

INDIAN PHARMACEUTICAL SECTOR: TRENDS AND POLICIES**Anu****Junior Research Fellow, Department of Economics, Indira Gandhi University,
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University, Meerpur, Rewari, Haryana, India.****Email: dshooda.igu@gmail.com****Abstract**

The pharmaceutical industry has become the most important sector of the economy. It works for the well-being of the people and their development to provide life-saving drugs and jobs. It is the leading sector of the Indian economy after independence. The economic reforms and Trade-Related Aspects of Intellectual Property Rights (TRIPS) have carried many changes to the pharmaceutical sector. In 2022, the Indian pharmaceutical industry (IPI) ranks 12th among all exporters worldwide. At the global market, it ranks 3rd in terms of volume and 14th in terms of production by value. It was the largest provider of generic drugs; supplies more than 50 percent of the world market demand for different vaccines. Also, providing 40 percent of generic drugs demand in the US market and 25 percent of all medicines in the UK. This study is based on secondary data available and it covers twenty-two years of trade data of the Indian pharmaceutical industry from 2000 to 2022. The purpose of this paper is to analyse the trends of export and import in the Indian pharmaceutical industry during post-TRIPS, especially during COVID times. Further, the paper will try to examine the data on export-import and find out the top destination to trade and the Production Linked Incentive Schemes in the pharmaceutical sector. The present paper concludes that exports of the Indian pharmaceutical industry have emerged post-TRIPS. Hence, it can be claimed that the patent act influenced the pharma sector trade. Now, the USA and the UK are both developed countries on the top destination of the Indian pharmaceutical sector for exporting generic drugs.

JEL Classification:F1, F13, L50, O34**Keywords:** Pharmaceutical industry, patents, formulation drugs, government incentives, domestic producers**I. Introduction**

The Indian pharmaceutical industry has been making significant development in terms of product manufacturing and exporting drugs. In the year 2013, the Indian pharmaceutical industry (IPI) ranked 3rd in terms of volume and 10th in terms of value at the global level. Its trade was US\$33.9 billion having a CAGR of about 13 percent up to 2013-14 (Akhtar, 2013). In 2022, IPI ranks 12th among all exporters worldwide. It ranks 3rd in respect of volume and 14th in production by value in the global market (Ministry of Chemicals and Fertilizers

Government of India, 2022). This sector has grown US\$19.2 billion and US\$6.3 billion respectively, in 2018-19. However, in 2020 Indian pharmaceutical industry was the largest exporter of generic drugs, it supplies more than 50 percent of the global demand for numerous vaccines. Also, it provides 40 percent of generic drugs demand in the US market and 25 percent of all medicines in the UK (Motkuri & Mishra, 2020). The evolution of the Indian pharmaceutical industry can be classified into two phases; the first phase is pre-patent regime and the second one is post-patent regime after 2005 (Rani, 2020). According to Pradhan, (2011) Indian generic exports have increased after the replacement of process patents with product patent regimes. The aspect of having technological skills for producing new drugs and cost competitiveness contributed India to becoming a pharmacy of the world (Bose, 2017). The off-patent drugs valued at billions of dollars in near future would provide a big opportunity for Indian generic domestic producers. The focus of exports has been shifted from intermediates and bulk drugs to formulation drugs (Joseph, 2009). Adopting a product patent system was very beneficial for the Indian pharmaceutical sector. It played the main role in the growth of the Indian pharma industry (Lalitha, 2002). This paper tries to analyse the trends in the export and import of the Indian pharmaceutical industry during post-TRIPS, to see how patent regime and other factors contributed to its development. The rest of the paper is divided as under: The section II consists of background of the Indian pharmaceutical industry followed by the methodology adopted in section III. The section IV of the paper discusses about the trends of pharmaceutical industry and top destinations of trade. The section V highlights the government incentives to motivate the producers' and at the end the section VI concludes the paper.

