



# “RADICAL CHANGE IN FDI POLICY REGIME IN THE PHARMACEUTICAL SECTOR”

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**Abstract:** Foreign Direct Investment (FDI) is a cross-border investment that has been an integral part of economic development strategies of India. The Indian Pharmaceutical Industry witnessed higher levels of FDI in past years. India is a prominent and rapidly growing presence in global pharmaceuticals. It is the largest provider of generic medicines globally. With a highly skilled workforce, technological advancements, and sales affected by the pandemic normalizing, the pharma sector is expected to do well in 2022, predicted to grow by about 11 % over the next two years. The Indian pharmaceutical industry has developed through a range of government incentives and foreign firms that have invested in the industry have additionally contributed to the growth - factors such as market structure, competitiveness, trade, and technological policies. National Pharmaceutical Pricing Policy has been framed to control prices and marketing pricing.

**Keywords:** Foreign Direct Investment, Pharmaceutical Sector

## I. INTRODUCTION

India is recognized as a global hub for cost-effective generic medicines, which is vital in protecting the right to health in developing and underdeveloped countries. FDI is necessary to bring newer and safer technology to India. However, present policies on FDI in India need a relook. The government in India should also make sure that excessive foreign investment does not hamper the local business and companies (especially ones involved in Generic medicine), the market, and the pricing of medicines in India. The pharmaceutical industry, in India, plays a very crucial role in implementing the welfare state of the people. The government has remained active in formulating policies to ensure the overall growth of the industry. From 2001 onwards 100% FDI in the pharmaceutical Industry has been allowed. This has benefitted the pharma sector. From 2006-10, as many as 6 top Indian Companies have been acquired by the MNCs. This has not resulted in a price rise or a limited supply of generic goods. India is a huge potential market for MNCs with a competent and cheap workforce. The Central Government has notified that in cases of Brownfield investments in the pharmaceutical sector, FDI will be allowed through the FIPB approval path for a period of up to six months. To make the pharmaceuticals sector more attractive to foreign investors, FDI up to 100%, under the automatic route, has been permitted in brownfield pharmaceutical projects. FDI beyond the threshold of 74% is allowed through the government approval route. Since the liberalization of FDI policies started in the early 1990s. Foreign direct investment (FDI) is a direct investment into production in a country by a company located in another country, either by buying a company in the target country or by expanding the operations of an existing business in that country. Foreign direct investment is done for many reasons including to take advantage of cheaper wages in the country, and special investment privileges such as tax exemptions offered by the country as an incentive to gain tariff-free access to the markets of the country or the region. Foreign direct investment is in contrast to portfolio investment which is a passive investment in the securities of another country such as stocks and bonds. India is today recognized as one of the leading global players in pharmaceuticals. Europe accounts for the highest share of over 23% of Indian Pharma exports followed by North America and Asia.

Exports to the USA have crossed the landmark figure of US \$1 billion during 2006-07. The Indian pharmaceutical industry ranks among the top five countries by volume (production) and accounts for about 10% of global production. The top five export destinations of Indian pharmaceutical products are the USA, Germany, Russia, UK, and China. Generally, FDI is of three kinds: Brownfield investment, in which a company purchased an existing company or firm in a new country, Greenfield investment, in a company established a new company or firm in a new country the third type is Joint Venture, which means that in a host market there is the establishment of management and equity partnership between a domestic entity and a foreign company. According to Equity master, the Indian Pharmaceutical sector is in 3rd rank (10%) in terms of volume and 13th (2.4%) in terms of value globally. India's export in pharmaceutical export grew by 11.9% worth 16.89 billion USD and the USA is the largest exporter to India in this sector. Revenue from the Indian pharmaceutical market witnessed USD 36.7 billion in 2016. Pharmaceutical market advantages India due to various reasons such as low cost of production, low cost of treatment, increasing penetration of health insurance, over 10% of global pharmaceutical production, reduced approval time for new facilities to boost investments, and Pharma Vision 2020. The Indian Government unveiled 'Pharma Vision 2020' to make India a top leader in the pharmaceutical sector worldwide.

