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Master's Degree in Engineering and Management

DEPARTMENT OF MANAGEMENT AND PRODUCTION ENGINEERING

Thesis

Impact of FDI on Economic development of India (Pharmaceutical Sector) and difficulties faced during Pandemic

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I would like to express my sincere gratitude to my supervisor Prof.ssa Anna D'Ambrosio, who made this work possible. She has always given me the freedom to explore my own ideas for work while directing me in the appropriate route when necessary. Her guidance and advice have carried me through all stages of drafting this thesis. I would also like to thank my friends and family for their constant support and encouragement throughout my master's studies.

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Abbreviations:

FDI	Foreign Direct Investment
TNCs	Transnational Corporations
MNC's	Multi-National Companies
RBI	Reserve Bank of India
MoHFW	Ministry of Health, and Family Welfare
PMBJP	Pradhan Mantri Bhartiya Janaushadhi Pariyojana for Affordable Medicines
PPP	Pharmaceuticals Purchase Policy
EoDB	Ease of Doing Business
UNCTAD	United Nations Conference on Trade and Development
IBEF	India Brand Equity Foundation
TNC's	Transnational Corporations (TNCs)
FTZ's	Free Trade Zones
FERA	Foreign Exchange Regulation Act
OGL	Open general license
M&A	Mergers and acquisitions
FIPB	Foreign Investment Promotion Board
TRIP's	Agreement on Trade-Related Aspects of Intellectual Property Rights
DIPP	Department of Industrial Policy & Promotion
CRAMS	Contract research and manufacturing services
GDP	Gross domestic product
FDA	Food and Drug Administration
QRM	Quantitative Risk Management
WHO	World Health Organization
USFDA	United States Food and Drug

	Administration
CGMP	Current Good Manufacturing Practice
GDUFA	Generic Drug User Fee Act
IPR	Intellectual property rights
SME	Small and medium enterprises
EUL	Emergency use listing
AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy
WTO	World Trade Organization
IMF	International Monetary Fund
PMGKY	Pradhan Mantri Garib Kalyan anna Yojana
CLs	Compulsory licenses
CAGR	Compound annual growth rate
PTO	Patent & Trademark Organization
MOSPI	Ministry of Statistics and Program Implementation
SII	Serum Institute of India
RIDF	Rural Infrastructure Development Fund
FTA	Free Trade Agreement
PPP	Public-private partnership
CRO	Contract research organization
PLI	Production Linked Incentive Scheme

Abstract

The Indian pharmaceutical business has been seeing tremendous expansion in recent years, driven by increased domestic consumption and strong demand from export markets. The sector has made great progress in terms of infrastructure development, technical basis, and product variety. Because of Indian pharmaceutical companies' capacity to create cost-effective pharmaceuticals, demand from the export market has been constantly increasing.

The goal of this study is to examine the before and aftereffects of FDI in pharmaceuticals on Indian economy. Whether Indian pharma need Foreign Direct Investments for its global developments and influence of foreign direct investment on India's pharmaceutical industry. Evidence collected from **Invest India** (National Investment Promotion and Facilitation Agency) and **IBEF** (India Brand equity foundation) are presented that justifies the impact of FDI on Indian pharma growth. Following that, the challenges encountered by the pharmaceutical industry during the Pandemic are highlighted. The difficulties involved in the manufacture and distribution of medicines and other requirements. This review focuses on the Indian pharmaceutical industry's response to the epidemic and at the economic impact of COVID-19 across segments and what it means for the Indian economy.

This thesis is structured around the world pharma market and the competitive environment we see, India’s Pharma market, its exports and Key players, Economic attractiveness of the pharma market in India. It also offers an overview of the synergy that may be produced because of India's low-cost labor maximizing returns and its fast-growing economy allowing the expansion of the pharma industry.

1.INTRODUCTION TO THESIS

1.1 Introduction

The Indian pharmaceutical business has been seeing tremendous expansion in recent years, driven by increased domestic consumption and Export markets are in high demand. In terms of infrastructural development, technical foundation, and product diversity, the industry has achieved considerable progress. Demand from the export market has been steadily growing due to Indian pharmaceutical companies' ability to provide cost-effective drugs. Identifying novel drug research targets, obtaining regulatory clearances, and improving drug discovery and development procedures are some of the issues that the Indian pharmaceutical sector is facing today.

According to the India Brand Equity Foundation, The Indian pharmaceutical market is rated third in terms of volume and thirteenth in terms of value in the globe. Within 75 years of independence, India has built itself as a worldwide industrial and research center. The availability of raw materials and skilled labor gives the Indian Pharmaceutical Industries a competitive advantage. Furthermore, the Indian pharmaceutical industry is expanding at a 22.4 percent compound annual growth rate. The Indian pharmaceutical market is dominated by generic pharmaceuticals, which account for 70% of the market, with over-the-counter medications accounting for 21% and patented therapies accounting for 9% of the market, respectively.

While India produces over sixty thousand generic brands and generics exports are one of India's primary assets, many foreign direct investors are striving to engage in India's Medicinal and Pharmaceutical Industries. Indian Pharmaceutical Industries currently delivers 80 percent of the antiretroviral drugs required to combat AIDS throughout the world. Furthermore, under the automated procedure for green field pharma, the Government of India allows Foreign Direct Investors to make a 100 percent investment in Indian Pharmaceutical Industries.

How does permitting 100 percent investment in pharma affect/contribute to the growth of the Indian economy and how did India sustain post covid in boosting its economy?

1.2 Statement of purpose

The main reasons for me to focus on Indian Pharmaceutical Industry for this analysis is First, since the mid-1990s, in terms of manufacturing capacity, innovation, and technology adoption, the Indian pharmaceutical industry has been dramatically transformed. Secondly, The Indian government provides fiscal incentives for R&D as well as unique trade-related intellectual property rights to boost exports, which has significantly improved the efficiency of the Indian pharmaceutical sector. The Union Cabinet recently approved changes to current foreign direct investment policies in the Medical and Pharmaceutical industries, such as enabling 100 percent foreign direct investment through the automatic route for the manufacturing of medicinal products, subject to specified restrictions. According to the Department of Industrial Promotion and Internal Trade, India's pharmaceutical industry will earn $ 16.25 billion in FDI from 2000 to 2020. Recent government initiatives and financial subsidies, such as the Pradhan Mantri Bhartiya Janaushadhi Pariyojana for Affordable Medicines (PMBJP), Pharmaceuticals Purchase Policy (PPP) approval, allocation of Rs 65,012 crore (US$ 9.30 billion) to the Ministry of Health and Family Welfare in the 2020-21 budget, allocation of budget to National Health Mission, Ayushman Bharat Health Insurance Scheme, establishment of Pharma Parks, National Health Protection Scheme, and 'Pharma Vision 2020' Third, because several nations want to create a COVID-19 vaccine, India's Ministry of Health and Family Welfare (MoHFW) has offered different incentives and support to Indian pharmaceutical businesses. These incentives are intended to help this business. As a result, all these factors encourage foreign direct investment in the Indian Medicinal and Pharmaceutical Industries. These factors motive an investigation of the impact of FDI in Indian Medicinal and Pharmaceutical Industries on the Indian Economy.

1.3 Literature review

Tamma Koti Reddy (2013)'s study on Foreign Direct Investments in the Indian Pharmaceutical Industry, even though India's foreign investment policy has been greatly liberalized, foreign direct investment inflows have remained much below target till recently. Market leaders in the pharmaceutical business should increase their R&D spending. Academic partnership would benefit the pharmaceutical sector in terms of drug development.

Annika Bergman The implications of FDI and spill overs in the Indian pharmaceutical business are investigated. This paper investigates FDI and its consequences in the Indian pharmaceutical business. The horizontal productivity spill over impacts of MNCs on indigenous Indian pharmaceutical firms are explored, as are the multiple transmission mechanisms via which spillover effects might occur. The pharmaceutical business is highly technology and capital demanding, with India being one of the few emerging nations with a comparative advantage.

Dr. Gulshan Akhtar an examination of the issue and prospects for FDI inflows into the Indian pharmaceutical business, while foreign direct investment provides Host enterprises benefit from local and worldwide comparative advantages through financial and managerial resources, access to enormous markets, technological assistance, and strategic assets such as trademarks. It has been acknowledged that there is significant potential for FDI concentration in the industry, particularly in terms of export and profitability.

Dr. Nishikant C. Dhande, Prof. Anshuman Vijay Magar According to studies, the fastest, safest, and most successful manner of introducing innovative technology to India is through foreign direct investment. India is a generics hotspot that will attract substantial FDI inflows in the next years.

Ronny Thomas, K. Narayanan and Vinish Kathuria He asserted that FDI and R&D in the pharmaceutical sector in India are critical sources of fostering innovation and technological knowledge in both developed and developing countries. Furthermore, as trade liberalization and cross-border investment have increased, so has the breadth of R&D spending.

Reji K. Joseph & K.V.K. Ranganathan Foreign Investment Trends in the Indian Healthcare Sector This demonstrates that Indian hospitals and clinics have relied on private equity investors that are just interested in making quick money and have no long-term growth objectives. This has major implications for the general population in India, where government investment in healthcare is minimal and out-of-pocket healthcare spending drives millions into poverty.

1.4 Methodology

The main aim of this thesis is:

- Research the role of FDI in pharmaceutical sectors in India's development.
- Analyzing the contribution of FDI in the pharmaceutical industry to India's GDP.

- To discuss the challenges faced by pharmaceutical sector during 2019 pandemic and how did they overcome it becoming “largest vaccine producer in world.”

The following study is solely based on secondary data obtained from multiple sources, including UNCTAD, IBEF, UN COMTRADE, the Reserve Bank of India, Invest India, the Ministry of Commerce of India, and the Pharmaceutical Products Export Promotion Council of India. Pharmaceutical Products are classified into six categories in India. Such as

In this study report, all these six items are referred as Medicinal/Pharmaceutical Products. Research involves both quantitative and qualitative analysis of data gathered. Based on requirement, for comparing growth of GDP before and after entry of FDI the data has been collected from time of Independence to 2020. For rest of analysis, the study spans from 2009 to 2020. The acquired data were analyzed using statistical method such as Trend Analysis and basic statistic tools used for data comparison.

2. FDI

2.1 Role of FDI in development of a Country

Foreign direct investments (FDI) are a form of investment in which a foreign investor retains ownership, control, and management of the company in which they have invested money to accomplish long-term objectives. These investments are the most essential strategy for attracting foreign capital since they represent a direct influx of funds into the host country's economic system. Foreign direct investment (FDI), an international capital mobility, contributes greatly to more efficient economic operations. They enable faster entry into the global market and, as a result, raise societal living standards. The examination of investment efficiency serves as the foundation for making investment decisions that result in economic progress from one country to the next. Foreign investments are a crucial aspect of modern economic development, and they, along with commerce, form the most important leverage of a business, production organization, and global supply of products and services.[1] FDI assists firms in organizing global production by ensuring an efficient supply of raw materials, energy, and labor as inputs and allowing for the beneficial positioning of products and services as outcomes in the key markets. Businesses may make the maximum use of their capabilities in technology, expertise, and economies of scale based on such operations. With enormous public debt and an unfavorable economic climate, developing countries are keen to encourage as much foreign investment as possible. It has become increasingly pressing since bank loans and other types of financial aid have failed to materialize in a number of countries. Countries in transition striving to succeed in a competitive economic system may benefit from foreign capital inflows to overcome worsening economic trends.

As a result of the monetary crisis, developing countries have been interested in increased foreign currency inflows, as foreign investments are the most significant component of total development projects. Foreign direct investment (FDI) entails not only the transfer of cash from one nation to another, but also the development of modern technology, management

[1] OECD (2019). *OECD.org - OECD*. [online] Oecd.org. Available at: https://www.oecd.org.

skills, and new markets. Furthermore, FDIs are significantly enhancing profit prospects despite heightened risks.

Foreign direct investments are long-term capital flows that are motivated by economic objectives, with profit as the primary goal. When we look at today's economic systems on the global market, we can see that they compete with one another to attract foreign money and progress their economic development.

2.2 Impact of Foreign Direct Investments in particular sector

Foreign direct investment in a particular industry will have two effects on the economy. The first is the good side, while the second is the negative side. Foreign direct investment may help the target country's economy thrive, creating a better environment for you as an investor as well as benefits for the local sector. The FDI investor opens the gates to limit traffic on their merchandise. The consistency of a country's import tax is one of the key reasons why trade with it is difficult. Other sectors demand a presence in foreign markets to achieve their sales and aims. All of this will be made easier by FDI. When investors establish new businesses in the target nation, they create new job opportunities. This raises people's income and purchasing power, causing an economic boom. One important advantage of FDI is the growth of human capital resources, which is sometimes underestimated since it is not immediately obvious. Human capital is the talent and knowledge of laborers, often known as the workforce. Exchange of training and expertise would improve a country's education and total human capital. Its resource is borrowed rather than a real asset owned by firms. With this in mind, a nation that allows FDI might profit immensely from improving its human resources while also maintaining ownership.[2]

[2] Susic, I., Stojanovic-Trivanovic, M. and Susic, M. (2017). Foreign direct investments and their impact on the economic development of Bosnia and Herzegovina. *IOP Conference Series: Materials Science and Engineering*, 200, p.012019. doi:10.1088/1757-899x/200/1/012019.