II. The background of the Indian Pharmaceutical Industry

The modern pharmaceutical industry in India was started by Indians dated to 12 April 1901 when Acharya Prafulla Chandra Roy established the first Indian-owned drug firm, Bengal Chemical and Pharmaceutical works at Calcutta. Alembic Chemical Works in Baroda was started in 1907 by T.K. Gajjar and Rajmitra B.D. Amin (Pradhan, 2011). The Patents and Design Act has been established in 1911, which provided product patents for new creations for 16 years from the date of application (Chadha, 2009; Kumar & James, 2021; Neogi et al., 2014). In 1947, at the time of independence, foreign companies dominated domestic firms. Domestic firms were only involved in re-packaging drugs made by foreign companies. The government of India was concerned about this situation. In 1970, the government of India appointed Justice N. Rajagopalan Ayyangar to design the patent act. The patent act can be considered an emerging point in the history of the pharmaceutical sector (Chittoor et al., 2008; Lalitha, 2002; Mondal & Pingali, 2017; Rao, 2008). According to the Patent Act of 1970, the only process can be patented and firms were more interested in inventions. It had a seven-year patent term in the pharmaceutical industry (Chaudhury, 2014b; Lalitha, 2002). The World Trade Organisation (WTO) came into force in 1995. After ten years, developing member countries of the WTO adopted the TRIPS agreement in pharmaceuticals and agricultural chemicals for process patent systems (Chaudhury, 2014a). Trade-Related Aspects of the Intellectual Property Rights (TRIPS) Agreement 2005 came into force with special changes reintroduction of product patents, an extension of the patent period from seven years to twenty years and compulsory license for products (Aggarwal, 2021; Chaudhuri, 2021; Rao, 2008). Under the TRIPS, the Indian government has been required to grant product patents in the pharmaceutical sector. The study by (Chaudhuri, 2014b, 2014a) highlighted the evolution of the Indian pharmaceutical industry. The pharmaceutical industry of India is one of the largest and most advanced industries among developing countries. It was a revised version of

the Patent Act, of 1970. TRIPS gives opportunities to Indian firms to use reverse engineering processes and produced low-cost drugs. The real jump-started in the domestic market post-TRIPS. (Joseph, 2012) highlighted the trends and patterns of the Indian pharmaceutical industry. This study described that India became the top exporter of formulation drugs to the US, African and Latin American markets and other developing countries. The authors used secondary data to examine the trends in imports-exports and the production of bulk drugs. The dependence on China for raw materials puts the Indian domestic market in a problem because they face a negative trade balance in raw material drugs. (Mahajan, 2019) revealed the impact of process patents and product patents on growth, trade competitiveness, R&D, investment and comparative advantage and disadvantage. Rani (2020) analysed the data on exports and imports of the Indian pharma sector from 1991 to 2018; available on the Centre for Monitoring Indian Economy. The authors found that the exports of drugs specially formulation drugs were more than the imports of drugs. Manju & Sharma, (2020) examined the export performance of the Indian pharmaceutical industry post-TRIPS. They found that the export performance of domestic firms was influenced by licencing policy, economic reforms and patent regime. Bose (2017) investigated the reasons behind trends of Indian generic drugs to European countries in pre and post crisis of 2008. A comparison has been made between ten countries which have been divided into two groups. Five Countries have been impacted more by the crisis than other less impacted countries. Ten years of data, from 2005 to 2014, were used to enforce the variables. The author has used a correlation function between the growth rate of GDP and per capita pharmaceutical expenditure that were imported from India. More impacted countries have shown a negative correlation between GDP and per capita pharmaceutical expenditure that were imported from India. The study by Kumar & James (2021) revealed a remarkable growth in the performance of the pharmaceutical industry of India. It also recognised the importance of the Indian pharma sector for supplying low-cost generic drugs to both developed and developing countries. It confirmed the view that the exports of the Indian pharma industry have been influenced by a strong patent regime. This study further added a production-linked incentive scheme launched by the government of India. The purpose of this scheme is to make domestic firms self-reliant. Joseph (2009) confirmed that economic reforms and patent regimes impact the pharmaceutical trade in India. It was expected that imports would be increased after economic reforms but the industry produced value-added segments. However, exports of formulation drugs have increased. This study pointed out that in 2005-06, exports have increased from 1648 million dollars to 2185 million dollars due to TRIPS. Mahajan (2019) also arrived at a similar conclusion and revealed emerging trends in the Indian pharmaceutical trade post-IPR regime. Joseph & Kumar (2022) based on the international and national trade agencies' classification of pharmaceutical drugs. It provided a brief analysis of the trends in India's trade in pharmaceutical products. Being solely dependent on China for Active Pharmaceutical Ingredients (APIs) which is the cause of the Indian pharmaceutical industry's trade deficit with China, presents a difficult situation. All these studies claimed the expansion of the Indian pharmaceutical industry's exports post-patent regime. However, no major studies exist that provide a detailed analysis of pharmaceutical trade post-TRIPS and COVID pandemic time. The present study attempts to fill this gap.

