mr. Arun Singh, Indian Ambassador to the US. Branded generics dominate the pharmaceuticals market, constituting nearly 80 per cent of the market share (in terms of revenues). India has also maintained its lead over China in pharmaceutical exports with a year-on-year growth of 11.44 per cent to US$ 12.91 billion in FY 2015-16, according to data from the Ministry of Commerce and Industry. Imports of pharmaceutical products rose marginally by 0.80 per cent year-on-year to US$ 1,641.15 million.

Overall drug approvals given by the US Food and Drug Administration (USFDA) two Indian companies have nearly doubled to 201 in FY 2015-16 from 109 in FY 2014-15. The country accounts for around 30 per cent (by volume) and about 10 per cent (value) in the US$ 70-80 billion US generics market. India's biotechnology industry comprising bio-pharmaceuticals, bio-services, bio-agriculture, bio-industry and Bioinformatics is expected to grow at an average growth rate of around 30 per cent a year and reach US$ 100 billion by 2025. Bio-pharma, comprising vaccines, therapeutics and diagnostics, is the largest sub-sector contributing nearly 62 per cent of the total revenues at Rs 12,600 crore (US$ 1.88 billion).

Government Initiatives

The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments. Further, the government introduced mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to deal with the issue of affordability and availability of medicines.

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Mr.Ananth Kumar, Union Minister of Chemicals and Petrochemicals, has announced setting up of chemical hubs across the country, early environment clearances in existing clusters, adequate infrastructure, and establishment of a Central Institute of Chemical Engineering and Technology.

Some of the major initiatives taken by the government to promote the pharmaceutical sector in India are as follows:
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The Government of India plans to set up around eight mini drug-testing laboratories across major ports and airports in the country, which is expected to improve the drug regulatory system and infrastructure facilities by monitoring the standards of imported and exported drugs and reduce the overall time spent on quality assessment.

- India is expected to rank among the top five global pharmaceutical innovation hubs by 2020, based on Government of India's decision to allow 50 per cent public funding in the pharmaceuticals sector through its Public Private Partnership (PPP) model.

- Indian Pharmaceutical Association (IPA), the professional association of pharmaceutical companies in India, plans to prepare data integrity guidelines which will help to measure and benchmark the quality of Indian companies with global peers.

- The Government of India plans to incentivize bulk drug manufacturers, including both state-run and private companies, to encourage 'Make in India' program and reduce dependence on imports of Active Pharmaceutical Ingredients (API), nearly 85 per cent of which come from China.

- The Department of Pharmaceuticals has set up an inter-ministerial co-ordination committee, which would periodically review, coordinate and facilitate the resolution of the issues and constraints faced by the Indian pharmaceutical companies.

Share of top five countries attracting FDI equity inflows for drugs & Pharmaceuticals
(From January, 2000 to December, 2014)

Ranks	Country	Amount of FDI equity inflows		%age with total FDI inflows for Drugs & Pharma ceuticals
	Japan	**Rs.Crore**	**US$ Million**	
1.	United Kingdom	21,697.40	4,402.38	34.25
2.		18,217.64	3,764.60	29.29
3.	Singapore	11,096.65	2,102.38	16.36
4.	Mauritius	5,578.51	1,182.60	9.20
5.	U.S.A	1,444.16	309.01	2.40
Total		**58,034.36**	**11,760.97**	**91.5**

Source : Department of Industrial Promotion Policy

Share of top five RBI's regions-wise (with states covered) FDI equity inflows for drugs & Pharmaceuticals
(From January, 2000 to December, 2014)

Ranks	RBI's Regional Office	States Covered	Amount of FDI equity inflows		%age with total FDI inflows for Drugs & Pharmaceuticals
			Rs.Crore	US$ million	
1.	Mumbai	Maharashtra, Dadra & Nagar Haveli, Daman & Diu	21,130.97	4,346.90	33.82
2.	Chennai	Tamil Nadu, Pondicherry	4,546.73	903.33	7.03
3.	Hyderabad	Andhra Pradesh	2,680.70	550.68	4.28
4.	Bangalore	Karnataka	1,781.21	356.20	2.77
5.	Ahmedabad	Gujarat	1,793.13	302.20	2.35
Total			**31,932.74**	**6,459.31**	**50.25**

Source: Department of Industrial Promotion Policy

Customs duty increase
During January of this year 2016, the Government increased customs duty on medical devices from 5% to 7.5% and also 4% Special Additional duty. During the first week of February 2016 the Government has withdrawn customs duty waiver from 76 drugs. This will increase the cost of the pharma products by which the ultimate consumers will be affected. The Government is to look into this matter and reduce the burden imposed on the industry and also on the consumers.