In order to get extra knowledge, technology, and commodities, parent companies would also offer foreign direct investment. As a foreign investor, you may be eligible for tax breaks that may be extremely beneficial in your chosen business. Foreign direct investment will allow resource exchange and knowledge transfer, providing other nations with access to innovative technology and capabilities.

Few advantages of FDI:

1. Stimulation of Economic Development

2. International Trade.

3. Human Capital Resource Development

4. Job Creation and Economic Growth

5. Tax Incentives.

Foreign Direct Investment's Disadvantages

1.A barrier to domestic investment.

Foreign direct investment can often restrict domestic investment since it diverts resources apart from the investor's home country.

2. Political shifts are dangerous.

Foreign direct investment is especially dangerous since political developments in other nations might change overnight. The overwhelming majority of the risk variables, however, are relatively high.

3. Currency exchange rates suffer as a result.

Foreign direct investments can occasionally impact currency rates in one direction or the other.

4. Increased costs.

You may discover that investing in other nations costs more than selling items. As a result, accumulating adequate money to launch your firm is critical.

5. Economic incapacity.

Foreign direct investments, while capital-intensive from the standpoint of the investor, might be very hazardous or financially unviable at any one time.

6. Expropriation.

Political Outbreaks can also lead to expropriation, which occurs when the government seizes your wealth and property.

2.3 Global scenario

The worldwide pharmaceutical market was projected to be worth $962 billion in 2021, with a 2.4% annual growth rate (on a constant currency basis). Following the patent expiration of key medications, market saturation, and decreased R&D productivity, regulated markets such as the United States, Europe, and Japan expanded at a slower rate. Furthermore, the global economic downturn has led to a lower price environment for branded medications, leading to an increase in generic drug substitution.

The trend of growth in developing markets maintained in 2012. The United States, Europe, and Japan dominate the global pharmaceutical sector. Pharmaceutical sales in the United States and Europe both declined by 1%, whereas sales in Japan were flat in 2012, Asia (excluding Japan), Africa, and Australia accounted for 17 percent of total worldwide pharmaceutical sales. Oncology was first in terms of therapeutic classes, accounting for 8% of total global pharmaceutical revenues.

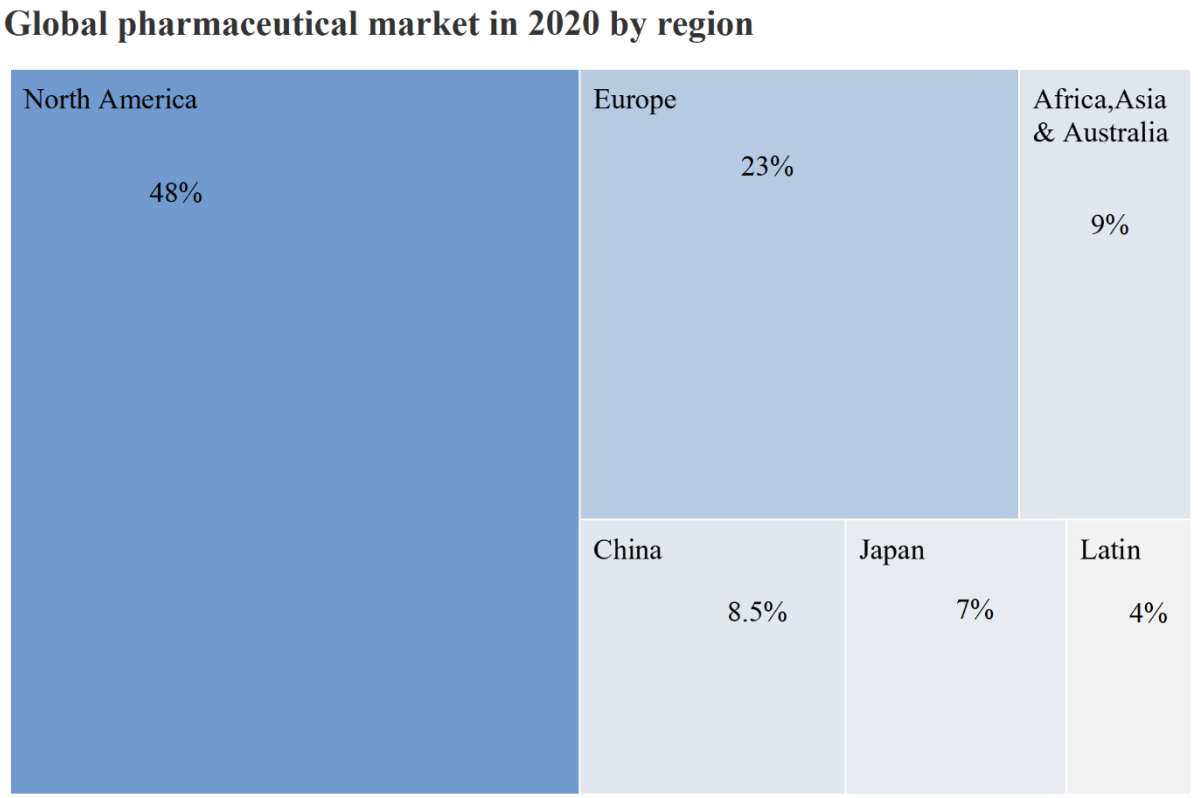

Fig.1 Global pharmaceutical market by region in 2020

Source: IQVIA

Global pharmaceutical exports (HS Code 30) rose at a 3.7 percent CAGR between 2009 and 2013, from US$ 420 billion to US$ 486 billion. In 2018, Germany was the largest pharmaceutical exporter, accounting for 15.4 percent of global pharmaceutical exports, followed by Switzerland (11.9%), Belgium (10.4%), and the United States (10.4%). Europe accounts for over 80% of global pharmaceutical product exports (US$ 389 billion).

China has emerged as a prominent pharmaceutical importer. Amongst pharma developing markets, India had substantial increase in exports, contributing for 2.4% of global pharmaceutical exports in 2018. India is rapidly being referred to as the "world pharmacy," since it exports pharmaceutical items all over the world. Indian pharmaceutical enterprises have been successful not just in satisfying domestic demands, but also in gaining a leadership place in the global pharmaceutical's scene during the last 50 years. India was able to achieve these heights with support of FDI in pharma, from a market with no share in global pharmaceutical to becoming pharmacy of World. The struggles of Indian pharmaceutical sector towards development phase are discussed detailed in the next chapter.

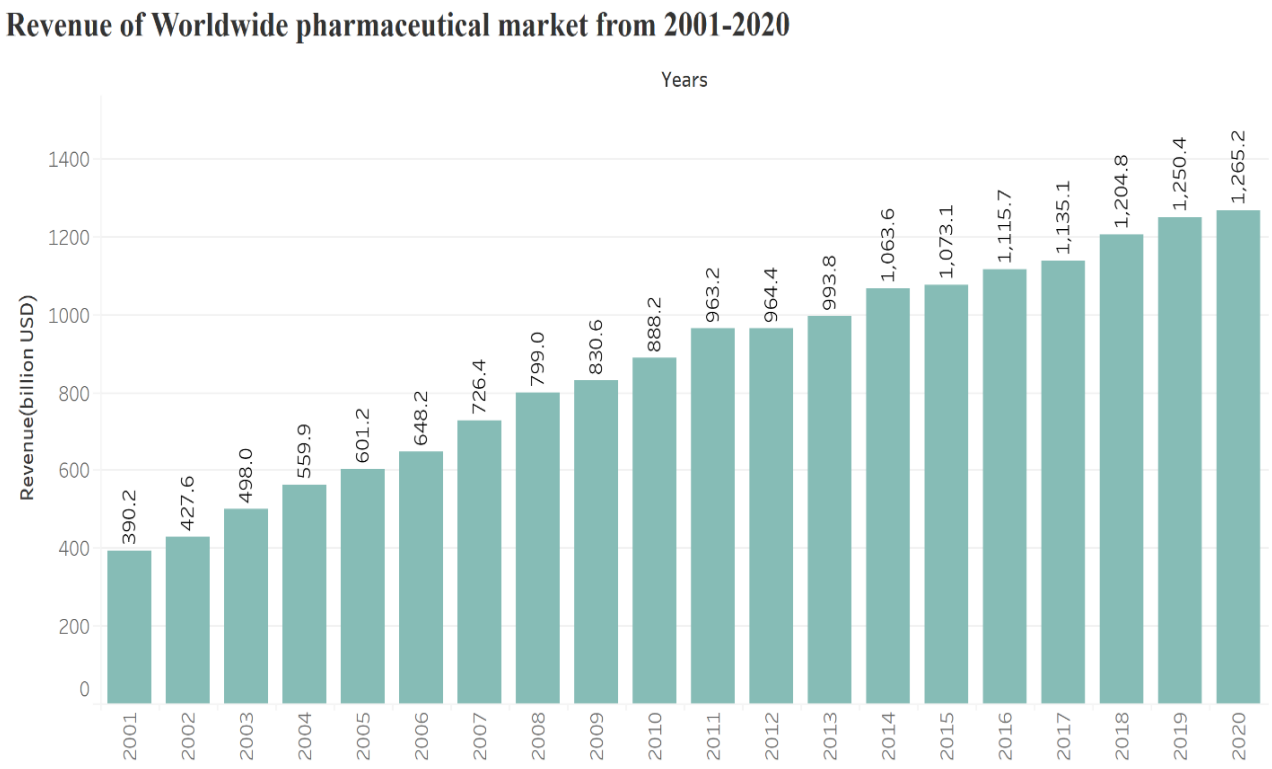

Fig.2 Revenue of Worldwide pharmaceutical market from 2001-2020

Source: IQVIA

3. FDI IN INDIA

3.1 FDI in Indian pharma

The pharmaceutical industry's FDI is examined. A summary of the FDI policies in the pharmaceutical business is provided, as well as the reasons why MNCs invest in India. In addition, a description of the industry's present market structure is included.

From 1950, Indian pharma industry was very lagging when compared to other developing countries in World. The main reasons include:

- Lack of Investment capital
- Lack of Technology (which is indirectly due to poor investments)

So, to be pointed the only main reason India noticed is “Lack of Investments” and then as solution for this Liberalization of foreign Investment policies was done and MNC’s were invited to invest. There by investments in Indian pharma have started and it resulted in huge growth of its value from 1947 - Rs.10 crore to 1952 -Rs.35 crore.

The most growth is from bulk drug manufacturing. Apart from this new strategy has been introduced to make Indian pharmaceuticals self-dependent. Public sector has played a lead role in it and India made it compulsory to manufacture complete product in their manufacturing unit in India only. It resulted expansion of MNC’s, and it contributed to enormous revenue generation by Indian pharma sector. By 1962 it grew by Rs.100 crore and by 1970 it became Rs. 450 crores.

In 1991, FDI inflow in drugs and pharmaceutical sector was only USD 0.3 million thereafter it got increased every year until 2005 where it decreased to USD 172 million from USD 292 million in 2004 and reached highest of USD 334.1 million in 2007 and again it declined and reached to USD 181.5 in 2008 which is 605 times from the figure of 1991.7 In 2014-15, FDI inflow in drugs and pharma was Rs. 9052 crores and in 2015-16 it was Rs. 4975 crores. The investment climate in India has greatly improved since the country's economy opened in 1991. This is primarily owing to India's liberalization of FDI rules. India is now ranked among the top 100 nations in terms of ease of doing business (EoDB).

Indian Pharmaceutical market:

To assess the impact of FDI on the Indian pharmaceutical industry, it is necessary to first comprehend the Indian pharmaceutical market.

India is the world's largest supplier of generic pharmaceuticals. The Indian pharmaceutical industry supplies more than half of the world's vaccine demand, 40% of generic medicine demand in the United States, and 25% of total drug demand in the United Kingdom.

In terms of volume, India is third in the world, and fifteenth in terms of value. In the domestic pharmaceutical sector, there are 3,000 pharmaceutical enterprises and 10,500 manufacturing units.

"India is a significant player in the global pharmaceutical industry." (“Best Pharma stocks to buy in India 2022 - Rakshith Pai”) The country also boosts a vast number of scientists and engineers that can help the industry develop further. Currently, Indian pharmaceutical companies supply more than 80% of the antiretroviral medications required to battle AIDS worldwide (Acquired Immune Deficiency Syndrome).

The Indian pharmaceutical industry is divided into three primary segments.