III. Methodology

In the present paper, secondary data will be used and the Ministry of Commerce & Industry and Directorate General of Commercial Intelligence & Statistics are the sources of data. Data for pharmaceuticals is collected commodity and country-wise from chapter 30 regarding

pharmaceutical products. The literature review is based on various sources which include annual reports of the department of pharmaceuticals, articles, research papers and reports. The study covers a period of twenty-two years from 2000-01 to 2021-22, based on secondary data. Indian pharmaceutical industry's export-import percentage share out of total India's export has been examined to find the result of the trends in the pharmaceutical industry. The export-import data are analysed to find out the top destinations of the Indian pharmaceutical sector. The percentage share of the countries have been calculated to find the result. Further, this paper also examines government incentives and promotions to increase production in the domestic pharmaceutical sector.

IV. Trends in the pharmaceutical industry

The present paper is an attempt to capture the data on export and import of Indian pharmaceutical industry during the period 2000-01 to 2021-22. The below table 1 shows trends of the export and import in pharmaceutical products during the period 2000-01 to 2021-22.

Table 1: Export-import of pharmaceuticals (INR in Lakh)

Year	Export value	Import value
2000-01	4,31,767.06	68,789.87
2001-02	5,03,510.58	79,434.90
2002-03	6,77,911.10	1,15,209.99
2003-04	7,44,452.62	1,14,987.72
2004-05	9,26,341.59	1,30,277.30
2005-06	10,82,124.37	1,94,913.79
2006-07	14,38,027.37	2,91,382.50
2007-08	16,71,164.90	2,81,855.98
2008-09	23,37,933.54	4,26,218.90
2009-10	24,56,627.07	5,19,663.33
2010-11	30,38,320.35	5,50,446.68
2011-12	40,81,685.87	8,13,114.20
2012-13	54,77,366.87	9,52,244.92
2013-14	67,40,371.23	9,37,138.95
2014-15	70,81,510.40	9,96,129.16
2015-16	84,48,106.41	10,74,208.22
2016-17	86,70,548.95	11,51,503.04
2017-18	85,44,729.55	12,24,113.29
2018-19	1,03,23,992.70	14,58,113.31
2019-20	1,15,47,303.19	16,53,036.52
2020-21	1,43,73,839.00	18,93,435.61
2021-22	1,44,58,085.76	25,60,296.29

Source: Ministry of Commerce and Industry (Government of India)

The above table 1 highlights the year-wise export-import data of the pharmaceutical industry. The data have been compiled from the Ministry of Commerce and Industry for the study

period 2000-22. The export-import values are shown in the Indian currency. Indian pharmaceutical exports were increasing slightly before 2005 but they quickly grew after that. The primary cause of this variation was changed in patent act. In the year 2019-20, pharmaceutical industry trade increased on a global scale. During the pandemic, the demand for pharmaceutical products expanded sharply. Therefore, exports and imports, both have increased. The Indian pharma industry is known as an export-oriented industry. Thus, it produced off-patent drugs at low prices. It completely depends on other countries for bulk drugs. So, the paper observed that in values terms, exports and imports as well increased during the pandemic time.