Overview of pharmaceutical sector
Third largest pharmaceuticals market by 2020 in terms of incremental growth 20% of global exports in generics, making it the largest provider of generic medicines globally. USD 45 Billion in revenue by 2020, revenue of USD 55 billion by 2020 a base case, and can grow to USD 70 billion in an aggressive case scenario. USD 26.1 Billion in generics from 2016 USD 200 Billion to be spent on infrastructure by 2024. India's filing of Drug Master Files's (DMF's) with USFDA as of Dec 2013 is 3411, the highest filed by any country in the world. Total exports of Drugs, Pharmaceuticals for 2013-14 at USD 15,095 million, recording a growth rate 2.5% over the corresponding period of previous years.

Reasons to Invest
India is expected to rank amongst the top three pharmaceutical markets in terms of incremental growth by 2020. Will become the sixth largest market globally in terms of absolute size by zero. India's generic drugs account for 20% of global exports in terms of volume, making the country the largest provider of generic medicines globally. India's cost of production is significantly lower than that of the USA and almost half of that of Europe. A skilled workforce as well as high managerial and technical competence. Economic prosperity is likely to improve affordability for generic drugs in the market. Approval time for

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new facilities has been drastically reduced.

Statistical Notes

The country's pharmaceutical industry is expected to account for about 3.1-3.6% of the global pharma industry by value and currently accounts for 10% by volume, by 2016. Industry revenues are expected to expand at a CAGR of 12.1% during 2012-20 and reach USD 45 Billion. The healthcare sector in India is expected to grow to USD 250 Billion by 2020 from USD 65 Billion currently. The generics market is expected to grow to USD 26.1 Billion by 2016 from USD 11.3 Billion in 2011.

Growth Drivers

The Indian pharmaceuticals sector growth drivers between 2011 and 2016, patent drugs worth USD 255 Billion are estimated to go off-patent leading to a huge surge in generic product and tremendous opportunities for companies. By 2020, it will grow to USD 11 billion - a CAGR of 18%, with the potential to reach USD 13 billion - at an aggressive CAGR of 20%. With increasing penetration of chemists, especially in rural India, OTC drugs will be readily available. Pharma companies have increased spending to tap rural markets and develop better infrastructure. The market share of hospitals is expected to increase from 13.1% in 2009 to 26% in 2020. Following the introduction of product patents, several multinational companies are expected to launch patented drugs in India. The purported rise of lifestyle diseases in India is expected to boost industry sales figures. Over USD 200 Billion is to be spent on medical infrastructure in the next decade. Rising levels of education are set to increase the acceptability of pharmaceuticals. India's patient pool is expected to increase to over 20% in the next 10 years, mainly due to the rise in population.

FDI Policy for Pharmaceutical Sector

Foreign Direct Investment (FDI) 100% is allowed pharmaceutical sector under the automatic route for greenfield pharma. 100% Foreign Direct Investment (FDI) is allowed under the government route for Brownfield pharma in up to 74% FDI is under the automatic route and beyond 74% is under the government approval route. Other conditions: 'Non-compete' clause would not be allowed except in special circumstances with the approval of the Foreign Investment Promotion Board. The prospective investor and the prospective investors are required to provide a certificate along with the FIPB application as per Annexure-1. Government may incorporate appropriate conditions for FDI in Brownfield cases, at the time of granting approval.

R&D Benefits

Industry/private sponsored research programmes:

A weighted tax deduction is given under section 35 (2AA) of the Income Tax Act. A weighted deduction of 200% is granted to assess for any sum paid to a national laboratory, university or institute of technology, or specified persons with a specific direction provided that the said sum is used for scientific research within a program approved by the prescribed authority.

Companies engaged in manufacture having an in-house R&D center:

A Weighted tax deduction of 200% under section 35 (2AB) of the Income Tax Act for both capital and revenue expenditure incurred on scientific research and development. Expenditure on land and buildings are not eligible for deduction.A national center to help develop bulk drugs and facilitate their research is being set up in Hyderabad. Duty free import of Pharmaceuticals reference standards.

Investment Opportunities

India is expected to be the third largest global market for active pharmaceutical ingredients by 2016, with a 7.2% increase in market share. Indian pharma companies registered 49% of overall DMF filed in the US in 2012. The Contract Research and Manufacturing Services industry – estimated at USD 8 Billion in 2015, up from USD 3.8 Billion in 2012. The market has more than 1000 players. The formulations industry – India is the largest exporter of formulations with 14% market share and ranks 12th in the world in terms of export value. Double-digit growth is expected over the next five years.

Road Ahead

The Indian pharmaceutical market size is expected to grow to US$ 100 billion by 2025, driven by increasing consumer spending, rapid urbanization, and raising healthcare insurance among others. Going forward, better growth in domestic sales would also depend on the ability of companies to align their product portfolio towards chronic therapies for diseases such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers that are on the rise.

The Indian government has taken many steps to reduce costs and bring down healthcare expenses. Speedy introduction of generic drugs into the market has remained in focus and is expected to benefit the Indian pharmaceutical companies. In addition, the thrust on rural health programmes, life saving drugs and preventive vaccines also augurs well for the pharmaceutical companies.