### **Foreign Direct Investment Policy (FDI)**

On 28th August 2017, the Government of India through DIPP i.e., the Department of Industrial Policy and Promotion issued a consolidated and updated FDI policy that is transparent, easily comprehensible, and predictable. FDI is prohibited in some sectors which are the lottery business, Nidhi company, gambling and betting, chit funds, trading in transferable development rights, manufacturing of cigarettes, tobacco, or cigars, real estate business, and sectors not open to private investment. In the pharmaceutical sector, conditions that are imposed by a government through the approval process will continue to apply to all Brownfield investment proposals. If prior government approval is obtained for foreign investment in a wholly owned subsidiary, then prior approval for further investment is not required provided that the aggregate investment is not more than Rs. 5000 crores and if it is more than the provided amount then the prior approval is required. Under this policy, if the investment is coming from the country of concern through an automatic route, then prior approval is required and the application would be processed by DIPP for government approval. Under the government approval route also security clearance is required concerning the country of concern.

### **Advantages Of FDI**

- FDI helps a country to be more economically developed in a global market.
- It increases competition among firms in a domestic country which results in the availability of cheap drugs and medicines and reduces the number of inefficient firms.
- It increases employment or creates jobs, and new posts.
- It helps a country to access the international market.
- It helps in raising the level of quality and standards of the product by increasing competition.
- It helps in the availability of advanced technology and skilled manpower.

### **Disadvantages of FDI**

- It would increase inflation as a result of foreign influence which means huge spending on advertisements to attract customers.
- It helps in the increasing competition which results in the destruction of small firms or domination over small firms by large firms which will hamper the growth of the country, especially developing countries.
- It would affect the selling and cost of production of domestic firms.
- It helps in maintaining the relationship between foreign and domestic firms.

### **Strategies to gain maximum benefits from FDI**

The development of advanced technology and high-quality products by domestic firms has made India a preferred destination to attract FDI. There is a need to regulate FDI in a manner so that we can get the maximum benefit from FDI. There are some suggestions to achieve these goals:

- The policy of FDI should be made in terms of Indian conditions and there should be a balance between the medical needs of our society and the FDI policies.
- FDI policies should be such that technology and skilled manpower would increase to improve the research and development capabilities of a firm.
- Medicinal or drug pricing should be compatible with the FDI policy. So that maximum people can fulfill their needs by availing benefits of cost-effective medicines.
- Expenditure on healthcare should be increased to improve healthcare infrastructure.

### Major challenges faced by the industry

The industry faces several challenges in the form of pricing pharmaceutical products and the impact of some agreements. This section touches upon several key issues and challenges faced by the industry.

### Factors Influencing Industry's Growth

The Indian pharmaceutical industry ranks 14th in the world by value of pharmaceutical products. With a well-established domestic manufacturing base and low-cost skilled manpower, India is emerging as a global hub for pharma products, and the industry continues to grow. Moreover, India is significantly ahead in providing chemistry services such as analog preparation, analytical chemistry, and structural drug design, which will provide it ample scope in contract research and other emerging segments in the pharmaceutical industry. Some of the significant factors that would drive growth in the industry are as follows:

- Increase in domestic demand
- The rise in outsourcing activities
- Growth in healthcare financing products
- Demand from emerging segments
- Demand in the generics market

### FDI Investment Routes

Foreign Direct Investment (FDI) can be made through two routes that are:

1. **Automatic Route:** Indian companies engaged in various industries can issue shares to foreign investors up to 100% of their paid-up capital in Indian companies
2. **Government Approval Route:** Certain activities that are not covered under the automatic route require prior Government approval for FDIs.
  - Category 1- Sectors in which FDI is permitted up to 100% under automatic route
  - Category 2- Sectors in which FDI is permitted up to 100% under Government Route
  - Category 3- Sectors in which FDI is permitted beyond a certain limit with the Government
  - Category 4- Sectors where FDI is permitted up to a certain limit under both Government and Automatic routes subject to applicable laws/ regulations security and other conditionalities

## II. REVIEW OF LITERATURE

**Tamma Koti Reddy (2013)** Studied Foreign Direct Investments in Indian Pharmaceutical Industry they stated that, Although India has substantially liberalized its foreign investment policy, the foreign direct investment inflows had been much below the targets until recently. Market leaders in the pharma industry should raise their expenditure on Research & Development. Academic collaboration would help the pharma industry with Drug development.