1. A large multinational corporation that develops new proprietary medications.

2. Major Generic Manufacturers, both domestic and international.

3. Domestic Medium and Small-Scale Businesses

Market size:

Fig.3 Indian pharmaceutical market size

Source: UN comtrade / Pharmexcil Observation

Fig.4 Pharmaceutical exports from India

Source: IBEF

Government expenditure:

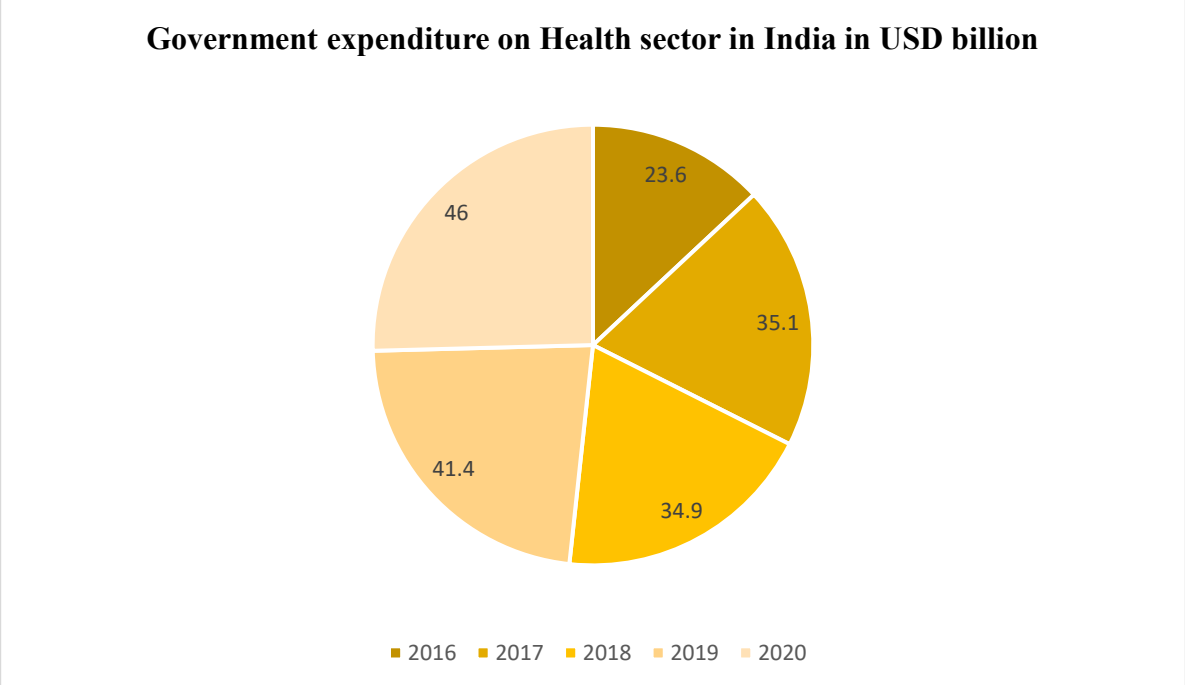

Fig.5 Government expenditure on Health sector in India

Source: IBEF

3.2 Efforts by India to attract FDI in pharma

India's literacy rate was barely 17 percent at the time of independence, with a life expectancy of 32.5 years. Following India's independence in 1947, the government faced enormous challenges in restructuring the economy. The political leadership was under pressure to offer growth and progress as the country flew on promises and sentiments of national joy. By 1956, India had made a number of significant and strategic decisions that continue to shape the country's economic destiny to this day.

During the 1950s and 1980s, policy was cantered on a conflict between the state and independent foreign interests, with oil firms serving as the major Transnational Corporations (TNCs). The creation of Free Trade Zones (FTZs) with a plethora of tax and other agreements has failed to attract FDI.

In 1969, the government created three industrial categories for foreign investment:

FDI without technical collaboration, FDI with technical collaboration, and FDI with international involvement. The External Finance Management Act (FERA) went into effect in 1974, following the adoption of the 1973 Industrial Policy Statement, outlining a detailed list of industries in which foreign firms could participate in or out of FDI, apart from tea plantations and the drug and pharmaceutical sectors. As a result, the period 1970-1980 was dubbed the "FDI limitation period," since FERA served as a regulatory tool rather than a compensation provider.

From 1980 through 1991, the Indian government liberalized FDI via Industrial Policy Statements in 1980 and 1982, followed by the Technology Policy Statement in 1983. During this time, there was also significant trade liberalization in the form of tariff reductions and the transfer of numerous import commodities from the licensing category to the open general license (OGL) category. For the first time, in the early 1990s, FDI surpassed loans and other forms of financial channels as the preferred method of mobilizing financial resources. Foreign equity of up to 51 percent was permitted in certain enterprises manufacturing intermediate and capital goods under the RBI's automatic approval mechanism. Foreign direct investment was seen as a vehicle for bringing in foreign technology that was not available domestically, and the word "Indigenous" was replaced with "sophisticated and advanced technology."

3.2.1 Series of measures initiated by India to encourage FDI

Automatic route

Under the Automatic Route, the non-resident investor or Indian firm does not need Indian government clearance for the investment.

The Government Route

Prior to investment via the Government Route, authorization from the Government of India is necessary. Proposals for foreign direct investment through the government channel are reviewed by the relevant Administrative Ministry/Department.

Measures include:

(a) Implementation of a dual route consisting of the RBI's automated route and the government's permission route.

(b) Automatic approval of technology agreements in high-priority industries, as well as the elimination of restrictions in low-technology regions and the liberalization of technology imports .

(c) Permission for non-resident Indians and outside business organizations to invest up to 100% in high-priority areas.

(d) Raising the foreign equity involvement limit for existing enterprises to 51% and liberalizing the use of foreign "brand names."

(e) Joining the Multilateral Investment Guarantee Agency to safeguard foreign investments.[3]

Even though portfolio investment declined due to the East Asian crisis after 1997, these measures resulted in a significant increase in FDI. To encourage FDI, the automatic route authorized foreign equity participation of up to 100 percent with a '15 billion thresholds in the infrastructure sector, which included energy supplies, roads, ports, and harbours.

The general rate of import tariffs in India has decreased from approximately 300% in 1990 to around 80% in 1994, and then to 10% now. The notion that allowing TNCs (or FDI) in some industries would assist enhance exports impacted the route liberalisation followed. As a result, foreign direct investment has shifted away from natural resource-based industries and

toward manufacturing, services, and ***pharmaceuticals***. Few elements created a significant influence on attracting pharmaceutical investments during its early stages, which can be called as drivers of FDI.

Entry gates to FDI

The foreign dependency of domestic enterprises was quite large during the 1985-90, when the direction of foreign firms was comparable to that of domestic and foreign firms. Foreign corporations, on the other hand, were more focused on outsourcing than local firms from 2001 to 2010. Rather than attempting to import technology, between 2001 and 2007, the presence of foreign corporations aided indigenous firms in increasing their productivity through indirect 'learning by doing.'

'Trade and FDI' were usually seen to be separate issues until the 1980s, when FDI, like other forms of international investment, was seen to be determined by differences in the rates of return on capital across countries. Horizontal FDI arises among similar countries in the absence of trade costs where trade and FDI are substitutes. In the case of dissimilar countries in the presence of trade costs, there exists a complementary relationship. Empirical investigations have found broad support for the complementary relationship as compared to substitution.[4]

Domestic enterprises, contrary to common belief, have more capital than international firms. As a result, foreign corporations are encouraging increased spending and diminishing job possibilities may be exaggerated. For local and international enterprises, there were minor disparities in effective tax rates and interest rates. In the case of international enterprises, the percentage of sales income paid to the treasury fell dramatically from 1980's to 2000's.

Until the year 2000, India's FDI policy prohibited long-term investment unless it was supported by a significant export commitment, and it was sluggish to renegotiate tax treaties.

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[3] Goyal, A.K. (2018). Effects of FDI Inflows in India: Growth Perspective. *FOCUS: Journal of International Business*, 4(02). doi:10.17492/focus.v4i02.11689.

[4] Anwar, J. (2018). A Historical Perspective of FDI Policy in India. *LAW REVIEW*, 38(1). doi:10.29320/jnpglr.38.1.17.

Others imposed restrictions on foreign ownership, but the relaxation or tax benefits were linked not just to export performance, but also to critical domestic policy factors such as employment, local content, and location. The Uruguay Agreement of 1995, which stated that foreign enterprises may no longer be treated unfairly, had a significant impact on India's foreign investment policy after 1995. In addition, the communications revolution gave rise to a whole new group of enterprises that were classed as "Industries" under FDI legislation. There are two types of Foreign direct investments and are discussed in the following.

3.2.2 Recent improvements in FDI policy:

On August 28, 2017, the Government of India published a unified and revised FDI policy that is clear, easily understandable, and predictable through the DIPP, Department of Industrial Policy and Promotion. Lotteries, gaming and betting, chit funds, trading in transferable development rights, production of cigarettes, tobacco, or cigars, real estate industry, and other industries not available to private investment are all forbidden from accepting FDI.

Conditions imposed by the government through the clearance procedure in the pharmaceutical industry will continue to apply to all Brown field investment requests. If prior government approval is acquired for foreign investment in a fully owned subsidiary, prior approval for future investment is not necessary if the aggregate investment does not exceed Rs. 5000 crores; if the aggregate investment exceeds the given amount, prior approval is required. Under this policy, prior approval is necessary if the investment is coming from a nation of concern via an automated route, and the application would be reviewed by DIPP for government approval. Security clearance is also necessary for the nation of concern through the government approval method.

3.3 Drivers of FDI in Indian Pharma

Several factors have helped India attract foreign direct investment in the pharmaceutical sector. India's large market base and rapidly expanding middle class purchasing habits, favourable business environment, good administrative machinery, appealing foreign policy,

an abundance of skilled labor, and appealing investor incentives have all contributed to the country's status as one of the most appealing investment destinations.

In addition, India has an advantage over other nations because of its lively democratic setup, independent judicial system, well-developed local supply chains, well-functioning infrastructure, and information creating institutions.

Major factors are:

1.Cost Efficiency

For pharmaceutical businesses, India is a cost-effective manufacturing hub. The key benefit of pharmaceutical companies in India is lower cost of production, which stimulates lower costs in R&D, making it one of the preferred investment options. Indian pharma export has reached US $24.44Billion in FY 2021.

2. Economic Driving Forces

Increasing economic development, along with increased coverage of health insurance, will drive up spending on health care and drugs in India. Indian pharmaceutical firms played a critical role due to their improved ability to mass-produce vaccinations at a lower cost and in distributing COVID-19 vaccinations internationally following the emergence of the COVID-19 pandemic scenario. This acted as a stimulus for the Indian economy to improve.

3. Policy

The Indian government aids Indian pharmaceutical sector players on a regular basis by implementing appropriate legislation. The Pharma Vision 2020 aims to make India a global leader in drug discovery and development, as well as mass manufacture of low-cost generic medicines. The Indian government has also shown its willingness to assist the Indian pharmaceutical industry in growing by adopting adequate foreign investment laws.

4. Heterogeneous profile

According to UNCTAD, FDI flows to India in 2021 would be 26% lower than in 2020, owing mostly to a lack of large M&A deals in 2020. According to the Investment Trends Monitor, global foreign direct investment flows are likely to climb by 77% in 2021 to USD 1.65 trillion, up from USD 929 billion in 2020, reaching the pre-COVID-19 level.

5. Market

Companies may seek access to promising new markets by investing abroad. India has already proven as one of the top producers of pharmaceuticals which attracts FDI to invest and expand their market widely.

3.4 Types of Foreign Direct Investments (FDI) in pharma

Companies seeking to develop their worldwide interests typically undertake physical investments and purchases in other nations. This is referred to as foreign direct investment (FDI). In their host nation, they buy, lease, or receive assets like as plants, office space, or other sorts of structures.

In general, there are three types of FDI:

GREENFIELD INVESTMENT:

A greenfield investment occurs when a parent company establishes a subsidiary in another country. Rather of acquiring an existing facility in that country, the firm creates a new company by building a new factory there. A manufacturing plant might be part of a building project. Offices, staff and management houses, and distribution centres may also be completed.

- Under the automatic route for green-field pharma, India allows 100 percent FDI in pharmaceuticals.

BROWNFIELD INVESTMENT:

A brownfield investment occurs when a firm buys or rents an existing facility to begin new manufacturing. Companies may find this method to be a huge time and money saver because it eliminates the need to go through the procedures of creating a brand-new facility.

- In India, 100 percent FDI in drugs and pharmaceuticals is authorized in brownfield pharma, while 74 percent FDI in the pharmaceuticals sector is approved through the automated method and then by government permission.

3.4.1 Issue due to allowing 74% through Brownfield - Automatic route:

Based on recent FDI Policy, there is an argument running in India which is:

Would 74 percent FDI in brownfield pharma (automatic route) harmful to Indian generics?

The revised policy allows 74 percent of foreign investors to purchase 74 percent shares in an existing Indian pharmaceutical business utilizing the automated technique without seeking authorization from the Foreign Investment Promotion Board (FIPB).

Medicins Sans Frontières' Leena Menghaney (lawyer working on access to medicines in developing countries) responds, saying, **"**The new pharma FDI policy weakens Indian generics, potentially raising medicine prices.**"** The government is paving the path for global firms to take over 'Make in India' generics enterprises by easing brownfield pharma FDI regulations. The long and short of it is that this new policy would allow powerful Western pharmaceutical companies, such as Cipla, to take over important Indian pharmaceutical companies, reducing them to mere cogs in a multinational pharmaceutical industry "whose sole aim appears to be to generate supra-normal profits for its CEOs and shareholders." Such an approach, she claims, would result in India losing an independent generic industry that actively competes with patent-holding multinational pharmaceutical businesses to deliver low-cost crucial pharmaceuticals.

3.4.2 Red flags in brownfield FDI

Menghaney isn't the only one concerned about the current scenario. Three years ago, the 110th Report of the Department Related to Parliamentary Standing Committee on Commerce, led by ***Shanta Kumar***, raised a substantially larger red flag. The Committee has taken note of "the threat posed by FDI in brownfield pharma projects to our country's entire health and IPR

framework in terms of access and affordability of medicines, dominance and elbowing out of our pharmaceutical industry, which primarily consists of small and medium pharma units, undue demand and pressure on TRIPS arrangements, and so on."

Based on this judgment, the Commerce Committee pronounced itself "persuaded that the government should impose a blanket bar on any FDI in brownfield pharma projects." The committee also "strongly recommends that the Department take all necessary efforts to prevent any additional takeover/acquisition of local pharma enterprises."