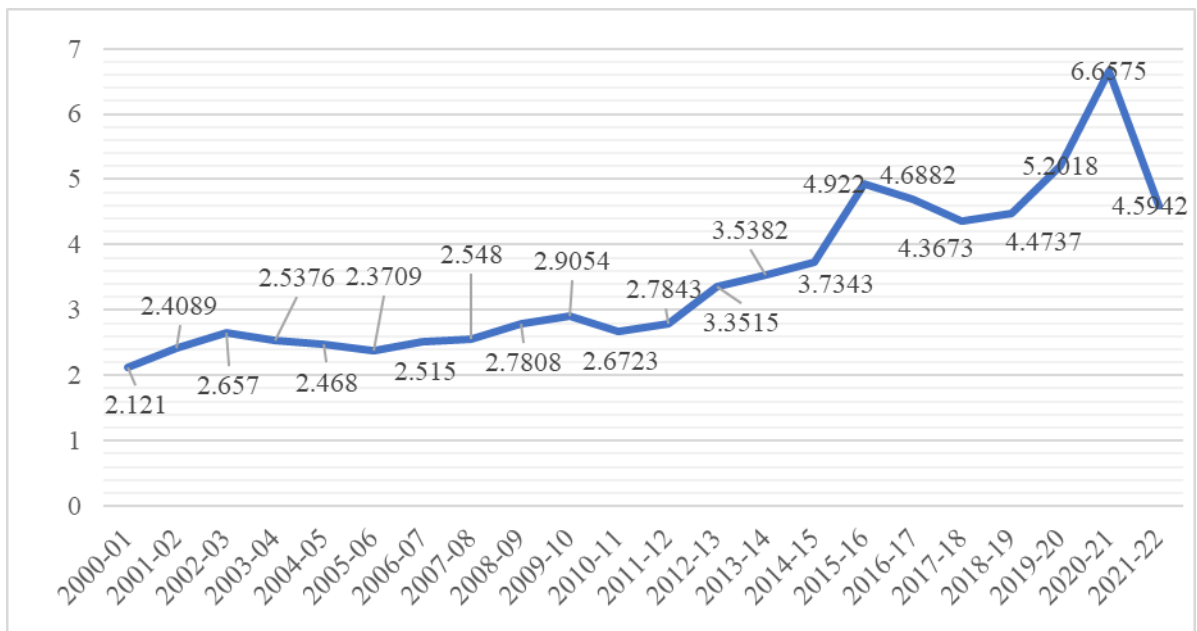


Figure1: Trends in exports of Indian pharmaceutical industry (In percentage)

Source: Ministry of Commerce and Industry (Government of India)