**Dr. Vikarant sopan Yadav (2001)** studies an analytical study of foreign direct investment in the pharma sector of India. However, present policies on FDI in India need a relook. The government in India should also make sure that excessive foreign investment does not hamper the local business and companies (especially ones involved in Generic medicine), the market, and the pricing of medicines in India. The startup policies of the current NDA government, Pharma Vision 2020, and its proper implementation are important in this regard.

**Harshvardhan Jain & Mayank Rautela (2018)** Research on FDI in Indian Pharmaceutical Sector. But policy should be such to minimize or even remove all objections or disadvantages from FDI inflows into a country. It is also needed because 100% FDI is allowed in this sector which “poses a direct threat to the entire health and IPR framework of our country in terms of access and affordability of medicines, domination and elbowing out of our pharmaceutical industry, undue demand and pressure on TRIPS arrangements”<sup>17</sup> as per parliament committee report.

### III. RESEARCH METHODOLOGY

#### Source/s of Data

The secondary source we collect data from is Internet searches or libraries, for extensive research surveys, various published sources like printed books, online journals, research thesis, dissertations, and various online websites were used like RBI, Make in India, Pharma industry, etc.

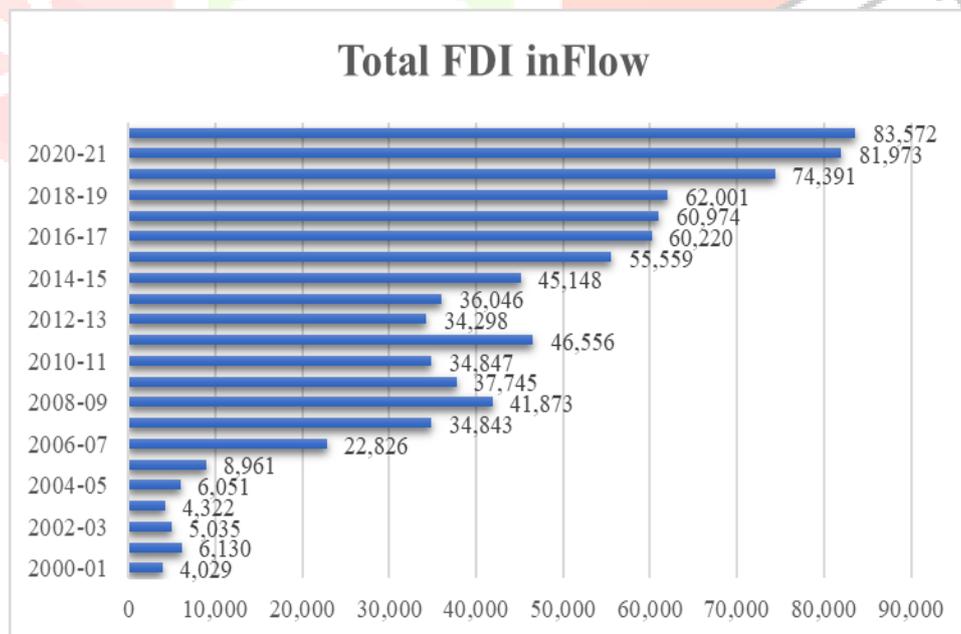
#### Data Collection Method

Existing data Research Journals – like Economic times, Business Standard, Financial Chronicle, Financial Express newspapers, Outlook Money, Money Today, and Wealth Insight magazines, research journals are intended for an academic or technical audience, not general readers. A journal is a scholarly publication containing articles written by researchers, professors, and other experts.