Such constraints, according to the committee, are needed because the pharmaceutical industry "must be regulated by public benefit rather than foreign investments, profit, and revenue."

3.5 Recent developments and Growth data:

3.5.1 FDI inflows in pharma

• Total FDI inflows in the nation in the previous 21 years (April 2000 - March 2021) are $763.5 billion, whereas total FDI inflows in the last 5 years (April 2014 - September 2019) are $319 billion, accounting for roughly half of total FDI inflows in the last 20 years.

• FDI inflows into India totaled $45.15 billion in 2014-15 and have steadily climbed since then. Furthermore, overall FDI inflows climbed by 65.3 percent, from $266.21 billion in 2007-14 to $440.01 billion in 2014-21, and FDI equity inflows surged by 68.6 percent increase (2014-21). From $185.03 billion in 2007-14 to $312.05 billion in 2014-21,

• $58.37 billion in total FDI inflows for fiscal 2020-21, a 22% increase over the first eight months of 2019-20. From April to November 2020, the overall amount of FDI equity inflows received is $43.85 billion, which is 37% larger than the total amount received from April to November 2020 ($32.11 billion).

• In the first four months of fiscal year 2021-22, India received $27.37 billion in FDI inflows, a 62 percent increase over the same time in fiscal year 2020-21 ($16.92 billion).Due to India's loosened FDI policy, FDI capital inflows in the first three months of FY 2021-22 ($17.57 billion) are up 168 percent over the same time last year ($6.56 billion).

• Foreign Direct Investment (FDI) inflows totaling $ 54.10 billion have been recorded in the nation for the current fiscal year, 2021-22 (up to November 2021).

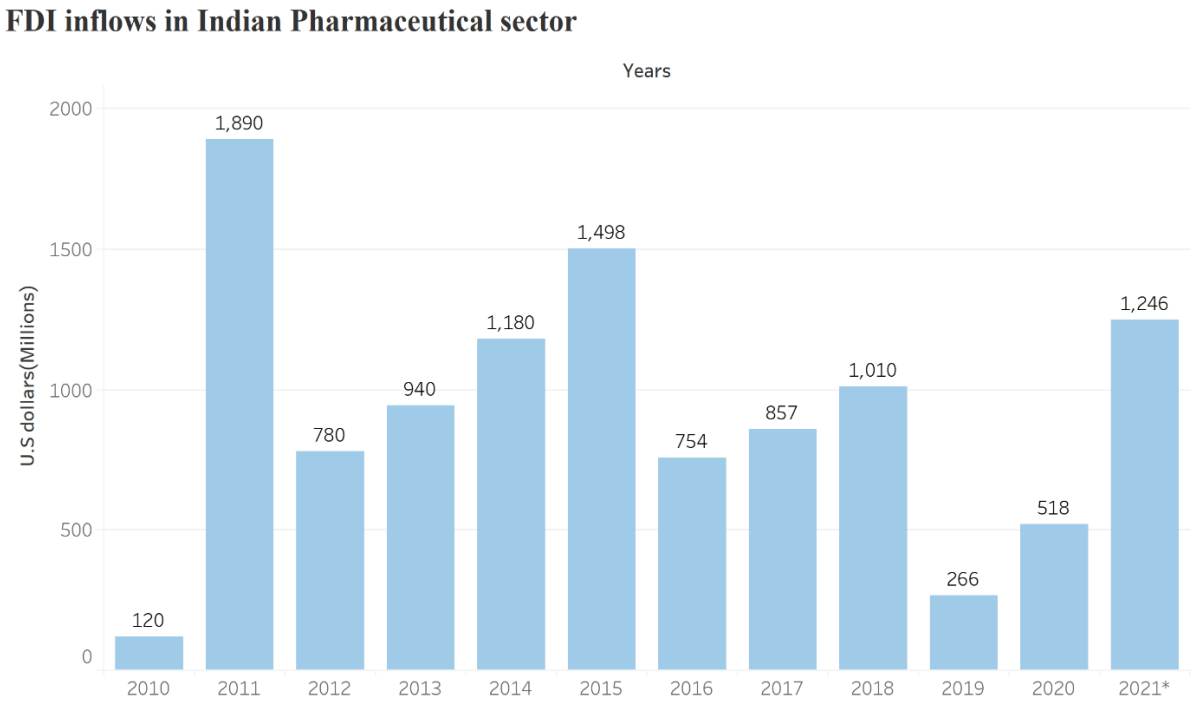

Fig.6 FDI inflows in Indian pharmaceutical sector

Source: Department for Promotion of Industry and Internal Trade (India)

3.5.2 Growth of FDI in pharma

International capital inflows supply numerous benefits for a developing country's economy. Several experts expressed their opinions on the influence of FDI on economic growth. Most examples and analyses have shown that FDI has a favorable influence on a country's economic development. It has been seen that countries with effective economic policies and good organizations receive help from capital inflows. In recent years, India has appeared as a

prominent destination for European investors seeking FDI. The Indian pharmaceutical business is one of the primary industries that draws a significant amount of FDI.

Recently, FDI in the pharmaceutical sector has experienced a 200 percent rise in 2020-21. According to medical experts, the unprecedented surge in foreign investments in the pharmaceutical sector is mostly due to efforts to satisfy Covid-related needs for treatments and vaccinations.

3.6 Key developments

Some of the regulatory developments and critical trends that may have a significant impact on the global pharmaceutical business include:

a. A change in the US Food and Medicine Administration's (US FDA) stance on generic drug labelling, allowing generic firms to alter their labelling under specific conditions in the same way that brand companies
b. The United States Supreme Court's decision against reverse payment arrangements (pay for delay)
c. The USFDA announces a new pricing structure for the GDUFA program for the period October 2014 to September 2015.
d. Greater focus on Quality Risk Management (QRM), with risk management becoming a critical part of any regulatory inspection and regulatory file; tougher medication serialization laws; anti-counterfeiting efforts negatively harming generics.
e. To counteract the spread of counterfeit drugs, the WHO has launched a new initiative called Substandard/Falsely labeled/Falsified/Counterfeit medical goods (SSFFC); the USFDA has enhanced its scrutiny of pharma-units for Current Good Manufacturing Practices (CGMP).
f. Product tweaking by innovator businesses and patent filing as new medication; innovator corporations engaging into license deals with generic companies in emerging nations as a creative economic strategy for controlling competition, as well as weakening patent rules in such countries.
g. A rise in the amount of import advisories and restrictions issued by the USFDA, notably in Asian countries.

The following are some significant changes in the global pharmaceutical market that have had a significant impact on the sector's development:

Mergers and acquisitions - with approximately 615 deals worth US$100 billion announced in 2013, up 34% year on year.

Intellectual property embankment - with an estimated US$38.7 billion in healthcare revenues at risk from patent expiry in 2014, and another US$47.5 billion in 2015.

Growth of the generics sector - with a CAGR of 9% between 2009 and 2014, and currently projected at US$129 billion; increase in R&D investment - by pharmaceutical companies

3.6.1 IPR & Patents

Support the implementation of the TRIPS Agreement, there has been an increase in patent activity in India. Most of patent operations in the Indian pharma business are carried out by large pharmaceutical firms in India and multinational corporations (MNCs), and a higher percentage of applications are connected to new or enhanced procedures for goods rather than products themselves. The application-related goods are concerned with intermediates and formulations with the greatest contribution in modified-release dosage forms. Furthermore, as comparison to large corporations, the R&D intensity of SME pharmaceutical enterprises is small. SME enterprises have little to no engagement in IPR activity due to a lack of technological aid and funding for upgrading and expanding their internal R&D capabilities. To increase IPR activity in the Indian pharmaceuticals business, pharmaceutical firms must be encouraged to conduct new drug discoveries, develop new dosage forms, and find new applications for current treatments. This might be carried out by paying the costs of patent filing and maintenance, as well as supporting the costs of litigation and other legal formalities. For their survival and expanded engagement in IPR activities, SMEs must build a collaborative research culture with publicly and privately supported research organizations.

3.6.2 Government initiatives

Some of the initiatives taken by the Government to promote the pharmaceutical sector in India are as follows: ("Pharmaceutical Companies in India, Indian Pharma Industry-IBEF")

- In August 2021, Union Health Minister, Mr. Mansukh Mandaviya announced that an additional number of pharmaceutical companies in India are expected to commence manufacturing of anti-coronavirus vaccines by October-November 2021. This move is expected to further boost the vaccination drive across the country.

- In June 2021, Finance Minister Nirmala Sitharaman authorized an extra Rs. 197,000 crore (US $26,578.3 million) investment for the Pharma PLI plan in 13 important areas such as active pharmaceutical ingredients, pharmacological intermediates, and vital raw materials.

- As part of Atmanirbhar Bharat 3.0, the Government of India announced Mission COVID Suraksha in May 2021 to accelerate the development and manufacture of indigenous COVID vaccines. As part of the mission, the Government of India's Department of Biotechnology provided financial support in the form of a grant to vaccine manufacturing facilities, with the aim of boosting production capacity to more than 10 crore doses per month by September 2021.

- The Union Government decided in April 2021 to simplify and accelerate the regulatory processes for COVID-19 vaccines licensed for limited use by the US FDA, EMA, UK MHRA, PMDA Japan, or those on the WHO Emergency Use Listing (EUL). This measure is expected to increase India's access to international immunizations and imports.

- In February 2021, the Punjab government announced intentions to build three pharma parks in the province. Another medical park of Rs. 180 crore (US$ 24.56 million) has been planned, as has a greenfield project in Wazirabad.

The Ministry of Health and Family Welfare received Rs. 73,932 crore (US$ 10.35 billion) in the Union Budget 2021-22, while the Department of Health Research received Rs. 2,663

crore (US$ 365.68 billion). The government has set aside Rs. 37,130 crore (US$ 5.10 billion) for the "National Health Mission.' During a six-year period, the Prime Minister's Aatmanirbhar Swasth Bharat Yojana got Rs. 64,180 crore (US$ 8.80 billion). The Ministry of AYUSH received Rs. 2,970 crore (US$ 407.84 million), an increase over the previous year's Rs. 2,122 crore (US$ 291.39 million). To achieve self-sufficiency and reduce reliance on imports for the country's basic bulk medications, the Department of Pharmaceuticals launched a PLI strategy to boost local production by establishing greenfield facilities with little domestic value addition in four distinct 'Target Segments' with a cumulative outlay of Rs. 6,940 crore (US$ 951.27 million) from FY 2021 to FY 2030.

3.7 Globalization

"Globalization is a process that entails the economic interdependence of countries all over the world, erasing all obstacles to economic integration as if the entire world were a single town. Clearly, the wealthier nations, with their greater financial might, control the scene, while the poor and growing nations are forced to integrate, giving up their economic independence, knowing full well that what they are forced to accept is really destructive to their own interests. International financial bodies such as the World Bank, IMF, and even the WTO solely serve the interests of wealthier countries in this process.**"** ***D.P. Dubey: General Secretary of the Federation of Medical and Sales Representatives of India.***

Between 1984 and 1990, the World Bank and IMF's harsh structural adjustment programmes resulted in a net transfer of $178 billion from impoverished countries to commercial banks in affluent ones.

The Indian pharmaceutical industry began to globalise in the early 1990s, when the government opened its markets to international investment. In 1991, the Indian government changed its economic strategy to open its economy to international corporations, resulting in the globalization of the Indian pharmaceutical industry. But it resulted in both in benefits and as well as some disadvantages.

3.7.1 Benefits of Globalization:

The numerous advantages of the globalization of the Indian pharmaceutical sector include the entrance of enormous amounts of foreign money into the industry, which has helped the

Indian economy. The arrival of major international pharmaceutical corporations into the Indian pharmaceutical business increased the number of jobs available to the country's citizens. The introduction of extremely advanced technology into the business, which boosted the quality of pharmaceuticals delivered to the people, is one of the benefits of the globalization of the Indian pharmaceutical sector. Many Indian pharmaceutical corporations have bought global pharmaceutical companies, including Ranbaxy's acquisition of Crosland's, Wockhardt's acquisition of Merind, and Nicholas Piramal's acquisition of Sumitra Pharma. This helped Indian pharmaceutical companies expand and make more money.

3.7.2 Disadvantages of Globalization:

The major drawbacks of Indian Pharmaceutical Industry Globalization include increasing rivalry in the Indian market between global pharmaceutical businesses and native ones. As a result, numerous Indian pharmaceutical businesses, including Hindustan Ciba Geigy, Park Davis, Boehringer Mannheim, and Abbot, had to close their doors. Many people have lost their employment because of this, with over 30,000 people losing their jobs in Mumbai's Thane district, Maharashtra, between 1997 and 1999. The downsides of the Indian pharmaceutical industry's globalization include that numerous foreign pharmaceutical corporations are acquiring Indian pharmaceutical businesses, such as SKB acquiring Sterling, Ciba Geigy acquiring Sandoz, and Rhone Poulenc acquiring Fashions. As a result, there is concern that foreign pharmaceutical corporations would take over the Indian pharmaceutical industry.

3.8 Pharmaceutical Industry’s Contribution to India’s GDP

With vast investments and major developments in pharmaceutical Industry it contributes a noticeable share in overall country GDP. On average it contributes about 2% of total GDP.

Below is **trend analysis** of percentage share contributed from 1991 to 2020.