Future Perspective

The pharmaceutical industry will have a future in India as well as globally. The future perspective of this industry is based on the high burden of disease, good increase in higher disposable incomes of the individuals, improvements in healthcare infrastructure and improved health care financing. The Indian pharma industry has been growing at a compounded annual growth rate (CAGR) of more than 15% over the last five years.

The industry has significant growth opportunities. The pharma companies in India will have to rethink their business strategy to sustain the robust growth till the year 2020. The companies are to adopt new business models and think of innovative ideas to the best satisfaction of the consumers.

The Pharma companies in India may continue to grow organically and inorganically through alliances and partnerships. They have to focus on improving operational efficiency and productivity continuously. The developments in the health insurance, medical technology and mobile telephony can help the growth of the pharma industry by removing financial and physical barriers to health care access in India.

Conclusion

The pharma market is expected to touch US$74 billion in sales by 2020 from the current US$11billion. According to Barclays Capital Equity Research report on India Healthcare & Pharmaceuticals, the Indian Pharmaceutical market is expected to grow at a Compound Annual Growth Rate of 15.3 per cent during 2011-12 to 2013-14. Although India has substantially liberalized foreign investment policy, the foreign direct investment inflows had been much below the targets until recently. Market leaders in pharma industry should raise their expenditure towards Research & Development. Academic collaboration would help the pharma industry with regard to

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Drug development. India is the third largest manufacturer of pharmaceutical products in terms of volume and it's growing steadily. The market has seen the entry of many foreign players as well as rise of many domestic manufacturers. After the formation of the new Government under Mr.Narendra Modi, the sector has been given a major boost. The Government is trying to implement policies like 'Make in India' and 'Swach Bharat Abhiyaan'. So with plans to make India a superpower and improve the market, the Government is on the right track.

- Compliance issues and good manufacturing practices
- Highly fragmented industry
- Low margin of profits due to government pricing policies – Drug Price Control Order
- Low input for research and development due to pricing norms
- Stronger IP regulations

References:

1. Gupta, M.S. (2004), “Foreign direct investment in India: Trend and policies”, Bihar Economic Journal.
2. Mishra.S.K and V.K Puri “Indian Economy”. Himalayan Publishing house, Mumbai.2008.p, 510.
3. Mahajan V.S. “Economic reforms and liberalization” Deep and Deep publications pvt.ltd New Delhi.
4. Prajnan (2008), “Journal of social and management sciences” vol. xxxvii no.2 July Sep 2008.
5. CMIE (2010), Monthly Review of Indian Economy, Economic Intelligence Service, July 2010, p. 7.
6. Agarwal J, Khan MA (2011) Impact of FDI on GDP: A comparative study of China and India, Int. J. Business Management 6(10):71-79.
7. Kumar Gajendran Lenin, Karthika S (2010) Sectoral performance through inflows of foreign direct investment (FDI).
8. Singh, S (2009) Foreign direct investment (fdi) and growth of states of india. VISION 2020 - Managerial Strategies and Challenge, Wisdom Publications, Delhi.
9. Devajit Mahanta, (2012) Impact of foreign direct investments on indian economy, Research J. Management Sciences, 1(2):29-31.
10. Sharma RK (2006) FDI in Higher Education: Official Vision Needs Corrections, Economic and Political Weekly, pp. 5036.
11. Balasubramanyam VN, Sapsford David (2007) Does India need a lot more FDI, Economic and Political Weekly, pp.1549-55.
12. Bajpai Nirupam, Jeffrey D Sachs (2006) Foreign Direct Investment in India: Issues and Problems, Harvard Institute of International Development, Development Discussion Paper No. 759.
13. IBEF (2010).”Pharmaceuticals”, Indian Brand Equity Foundation. www.ibef.org (April).
14. ICRA Ltd. (2004).”Industry Watch: The Indian Pharmaceutical Industry”, Information and credit Rating Agency, New Delhi.
15. Iyer, Parvathi. K. (2008). “Structure and Performance of Small and Medium Scale Pharmaceutical Firms”, S&T and Industry, India, Science and Technology:11
16. Jha, Ravinder (2007). “Options for Indian Pharmaceutical Industry in the Changing Environment”, Economic and Political Weekly, Sameeksha Trust Publication, Mumbai, XLII (39): 3958-3967 (Mumbai).
17. Markusen, JR and AJ Venables (1997). “Foreign Direct Investment as a Catalyst for Industrial Development”, National Bureau of Economic Research, 1050 Massachusetts Avenue, Cambridge.
18. National Pharmaceutical Policy (2006), Department of Chemical and Petrochemicals, Government of India, 2005, Part A (28th December).
19. Pharmaceutical Policy (2002), Government of India, New Delhi.
20. Pharmaxil (2009), 6th Annual Report, 2009-10: 8

Web sites:

1. http://www.economywatch/fdi
2. http://www.imf.com
3. http://www.indiastat.com
4. http://www.isid.com
5. http://www.rbi.co.in
6. http://www.proquest.uni.com.
7. http://www.ssrn.co.in
8. http://www.tradechakra.com/india