### IV. DATA ANALYSIS AND INTERPRETATION

The pharmaceutical industry is currently valued at \$41.7 bn and is expected to reach \$65bn by 2024 and \$120 bn by 2030. India's pharmaceutical exports stood at \$24.44 bn in FY 20-21. The Pharmaceutical industry in India accounts for about 2.4% of the global pharmaceutical industry in value terms. Generic drugs with a 70% market share form the largest segment of the pharmaceutical industry in India. In the domestic market by revenue, Anti-Infectives (13.6%), Cardiac (12.4%), and Gastrointestinal (11.5%) had the most significant market share.

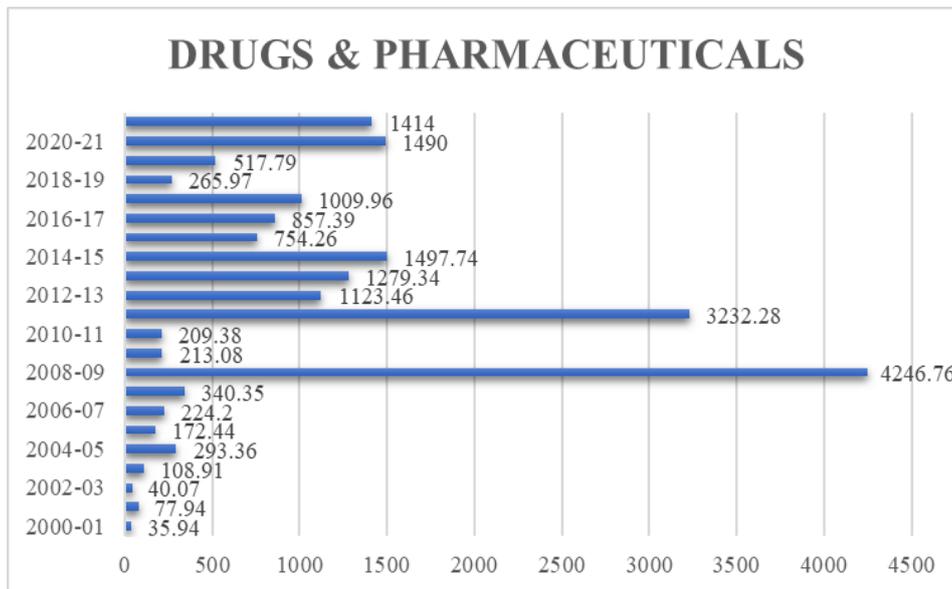
**Graph 1.1 FDI YEARLY DATA**



Source: <https://dpiit.gov.in>

FDI policy is an enabling policy that is uniformly applicable in the country. The government has put in place of liberal and transparent policy for FDI. Most of the sectors are open to FDI under an automatic route. The government reviews the FDI policy and makes changes from time to time and India remains an attractive and investor-friendly destination. FDI inflow has increased year by year. From 2005-06, India attracted a greater number of investors from various countries. The data also says that India is favored for doing business compared to other countries.