Year	GDP (million USD)	FDI pharma (million USD)	FDI Pharma as share of GDP	Share %
1991	2,74,842	4.63	0.001684604	0.002
1992	293262	3.46	0.001179832	0.001
1993	284194	50.47	0.017758996	0.018
1994	333014	10.1	0.003032906	0.003
1995	366660	52.1	0.014209349	0.014
1996	399787	49.03	0.012264031	0.012
1997	423160	32.72	0.0077323	0.008
1998	428741	25.83	0.006024616	0.006
1999	464344	51.47	0.011084455	0.011
2000	474692	35.94	0.007571225	0.008
2001	492379	77.94	0.01582927	0.016
2002	522798	40.07	0.007664528	0.008
2003	617573	108.91	0.017635162	0.018
2004	721585	293.36	0.040654947	0.041
2005	834217	172.44	0.020670881	0.021
2006	949117	224.2	0.023621956	0.024
2007	1238700	340.35	0.027476387	0.027
2008	1224097	4246.76	0.346930023	0.347
2009	1365373	213.08	0.015605992	0.016
2010	1710917	209.38	0.012237882	0.012
2011	1872845	3232.28	0.172586626	0.173
2012	1841717	1123.46	0.061000686	0.061
2013	1973500	1105.2	0.056002027	0.056
2014	2119700	1214	0.057272256	0.057
2015	2289200	1498	0.065437707	0.065
2016	2478200	754	0.030425309	0.03
2017	2652800	857	0.032305489	0.032
2018	2815100	1010	0.035877944	0.036
2019	2932800	266	0.009069831	0.009
2020	2631000	518	0.019688331	0.02

Table.1 Pharmaceutical Industry's Contribution to India's GDP

Source: Foreign Direct Investment: Impact on Indian Economy by Bhavya Malhotra

These numbers show that pharmaceutical FDI has contributed more to India's GDP after the country adopted TRIPS standards: FDI flows were equal to 0.08 percent of GDP on an annual basis from 2004 to 2012, compared to 0.01 percent for the prior 13 years (1991 to 2003). However, FDI flows into the pharmaceutical industry continue to be modest. Another indicator is the net value-added of India's pharmaceutical sector as a percentage of GDP,

which is crucial because most FDI in this sector is in the form of mergers and acquisitions rather than "greenfield" investments. In other words, not only does the entry of new foreign capital affect GDP, but so does the contribution of the existing stock of capital. These findings suggest that India has a significant opportunity to enhance FDI inflows into pharmaceuticals and improve the sector's contribution to GDP.

3.9 Indian pharma pre-patent and post-patent

The Indian pharmaceutical sector may be separated into two periods: pre-patent (before to 2005) and post-patent (after 2005).

Since 2005, While the pre-patent or process patent regime aided the sector's evolution into a world-class generics industry, the post-patent or product patent regime is intended to foster long-term medication innovation. Branded products, on the other hand, have been delayed in India. **"**India gained a foothold in the global arena with reverse-engineered generic pharmaceuticals and active pharmaceutical ingredients (API), and it now aspires to be a prominent participant in outsourced clinical research and contract research and manufacturing services (CRAMS). India has the most industrial facilities that have been certified in the world (332 locations). Pharmaceutical firms can create two sorts of pharmaceuticals: formulations and bulk medications.**"** [5]

3.9.1 Domination by Exports

Manufacturing prospects exist for Indian pharmaceutical businesses in two areas: formulations and bulk pharmaceuticals. Exports (including bulk medicines and formulations) account for about 60 percent of industry sales in 2018-19. Around 100,000 medicines in various therapeutic categories are made in India. The domestic formulations business is extremely fragmented in terms of both the number of manufacturers and the types of commodities supplied. There are around 300-400 organized players and over 15,000 unorganized players.

[5] EXPORT-IMPORT BANK OF INDIA © Export-Import Bank of India. (2015). [online] Available at: https://www.eximbankindia.in/Assets/Dynamic/PDF/Publication-Resources/ResearchPapers/39file.pdf.

However, organized players dominate the formulations sector in terms of sales. Indian medicines are sold to over 200 countries worldwide, with the United States of America being the largest market. India has established itself as the world's largest supplier of generic medicines, accounting for 20% of total global generic medication exports in terms of volume.

The United States is the largest importer of Indian pharmaceuticals, accounting for around 40.6 percent, or US$ 16.8 billion, followed by Europe, Africa, and Asian nations, which account for 19.7 percent, 19.1 percent, and 18.8 percent of India's total exports, respectively.

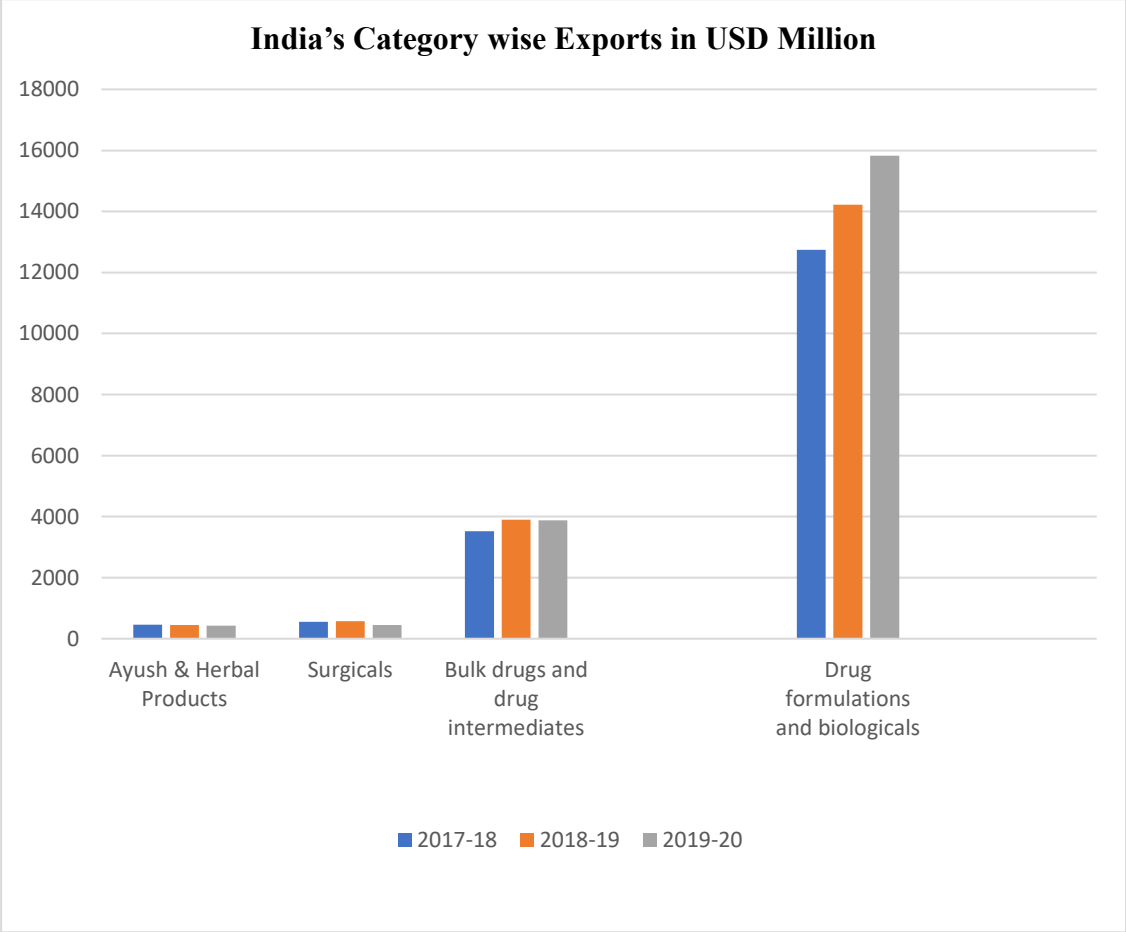

Fig.7 India's Category wise Exports in USD Million

Source: DGCIS

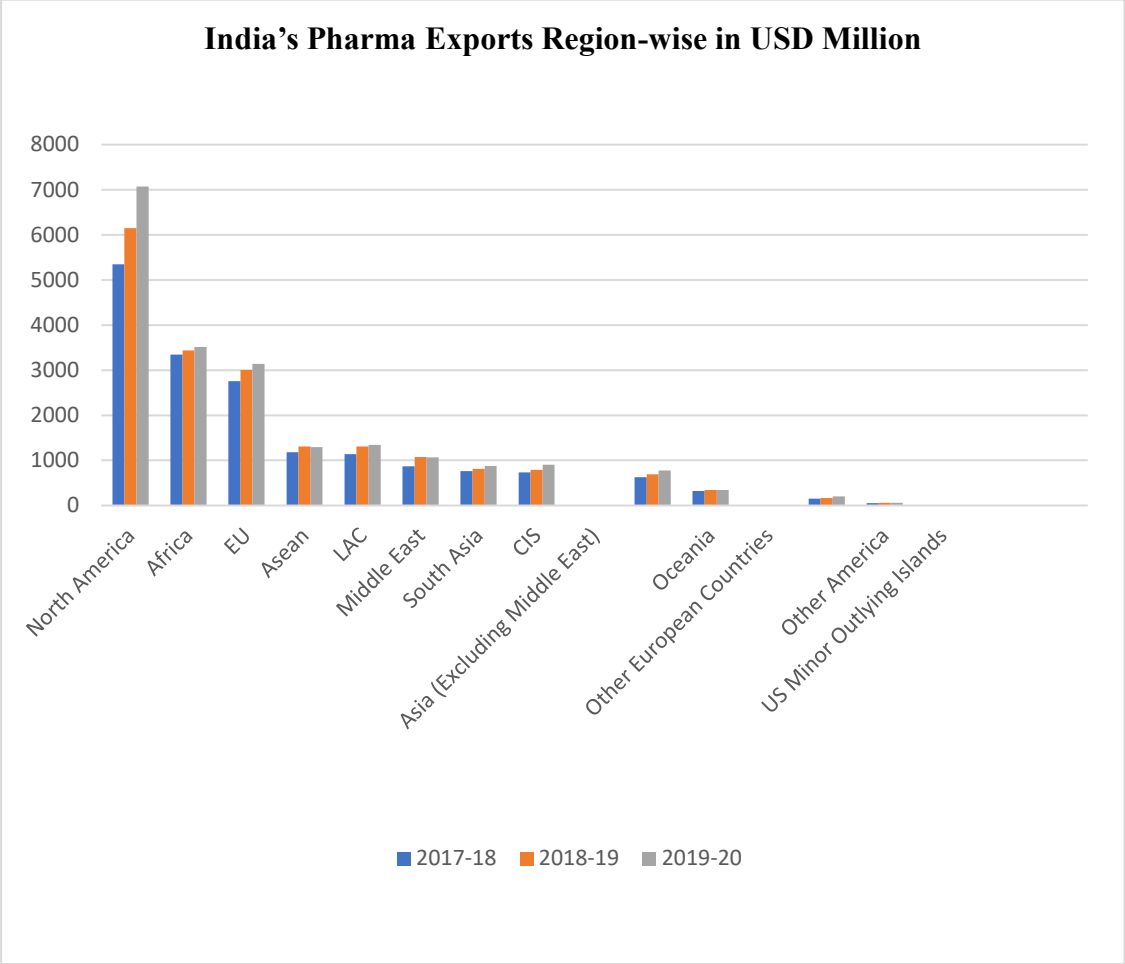

Fig.8 India's Pharma Exports Region-wise in USD Million

Source: DGCIS

4. IMPACT OF FDI IN PHARMA ON INDIAN ECONOMY

4.1 India' GDP before vs. after FDI

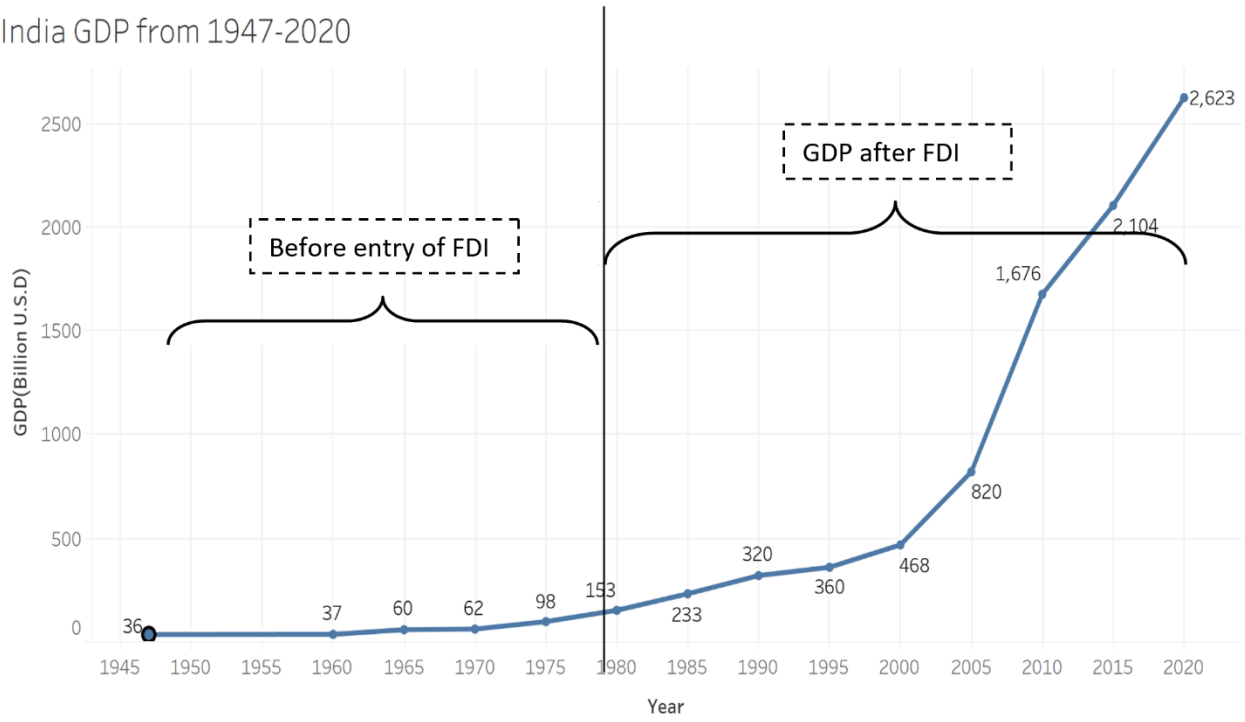

Fig.9 India GDP from 1947-2020

Source: IMF

This graph depicts Indian GDP data from 1947 to 2020, as we witnessed the level of financial growth in the Indian market changing through time but with no notable change. After inflow of FDI There have been significant changes in financial data following the arrival of FDI. Since 1990, the intake of FDI has been directed toward the development of information technology in the software area, and India has emerged as a prominent player in attracting FDI from 1990FY.[6]

[6] Macrotrends.net. (2019). *India GDP 1960-2019*. [online] Available at: https://www.macrotrends.net/countries/IND/india/gdp-gross-domestic-product.