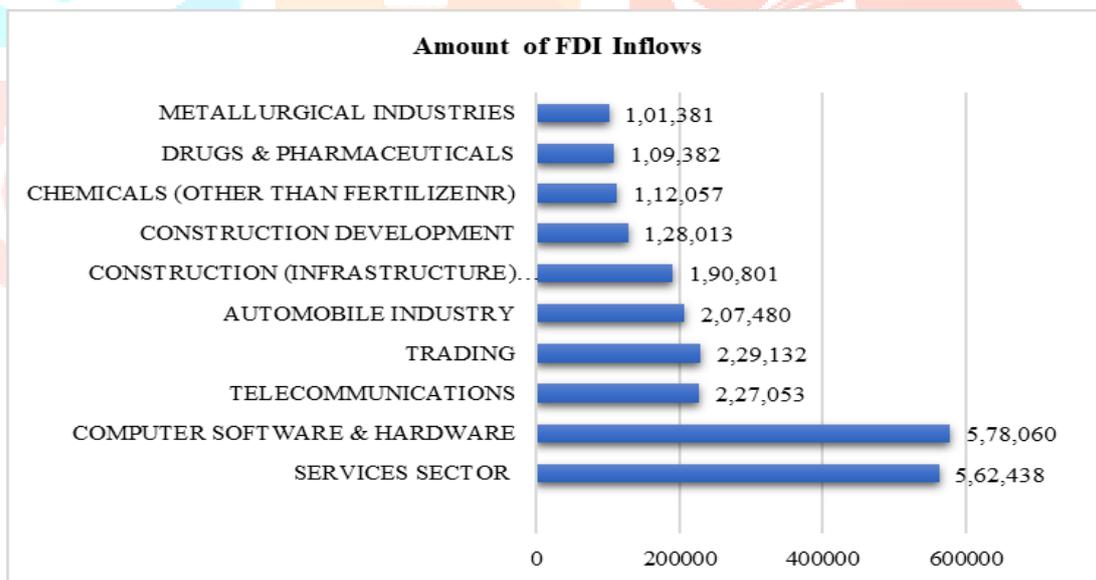
**Graph 1.2 PHARMACEUTICAL SECTOR**



Source: <https://dpiit.gov.in>

The pharmaceutical sector grew in 2008-09 many companies started investing in the pharmaceutical sector. Due to the lack of medical products many companies start investing in Indian pharma they came with innovation. Again, after COVID-19, many started investing in India, which effects a rise in FDI inflow into India in the pharmaceutical sector.

**Graph 1.3 SECTOR-WISE FDI EQUITY INFLOWS FROM APRIL 2000 TO MARCH 2022**



Source: <https://dpiit.gov.in>

The make in India initiative has been received and now focusing on the 27 sectors under make in India 2.0. The Department of promotion and trading industry is coordinating the 15 manufacturing sectors. India is emerging in the manufacturing sector. And the Department of Commerce is coordinating 12 service sectors.

## Graph 1.4 TOP 10 LISTED PHARMACEUTICAL COMPANIES IN INDIA BY MARKET CAPITALIZATION AS OF SEPTEMBER 2022



Source: <https://www.moneyworks4me.com>

Presently India is the largest provider of generic medicine occupying a market share of 20 percent concerning global supply by volume and fulfilling nearly 60 percent of the global demand for vaccines. Nearly, 80 percent of the Indian pharmaceutical companies are even supplying antiretroviral drugs in the international markets (Used in computing AIDS).

### V. FINDINGS

- Increasing competition in the pharmaceutical sector also attracts foreign investors. Increase in healthcare
- Spending such as Healthcare insurance policies, and life insurance policies result in growth in the pharmaceutical industry which attracts investment.
- Medical Tourism, pharma packaging, biopharma, and bio-generics are some of the emerging segments
- This may increase the growth of the pharmaceutical industry.
- The production cost of pharmaceuticals is also cheap in India.
- As a result of a large population, wide disease patterns attract pharmaceutical firms.

### VI. CONCLUSION

The Indian Pharmaceutical Industry has shown great potential and continues to grow consistently. Though, since health is an important subject, the industry continues to be regulated. However, the Indian generic drug sector is robust and is establishing its presence in foreign markets. The pharmaceutical sector is a growing and important sector in India which is for the welfare of the public. People from the country depend on this industry for their basic needs. As we discussed the merits and demerits of FDI in this sector, it is established that adequate FDI is the need of the country and it will be very helpful in making a country more efficient and developed. It helps in the growth of this sector by promoting public-private partnerships for the development of this industry, promotion of Pharma Brand India, environmentally sustainable development of this industry, enabling availability of drugs at an affordable price, and development of human resources.

### Reference

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2. <https://www.moneyworks4me.com>
3. <https://dpiit.gov.in>