4.2 Challenges faced

Data integrity standards utilized by various US-FDA certified divisions of Indian pharmaceutical businesses have lately emerged as a major source of worry for the industry. The investigators discovered many data integrity issues, including a failure to record procedures such as document backdating, copying old data as new data, re-running tests to produce better results, and modifying or destroying data. However, according to industry sources, the US-FDA has not evaluated the quality of final drugs. Nonetheless, such data integrity issues have resulted in import limitations, which have had a significant impact on the businesses' and medications' overall success.

4.2.1 Credibility of Clinical Trial Data

India has emerged as an attractive location for clinical trials due to its large pool of patients with varying treatment needs and the availability of a large scientifically trained workforce. However, clinical trial management capacity has not kept pace with this growth, resulting in unethical practices such as inadequate reimbursement for adverse events for patients, medication approval without clinical trials, and flaws in informed consent requirements. Recent attempts by the Indian government to improve the management of regulatory processes in clinical trials have resulted in clearance delays and other production delays, hindering the development of the clinical trial sector.

4.2.2 - The Patent (Amendment) Act, 2005, approved substantial reforms to Indian patent standards, bringing Indian patent laws in line with the TRIPS Agreement While patent protection in India has improved, recent issues such as the issuance of compulsory licenses (CLs) have proven troublesome. While CLs have been seen as unavoidable, they have also caused significant concern in the industry in developing nations such as India due to the revenue loss that CLs tend to cause. For bulk pharmaceutical intermediates and APIs, India is too reliant on China. In terms of value, China presently accounts for 58 percent of all such imports and more than 80 percent in terms of volume. API imports increased at an 18% CAGR during the previous decade. The Indian pharmaceutical industry is especially concerned about its overreliance on China for key bulk drugs and APIs, as any change in

Chinese policy or geopolitical conditions between the two countries could be disastrous for the Indian formulation industry, which is heavily reliant on API imports as raw material.

4.2.3 R&D - The Indian pharmaceutical industry's R&D profile comprises generic medication development, novel drug delivery systems, and new drug development. Patents awarded to Indian pharmaceutical businesses account for less than 5% of new medication research, according to the Patent and Trademark Office (PTO), with the balance focusing on novel procedures, dosage forms, and delivery systems. Furthermore, Indian firms' research and development operations are increasingly focused on global lifestyle disorders rather than addressing the demand for pharmaceuticals to treat local ailments such as TB and malaria. Despite trade liberalization regulations that encourage international investment in pharmaceutical R&D in India through contract research, cooperative research projects, out-licensing, and in-licensing partnerships, intellectual transfer and joint ownership prospects remain restricted. Furthermore, the Indian pharmaceutical business confronts regulatory challenges because of uncertainty in foreign direct investment regulations, the new pharmaceutical pricing strategy, a uniform code for sales and marketing operations, and obligatory licensing. These obstacles have stifled the industry's expansion.

4.3 Recent Developments

The Union Cabinet has authorized a revision to the existing policy on foreign direct investment in the pharmaceutical business, allowing up to 100% foreign direct investment via the automated route in medical equipment manufacture, subject to certain restrictions.

The Indian medical device and pharmaceutical sectors received a total of US$17.99 billion in FDI between April 2000 and March 2021.
The following are some recent developments/investments in Indian pharmaceutical sector:

Date	Company	Development
August 2021	Glenmark collaborated with SaNOtize	In India and other Asian countries, spray for COVID-19 therapy is available.

August 2021	Uniza Group signed an agreement with Lysulin Inc. (an US-based firm)	Nutritional product for Indian consumers
August 2021	Alkem Laboratories	In the United States, Famotidine and Ibuprofen pills are distributed and promoted under the trade name 'Oxra' to treat osteoarthritis and rheumatoid arthritis symptoms.
June 2021	Sun Pharmaceuticals acquired the patent license for Dapagliflozin from AstraZeneca	distributing and promoting the drug under the brand name ‘Oxra’.
June 2021	Lupin Ltd	to create the vaccine domestically to increase India's immunisation effort by providing a digital therapeutics platform for medical practitioners and patients in the country
May 2021	Cipla	COVID-19 detection kit ‘ViraGen’
May 2021	Indian Immunologicals Ltd. (IIL), Bharat Immunologicals and Biologicals Corporation (BIBCOL)	to develop the vaccine locally to boost India's vaccination drive.
May 2021	Eli Lilly, Cipla Ltd., Lupin Ltd., Natco Pharma & Sun Pharmaceutical Industries Ltd	to manufacture and sell Baricitinib, a treatment used to treat COVID-19.
April 2021	National Pharmaceutical Pricing Authority (NPPA)	fixed the prices of 81 medicines, including off-patent anti-diabetic drugs, allowing patients to reap the advantages of patent expiration.
February 2021	Telangana government partnered with Cytiva	to open a ‘Fast Trak’ lab to strengthen the biopharma
February 2021	Glenmark Pharmaceuticals Limited	business, the company released SUTIB, a generic form of Sunitinib oral capsules, for the treatment of kidney cancer.

February 2021	Natco Pharma	Brivaracetam for the treatment of epilepsy in India.
January 2021	Central government	It was announced that three bulk drug parks will be established at a cost of Rs. 14,300 crore (US$ 1,957 million) to produce chemical compounds or active pharmaceutical ingredients

Table.2 Recent developments/investments in the Indian pharmaceutical sector

Source: IMF

4.4 Covid impact

4.4.1 Covid scenario:

During India's first Covid outbreak in early 2020, the government struggled to organize not just ventilators but also vital things such as PPE kits and N95 masks. When the nation was battered by the terrible second wave a year later, the fundamental outlines of the difficulties shifted. As the number of daily patients reached a stunning 4 lakh by the end of April 2021, there was an immediate lack of hospital beds and oxygen supplies. During the second wave, India recorded over 350,000 new cases per day and over 2,800 fatalities per day. Because of the abrupt and significant surge in the number of patients, the country's medical system failed. Despite increasing healthcare spending following the first wave, diagnostic centers, oxygen facilities, ventilators, and ICU beds were in limited supply throughout hospitals in India. There are presently 8 physicians for every 10,000 inhabitants in India, as well as 8.5 hospital beds for every 10,000 people. By the third wave, India had begun immunization and there were fewer hospitalizations, but the only problem was a scarcity of medications. Also, the capacity to manufacture oxygen has increased significantly, since it was the primary issue during the second wave, which resulted in many fatalities. The government's top officials have acknowledged that the following wave may bring fresh obstacles. An examination of the components of the cabinet-approved '23,123 crore Covid preparation package' reveals a change in the government's objectives. By well preparedness India has resulted in comparatively less effect for third wave.

The COVID-19 pandemic has had a considerable influence on international trade as well as economic variables such as GDP, private consumption, job creation, and new investments. Unexpected economic disruptions caused by temporary limitations on public activities and regional blockades have harmed India.

According to the Ministry of Statistics and Program Implementation's National Statistical Office, India's GDP increased by 4% in fiscal year 2020 but fell by 7.3% in fiscal year 2021. India's GDP growth rate for FY20211 is predicted to be 11%, with a probable rebound in consumption and investment in the third quarter of 2021. (According to an economic survey.)

4.4.2 Detailed impact assessment of the pandemic in India

The world economy has been in shambles since the outbreak of the epidemic, and India is no exception. While the economy began to recover in early 2021, the second quarter was hampered by significant economic and social disruptions brought on by the second wave. However, by June-July 2021, India had begun to lift restrictions and vaccination efforts had been expanded.

On the first day of Covid Wave One in 2020, India's GDP fell 7.3 percent, with sectors like as service and manufacturing experiencing a decline in growth in 2020. In the second wave, growth returns to positive territory.[7]

[7] Ibef.org. (2019). *Business Opportunities in India: Investment Ideas, Industry Research, Reports | IBEF*. [online] Available at: https://www.ibef.org.

Impact assessment:

Time period	India GDP% Growth	Services GDP% growth	Manufacturing GDP% growth	Agriculture GDP% growth
FY 2021 (Covid-19 first wave)	-7.3%	-16%	-7.2%	3.4%
% Contribution to overall GDP	Nil	55%	17.4%	17.8%
FY 2022 Expected impact	8.2-9.3% (overall growth owing to base impact, although rating agency predictions have been lowered	Lower than the first wave	Lower than first wave	Higher than first wave

Table.3 Covid Impact assessment

Source: IBEF

4.4.3 Indian vaccines:

Made in India vaccines can be categorized into the following five groups:

1. Vaccines based on genetic material (DNA or RNA): These employ one or more coronavirus genes to elicit an immune response.

2. Vector-based vaccines: These employ other viruses (for example, adenovirus, which causes the common cold) to transfer coronavirus genes into cells and elicit an immune response.

3. Protein-based vaccines: These elicit an immune response by using a coronavirus protein or a protein fragment.

4. Weakened or inactivated viral vaccines: These induce an immunological response by using a weakened or activated type of coronavirus.

5. Repurposed vaccines: These are already licensed and used for other illnesses and are being studied for their role in COVID-19 virus prevention.

Countries that do not manufacture vaccines have rely on supply from other countries to inoculate their populations. The World Health Organization's (WHO) shared vaccination pool is insufficient to fulfil global demand. As a result, the large disparity in immunization rates throughout the world are hardly unexpected.

At a time when access to vaccines to combat the spread of COVID-19 is a top concern for all countries, the role of global vaccine manufacturers has become critical. India plays a significant role in this respect. India, known as the "global pharmacy," has excellent local production capabilities for finished pharmaceuticals, biologics (such as vaccines), and other health items (e.g., surgical products). The country is a significant exporter of medicines and vaccines to key global markets. India, the world's eleventh largest exporter, contributed for 2.6 percent of global pharmaceutical exports in 2019. In the same year, the country accounted for 3.9 percent of worldwide vaccine exports as the seventh largest supplier of vaccines.

COVID-19 vaccinations produced and supplied by Indian pharmaceutical firms such as the Serum Institute of India (SII), Bharat Biotech, and Dr. Reddy's Laboratories are being utilized to battle the pandemic in India and many other countries. Other local vaccines, like Biological E, Gennova Pharmaceuticals, and Zydus Cadilla's ZyCoV-D - a needle-free vaccination for children over the age of 12 - will be accessible for local and worldwide usage in the near future. India's domestic pharmaceutical firms' effective international relationships have a lot to do with the country's status as a global provider of vaccines. The partnership between AstraZeneca and the SII in the production of the Covishield vaccine is well known. Covishield has been WHO-certified for emergency use and is used in a number of countries.

Vaccine collaborations (International):

In collaboration with the Russian Infrastructure Development Fund, Dr. Reddy's Laboratories is distributing the Sputnik-V vaccine created by Russia's Gamaleya National Research Laboratory in India (RIDF).

More collaborative immunizations are on the way, including a Johnson & Johnson vaccine produced by Biological E. It will be a game changer since it is the outcome of the Vaccine Partnership, which was founded by the Quad group of countries — the United States, India, Japan, and Australia — to manufacture and transport vaccines throughout the vast Indo-Pacific region.

Collaborations between companies (B2B) have been crucial in bolstering India's capacity to be a key worldwide player in the fight against COVID-19. These collaborations ensure that India does not run short of vaccines at home. The only option for India and other rising economies to achieve such security is to combine foreign finance and marketing resources with local R&D and manufacturing capabilities.[8] These agreements situate India in an ideal position of strength, serving both its own people and the rest of the world.

Benefits to India by collaborations:

COVID 19 was critical in initiating a new cycle of international collaboration in India's pharmaceutical sector. These collaborations have huge benefits for India and the cooperating countries where firms working with Indian pharma are headquartered. This cooperation goes beyond COVID-19 vaccines. Notable examples include Gilead's voluntary licensing agreement with Indian generic manufacturers for the manufacturing of remdesivir, a drug used to treat COVID-19 patients in over a hundred countries, and MSD's (Merck, Sharpe & Dohme) attempts to license locally made Molnupiravir. The agreements emphasize the significance of international business collaboration in assuring access to critical pharmaceutical goods.

[8] India Brand Equity Foundation. (n.d.). *The Journey of Made in India Covid-19 Vaccine | IBEF*. [online] Available at: https://www.ibef.org/research/case-study/the-journey-of-made-in-india-covid-19-vaccine [Accessed 27 Jun. 2022].

No country has enough raw materials, crucial inputs, technical knowledge, manufacturing, financial resources, or distribution networks to avoid these collaborations.

Pharmaceutical sector cooperation is particularly advantageous in terms of developing local skills in terms of overall economic resilience and self-sufficiency. In this regard, the COVID-19 has presented India with the proper occasion and opportunity. The collaboration will ensure that India retains its position as the world's largest manufacturer of vaccines. They will also set the framework for the Indian pharmaceutical sector to become a leader in creating COVID-19 treatment drugs in the future.

Public health security is of crucial national concern to all governments, in addition to being a global issue. The fact that India and its primary geopolitical allies — the US, Japan, the UK, Australia, and Canada – have chosen to work to enhance global supply of health commodities underscores the pharmaceutical industry's strategic relevance. Drugs will undoubtedly act as a springboard for broader international partnerships between governments, with the world's finest democracies working together to combat the COVID-19 scourge.

COVID-19 has put India in an excellent position to engage in pharmaceutical alliances that will allow for larger global connections. With the best in global pharma keen to collaborate with India, the government must seize the opportunity. This might be India's opportunity to have a substantial impact on global health security.

4.4.4 Investments:

Despite early setbacks, India's healthcare system was able to withstand the outbreak. Various efforts by India in the manufacture of medical equipment, disposables, pharmaceuticals, and the most recent vaccination initiatives have positioned India as a worldwide leader. India not only met local needs, but also came up big and helped neighbouring countries. As a result, the healthcare industry looks to be a promising investment opportunity. The following are a few factors that are encouraging future investments in the area:

Medical infrastructure in Tier II and Tier III:

Shortages like as the needed number of beds or access to modern technology discovered during the pandemic's worst-hit times underscore the necessity for a healthcare emergency prepared for similar disasters in the future days. Hospital chains are increasing their capacity,

particularly in Tier II and III cities. Multiple hospital chains have begun to emerge in these cities, setting up small clinics and cooperating with notable local doctors. This is also compatible with the government's aim of expanding hospital beds per thousand people and narrowing the accessibility gap.

Health insurance awareness: There has been an increase in awareness about health insurance products in recent years, and more people are investing in health insurance each year.

Policies by the Government:

Despite having been planned before to the outbreak, the government's attempts to offer universal health coverage have expanded through 'Health for All' and programmes such as Ayushman Bharat and the National Digital Health Mission. These policies, which are intended to make healthcare more inexpensive and accessible to the general population, enable private actors to broaden their reach and presence.

Medical tourism:

The healthcare industry in India is appealing to international patients for the availability of high-quality treatments at lower rates than in Western Europe or the United States. As of 2019, Bangladesh has the largest number of medical foreign tourist arrivals, with 22%, followed by the Maldives, Afghanistan, and Iraq, with 17%, 9%, and 8%, respectively.

Use of technology:

Online consultations and technical platforms are becoming increasingly popular. The Ministry of Health and Family Welfare launched the 'E Sanjeevani' app, an integrated web-based telemedicine system, in August 2019. Its goal is to increase healthcare parity in India by closing the gap between urban and rural areas.

4.4.5 Relief packages:

In the aftermath of COVID-19 and following lockdown restrictions, the Government of India offered many fiscal and monetary relief measures to boost growth and to establish a self-sufficient India. On June 28, the Union Finance Minister announced a variety of steps to help various industries affected by the pandemic's second wave. The 84.9 billion USD relief and stimulus package focuses on strengthening healthcare facilities, offering low-interest credit loans to small enterprises in agriculture, exports, and tourism, and temporarily cancelling visa

fees in order to attract international tourists. These actions will help small companies and self-employed people survive and grow their operations. The efforts will stimulate economic activity, promote production and exports, and therefore create jobs. The administration is dedicated to implementing changes in the country, such as a result-linked power distribution plan and modernized processes for PPP (Public-Private Partnership) projects and asset monetization.

There is also a fourth addition to the relief measures offered to individuals and companies as part of attempts to stimulate the economy in the face of the epidemic. The relief package includes 17 measures, which includes extra subsidies for DAP (di-ammonium phosphate fertilizer) and P&K (phosphorus (P) and potassium (K)) fertilizers, as well as the continuation of the Pradhan Mantri Garib Kalyan anna Yojana (PMGKAY) till November 2021.

Loan Guarantee scheme:

Under the current rescue plan, the government established a credit guarantee scheme for COVID-affected industries and committed Rs. 1.10 lakh crore (US$ 14.76 billion). This package includes Rs. 50,000 crore (US$ 6.71 billion) to the health sector and Rs. 60,000 crore (US$ 8.05 billion) to other sectors. Except for eight major centers, the loan guarantee plan is designed to scale up medical infrastructure in undeveloped regions for both extension and new health/medical infrastructure projects.

Public health strengthening:

The government has committed Rs. 15,000 crore (US$ 2 billion) for the Emergency Health Systems Project in 2020-21. This resulted in a 25x increase in COVID-dedicated hospitals (7,929 COVID health centers and 9,954 COVID care centers were created), as well as a 7.5x increase in oxygen-supported beds. In addition, the number of ICU and isolation beds grew by 45x and 42x, respectively.

4.5 Challenges:

Despite being known as the "pharmacy of the world," the pharmaceutical industry failed to deliver medications when needed because of the obstacles the pharmaceutical sector encountered as a result of the epidemic.

1. Pharmaceutical processing facilities used at reduced capacity.
2. Industries were underused as millions of workers returned home.

3. In Indian pharma, a disrupted supply chain hampered the availability of services such as raw materials and packaging resources.
4. There are 3 major Cities that supply medicines all over India i.e., Goa, Sikkim and Baddi. Due to limited transportation options, drug transit became impossible, hurting both dealers and suppliers.
5. In places that are highly populated are worst hit by corona virus during every wave that resulted shortage of Hospital beds, oxygen supplies, Medications, accommodations in morgues and crematoriums.

4.6 India is preparing to take the lead in the post-pandemic world.

This is an opportunity for India's pharmaceutical industry to capitalize on its strengths and undertake significant changes in order to re-ignite innovation-led industrial growth and meet the target of US$130 billion by 2030.

COVID-19 has clearly emphasized the need of a strong health-care system, the absence of which may jeopardize a nation's economy and society. As India continues to tackle COVID-19 and stabilize its economic growth trajectory, the government should apply lessons learned and best practices from the pandemic's struggles. It is crucial to build the necessary healthcare infrastructure and make it accessible to the whole community.

The Indian pharmaceutical industry has contributed significantly to the country's healthcare and economic outcomes. The pandemic has accelerated the industry's reaction to a variety of potential and challenges. While India's rising trust gap with China gives an opportunity, other nations like Vietnam and Malaysia are increasing their competitiveness. China also supplies two-thirds of India's bulk pharmaceutical and drug intermediate imports.

To emerge as a leader in the post-pandemic era, the sector must capitalize on its strengths while also making a huge leap toward innovation. New capabilities must be implemented into corporate operations to enhance productivity and assist industry in moving up the value chain. The government must also offer the necessary enablers as well as a favourable business environment.

The other sections of the report look at the country's potential, problems, and future measures in achieving its objective of equitable and sustainable healthcare access. It also provides insight into how the sector may achieve its objective of being the chosen global source of new medicines.

5. FUTURE PHARMA

Future of Pharmaceutical Industry and role of India in it:

The pharmaceutical business is now nearly 30% larger, valued at $5.4 trillion and is among the top five in the world economy in terms of production and exports.

Despite widespread worries about sluggish, delayed innovation and ongoing cost restraints in pharmaceuticals, it is expected to develop significantly in the coming decades.

Between 2023 and 2060, the pharmaceutical industry's overall income will quadruple in real terms.

- Short-term growth is fuelled by rare illness medications and biologics.
- Long-term growth is fuelled by nucleic acids and implantable devices.

Major advances will continue to fuel the sector's scale and growth, with favorable consequences for global health.

Since the 1970s, when GSK Pharmaceuticals introduced the first blockbuster drug, cimetidine, both industry and regulators have been assured that the "blockbuster model" was the way forward for the industry: drug discovery and development were notoriously risky, costly, and time-consuming, and generic manufacturing would significantly reduce the cost of innovative drugs after patent expiration. New 'blockbuster' drugs, on the other hand, would be developed at regular intervals, and the money earned during their patent life would be more than enough to pay for future R&D. Consequently, the industry would continue to develop innovative medications that would be affordable to everybody after a short patent period.

For several years, this interpretation was correct, as a steady stream of new "blockbuster" pharmaceuticals came from the R&D divisions of several of the leading research pharmaceutical organizations. Unfortunately, this did not last, as it was discovered that simply "pulling the handle" of the R&D machinery would not guarantee the appearance of any new things, much alone a regular supply of new "blockbusters." In reality, pharmaceutical R&D efficiency has been falling for a long time. Since 1950, the number of new pharmaceuticals approved per billion US dollars spent on R&D has approximately halved every nine years, falling by an order of magnitude in inflation-adjusted terms.

The industry's initial answer to these difficulties was consolidation, with a series of large and subsequent mergers and acquisitions followed by a series of exceptionally large ones. The 30 research pharmaceutical businesses that existed in 1989 have merged by 2010, leaving just nine. Pfizer bought American Cyanamid, American Home Products, Pharmacia, Upjohn, Warner-Lambert, and Wyeth on its own.

5.1 Road Ahead

Over the next five years, India's medication spending is predicted to increase by 912 percent, driving the country into the top ten in terms of medicine consumption.

Better future domestic sales growth is also dependent on firms' capacity to adapt their product portfolios to chronic drugs for ailments including cardiovascular disease, diabetes, antidepressants, and cancer, all of which are on the rise.

The Indian government has taken a variety of efforts to reduce expenditure and healthcare costs. The rapid introduction of generic drugs into the market remains a goal, which should benefit Indian pharmaceutical companies. Pharmaceutical companies benefit from the emphasis on rural health programs, life-saving drugs, and preventative vaccines.

The adoption of managerial skills by domestic firms, as well as the expansion of Indian talent, has made India a preferred site for FDI. This is a positive FDI spill over effect cycle. Human capital has been improved because of prior FDI infusions, attracting further FDI.

Opportunity for India’s pharma sector to be the frontrunner:

What opportunities does the future present?

India's pharmaceutical business has been at the forefront, providing services to the country by ensuring medicine supply and manufacturing continuity. The presence of several global pharma businesses operating in India with an agreement on the R&D front with India's major corporations has been offering therapeutical assistance for lifelong diseases with the advantage of supplying revolutionary pharmaceuticals by their parent organizations. These worldwide corporations are a crucial element of India's pharma sector because of their inexpensive production, manufacturing, R&D, and development costs. These firms have played a vital role in the creation of CROs and the worldwide trials that are being done here.

Industry groups such as the Indian Pharmaceutical Alliance, OPPI, and others should take the initiative to reach out to people directly by running awareness campaigns, educating people on the necessity of clinical trials, and considering academy-industry collaboration. The goal is that the pharmaceutical business strives to improve healthcare. Despite the fact that pharmaceutical corporations are in the healthcare sector, their first goal should be human care.

According to 2019 research by the Indian Pharmaceutical Alliance (IPA), yearly sales would exceed USD ($) 90 billion by 2030, up from $38 billion in 2019. In the 'best-case' scenario, annual sales growth of 11 to 12 percent would bring revenues to $65 billion by 2024 and $120-130 billion by 2030.
Opportunities for advancement include:

- **Rising domestic consumption:** The government's objective of universal health care through the National Health Protection Scheme, as well as other government programmes, such as the creation of outlets offering cheaper generic pharmaceuticals, are all expected to contribute to larger volumes. Nationwide pharmaceutical spending in India is predicted to rise by 8% to 11% between 2019 and 2023, reaching $28-32 billion[9].

- **Loss of exclusivity:** Branded pharmaceuticals with total sales of $139 billion in developed nations will lose exclusivity between 2020 and 2024. This would enable Indian generic and biosimilars makers, as well as contract research organizations and manufacturers, to capitalize on their worldwide market domination.

- **Riding the wave of biosimilars:** By 2030, the worldwide biosimilars industry is anticipated to be worth $60 billion. If you can acquire only 10% of that market, the Indian pharmaceutical business might increase by 13%. Because biosimilars are made in more intricate ways than small molecule generics, the industry must address quality and regulatory compliance issues by implementing India-specific measures in tandem with global best practices in order to fully achieve this potential.

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[9] IndianCompanies.in. (2019). *Top 10 Pharma Companies in India 2020*. [online] Available at: https://indiancompanies.in/top-10-pharma-companies-in-india/.

Innovative drugs and 'Next Gen' therapies: With three to five new biologics coming to market or in late-stage clinical trials each year through 2030, the Indian pharmaceutical industry is building its pipelines of innovative medicines. This is predicted to increase the industry's value to $130 billion. With customized medicines gaining center stage in the treatment of chronic and uncommon illnesses, the worldwide cell and gene therapies market is predicted to rise at a CAGR of more than 36% between 2019 and 2025. This is a potential opportunity for the Indian pharmaceutical sector if it can make significant investments in this field over the next 8 to 10 years[10].

- **World's reliable drug supplier:** APIs are imported by Indian medical industries about 60%-90%. (Depending on API types). This reliance on other nations, as well as the interruption of supply lines caused by the COVID -19 pandemic, has sparked demands for self-sufficiency, with the goal of making India the world's most dependable provider of pharmaceuticals. The government's recent plan to spend $1.3 billion in three bulk medicine mega parks, as well as production incentives for 53 major bulk medications, may help the sector become self-sufficient in the next five to eight years[11].

- **Incentives for R&D:** The Indian pharmaceutical sector has long advocated for improved government incentives to help them compete with global corporations in creative R&D. In 2003, the Indian Pharmaceutical Alliance (IPA), which formed 11 major domestic firms, submitted to the Indian government a pre-budget memorandum describing the breadth of tax cuts that it desired. Their recommendations included tax breaks for performing clinical trials in other countries, research collaborations with educational institutions, and a method to help them in establishing the fundamental R&D infrastructure required for new operations. The international focus of these ideas was mostly motivated by Indian corporations' desire to expand their presence in the US market.

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[10] www.investindia.gov.in. (n.d.). *Ease of Doing Business in India During COVID-19 |Invest India*. [online] Available at: https://www.investindia.gov.in/siru/government-indias-measures-boost-business-improve-eodb-welcome-fdi-during-covid19

[11]Deloitte United States. (n.d.). *Challenges in the Emerging Cell Therapy Industry | Deloitte US*. [online] Available at: https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/challenges-in-the-emerging-cell-therapy-industry.

The price of completely clearing a formulation medicine for the US market is estimated to be one million dollars. The Indian government has recognized that it must respond to these demands in order to strengthen its domestic sector; nevertheless, while it has accepted some of the industry's requirements, it has adopted a cautious approach to altering its R&D policy. Nonetheless, it has established tax breaks to encourage creative R&D, including a ten-year tax break for R&D-related operations, and it has recently exempted all pharmaceuticals and materials imported or manufactured for clinical trials from customs and excise charges.

- **Moving ahead with innovation:** According to total levels of R&D expenditure, there are indicators that the Indian pharmaceutical industry's R&D intensity is increasing. India's low-cost manufacturing facilities and huge scientific base will assist fuel this trend over time. Although, creative R&D remains a long-term goal, Indian firms are expected to increase their generic activities in the near future. This is due to the fact that a number of high-profile pharmaceuticals have gone off patent, creating an opportunity for numerous Indian businesses to manufacture generic equivalents for sale in the US and European markets. For example, the percentage of Dr. Reddy's (Indian multinational pharmaceutical company) total income earned by exports increased from 36% in 1998 to 46% in 2001. The development for Aurobindo (Indian pharmaceutical manufacturing company) was more extreme, with export share growing from 32% in 1998 to 55% in 2001.The work in the generics industry has a good impact on Indian enterprises since it allows them to obtain more expertise working in global markets and working with regulatory bodies in these countries. Although generics will account for most of the activity in the next years, creative R&D is more than just a goal. Several large Indian businesses are developing new medication pipelines and innovative delivery systems, which will most likely be supported by income from generic product sales.

Current Challenges & Improvement Areas:

India is unquestionably a viable destination for FDI, but there are still some obstacles and opportunities for development. India will not become the main destination for FDI unless these sectors are improved. India is putting a premium on political and social stability, as well

as a stable regulatory framework. Despite the clear benefits of FDIs, bigger FDIs in India face several hurdles, including:

- **The equity challenge:** While India is developing at a far faster rate than in the past, it is obvious that growth has been unequal. This shows that, while more metropolitan areas have been explored, the poorer areas have been underutilized. To get a genuine picture of growth, make sure that rural and urban regions have nearly the same level of development. As a consequence, economic growth is balanced while social equality is encouraged[12].

- **Political Challenge:** The political structure must assist nations with foreign investment. This might be found when foreign investors submit their case for more FDI capital in sectors such as banking and insurance. As a result, there must be a point of agreement between the Parliament and the foreign countries that are investing in India. This would accelerate the country's developments in the FDI sector.

- **Resource challenge:** India is well-known for having an abundance of natural resources. There is labor as well as considerable fixed and working capital accessible. Simultaneously, certain resources are either underutilized or unutilized. Both rural and urban locations have easy access to the resources. The emphasis is on infrastructure expansion over the next ten years, which will cost around $150 billion. This is the first step in removing impediments to greater FDI.

- **Federal Challenge:** Among the key issues confronting bigger FDI is necessity to accelerate the adoption of policies, rules, and regulations. The major aspect is to support policy execution throughout all Indian states. As a result, requesting similar speed in policy implementation across the India's states is critical. India should prioritize poverty alleviation, trade liberalization, and banking and insurance reform. The obstacles that greater FDI face are not limited to the ones listed above, because trade connections with foreign investors will continually bring new challenges in investments.

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[12] KOPPIKAR-MOORTHY, A. (n.d.). *Understanding the coming challenges to India's pharma sector*. [online] ORF. Available at: https://www.orfonline.org/expert-speak/understanding-the-coming-challenges-to-indias-pharma-sector-66556/.

> COVID-19 (Corona Virus Disease) is a good example of how the environment can be VUCA (Volatile, Uncertain, Complex and Ambiguous). In future it will be a business case for management classes and any business forecast or future cast will need to include a section for whether one has proactively prepared for a COVID-19 like situation. Though however well we may prepare for such an eventuality, when it hits us, we will always be unprepared, as it is so unpredictable. The pharmaceutical industry was initially caught unawares but being resilient it was able to bounce back to some extent. De-growth has happened more with the acute care segment, but the chronic care segment is not de-growing to the same extent. ("Life Science World")

Trends that will rule the pharmaceutical sector

Artificial Intelligence

Chatbots, smart homes, self-driving vehicles, surgical bots, and other innovations are being driven by artificial intelligence (AI) and machine learning. The worldwide artificial intelligence software industry is expected to increase from $10.1 billion in 2018 to $126 billion by 2025, according to studies. AI has the potential to open a multitude of options for the pharmaceutical business, resulting in a drastic transformation in the pharma sector's innovation paradigm. Pharmaceutical businesses across the world are using powerful machine learning algorithms and AI-powered technologies to speed up the drug discovery process. Adoption of AI can increase the success rates of new pharmaceuticals, make treatments and cures more inexpensive, and, most crucially, lower operating expenses.[13]

E-Pharmacy

E-pharmacies proved to be a critical instrument in the fight against the epidemic, making life-saving pharmaceuticals available in every single corner of our country. Since the COVID-19, it has been non-stop activity on the ground for e-pharmacies throughout India.

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[13] Times of India Blog. (2021). *What are the trends that will rule the pharmaceutical sector in 2022?* [online] Available at: https://timesofindia.indiatimes.com/blogs/voices/what-are-the-trends-that-will-rule-the-pharmaceutical- [Accessed 27 Jun. 2022].

They have been in the frontline of delivering life-saving medications and other healthcare necessities to people's homes.3.5 million families in the nation received medications from e-pharmacies during the epidemic. During FY20, the industry attracted $700 million in investment and employed over 30 thousand trained people. With the increase in popularity, it is projected that the expansion of e-pharmacies will accelerate, and the total number of homes serviced will surpass 70 million by 2025.

Precision Medicine

Personalized or precision medicine is developed in response to a specific patient diagnosis. The primary goal is to ensure that the medicine is tailored for maximum efficacy and patient outcomes. Precision medicine has proven to be more successful than alternative treatment choices. Precision pharmaceutical manufacture necessitates specialised and smaller-scale facilities than conventional industries. Despite the difficulties for pharma makers, this is a trend that is expected to continue as technologies are developed.

Clinical Trials

Clinical trials are predicted to change in the next years as a result of digitization. With matching trials to patients through health record analysis to enhancing drug adherence, studies will become more global and remotely directed. Researchers are already improving patient well-being by using essential data with Internet of Things (IoT) technology and self-monitoring applications. With the rapid use of such technologies, the transfer to equivalent technology for clinical trials is projected to be quite smooth. In the near future, new technologies like as digital pills will improve monitoring process accuracy. Trackable medications, which feature ingestible sensors and cameras that allow medical researchers and healthcare practitioners to remotely monitor patient's condition, are already in the works.

Research and Development

The pandemic-related problem has undoubtedly focused emphasis on the need of pharmaceuticals. Pharmaceutical businesses all across the world are more concerned than ever about ensuring that research and development is successful. There is a continual attempt to improve efficiency and effectiveness in order to address the demands of patients while also sustaining the bottom line. For example, there is research being conducted to find drugs that can

improve patient's experiences and standard of living in a more comfortable way. This necessitates a review of pharmaceutical firms' research and development procedures to guarantee they are improved and focused.

There are major improvements and implementations are taking place in every aspect of pharmaceutical sector from discovery throughout clinical trials and development and advancements in therapy techniques. While the pandemic did not generate a revolution in the pharmaceutical business, it did speed fast change and create a feeling of urgency among healthcare and pharmaceutical experts, making the whole environment more amenable to change and digital transformation. Covid wave is the big hit to India to understand functional difficulties in treating huge population in emergency situation. The India pharmaceutical sector has adapted, innovated, and is anticipated to undertake a sea of change in the next years, from hi-tech implementations such as Artificial Intelligence, precision medicine, innovations in clinical trials to increasing investments in Research and development to the refinement of the product life cycle through digitisation. These trends that will have a significant impact on the growth of Indian pharmaceutical industry in coming years.

5.2 Conclusion

This study was made to provide that FDI is frequently seen as a driving force in the Indian pharmaceutical business and plays a key role in developing Indian economy. FDI delivers financial and managerial resources, access to large markets, technical assistance, and strategic assets such as brand name, allowing host enterprises to acquire both local and international comparative advantages. Because of favorable government policies, FDI in the pharmaceutical sector is increasing in the country. Stronger intellectual property (IPR) rules are luring innovative technology and R&D to the Indian pharmaceutical sector. It has been recognised that there is considerable opportunity for FDI concentration in the industry, particularly in terms of export and profitability. During the period 1991-2019, the sector's rate of return increased significantly. According to traditional theory, FDI expects vast profits. According to such hypothesis, foreign investment in the Indian pharmaceutical business should increase. However, there has been little statistical evidence to support this perspective. This suggests that structural limitations continue to play an enormous influence in FDI inflows to India. The economy is yet to create the investment climate essential for greater capital inflows. Furthermore, empirical research has revealed that the majority of the pharmaceutical sector's characteristics (Pharmaceutical investment, total output exports, and profit) are not functionally connected to FDI inflows. FDI inflows into the pharmaceutical industry, on the other hand, are lured by the high rate of return. All this data pointed to market flaws, which must be the largest impediment to India's ability to excel in the globalized market. The foreign direct investment route is the fastest, safest, and most effective mode of bringing in the most modern technology in India.

As substantial patents expire in the next years, there will be enormous potential for Generic Medication producers, leading to global majors shifting toward quality Generic drug production. India is a generics hub that will draw significant FDI inflows in the next years. A significant section of the population in undeveloped and underdeveloped nations is dependent on the Generic Pharma Industry for the most fundamental requirement, namely healthcare.

Suggestions for future growth of Indian pharma:

1. The Indian pharmaceutical sector is flooded with generic drugs. Therefore, FDI policies should be designed to promote drug research and knowledge transfer to enhance the R&D capabilities of Indian companies.

2. The medicine price strategy should also be aligned with the FDI policy, so that the drugs reach as many people as possible while avoiding losses for pharmaceutical firms that have spent a significant amount of time and money on research.

3. Government investment on healthcare should be increased from the present 3% of GDP, with a focus on upgrading the country's healthcare infrastructure. Overall, the Indian Pharma industry attracts 5% FDI, which is lower than in other industries.

4. The government should encourage greenfield FDI more to increase foreign capital inflows and create new employment opportunities.

5. Governments at all levels should play an active role in distributing information regarding IPRs (Intellectual Property Rights) and practical industrial strategies. The Chinese example should be used to draw lessons, since systematic efforts were made to educate bureaucrats, policymakers, and business about the WTO and product patents in the pharmaceutical industry. India would need to tighten the patent examination process and speed up the processing procedures.

6. False pharmaceuticals are a sensitive problem that affects not only the degree of FDI but also people's health and the prestige of the country's pharmaceutical trade interest. The government should take steps to combat the problem of counterfeit medications.

As a result, the government should link the medication price control law to FDI policies, which will assist to recruit, sustain, and expand the pharmaceutical business while also protecting low-income people from unfair medical practises. The government strengthens

intellectual property protection regulations, attracting the most modern technology and R&D in the sector.

The Department of Pharmaceuticals' "Pharma Vision 2020" might be viewed as a positive move in this direction. It is critical to create a favourable investment climate in order to attract more FDI in the pharmaceutical business. New FDI policies should be investor-friendly in terms of attracting greenfield investment and to encourage domestic enterprises to participate in R&D and technological advancement by offering appropriate fiscal and financial incentives to develop them and expand their network by creating new employment opportunities in the market. As a result, the Indian pharmaceutical business will continue to be one of the fastest expanding in the world for many years to come.

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