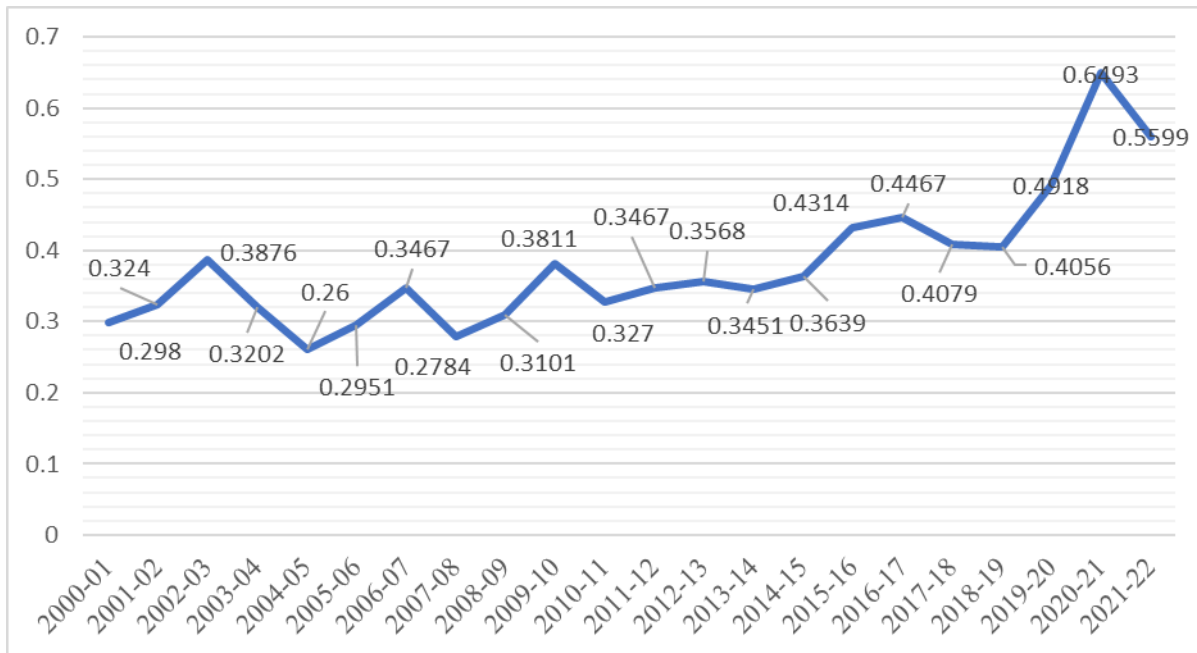


Figure2: Trends in imports of Indian pharmaceutical industry (In percentage)

Source: Ministry of commerce and industry (Government of India)

Figure 1 exhibits the trends of Indian pharmaceutical exports share in the percentage of India’s total export value during 2000-01 to 2021-22. The trends have emerged over the period. However, in the initial years, 2000-14 a low movement in share from 2.12 percent to 3.73 percent is shown. Pharmaceutical exports share was stagnant or stable before 2015-16. In 2007-08, export-import both were down because of the financial crisis worldwide. In 2015-16 exports share has been increased from 3.73 percent to 4.92 percent due to the amendments in the patent regime. After the introduction of product patents, domestic firms manufactured off-patent drugs at low prices. During the period 2015-16, exports to the US have grown over 27 percent and have contributed over 32 percent to the total. The US is the largest exporting partner of India by country. The pharmaceutical industry of India has filled the highest number of Drugs master files with the U.S. Food and Drug Administration and by the end of the year 2015, the number of applications were 3820. Thereafter, it has been a little down before 2019. The exports increased rapidly in 2019-20 reflecting a share percentage from 4.47 to 5.20. Probably the COVID-19 pandemic was the reason behind this growth. During COVID 19 period, the Indian pharmaceutical industry emerged very fast due to the low cost of generic drugs. It has exported affordable drugs to both developed and developing nations like the USA, the UK, South Africa and Russia. The share of the Indian pharmaceutical industry is 10 percent in the global market, exporting 60 percent of COVID drugs to more than 200 countries at low prices and holding the 12th position as an exporter at the world level. The share of the Indian pharma sector’s exports has been 6.65 percent in the year 2020-21. However, the Indian pharmaceutical industry has been expanding rapidly. Two of the reasons for that development are that Indian pharmaceutical companies have produced generic drugs and that drug prices are very low in India.

The above figure 2 shows the trends of Indian pharmaceutical import share out of total India’s imports for the period 2021-22 based on available secondary data. It goes up and down due to amendments in the patent act. It is observed that the Indian pharma industry

dependents on China to import bulk drugs. Therefore, some challenges have been faced by the domestic firms due to dependency on a single country for bulk drugs during COVID times. The government has taken many initiatives over the period to decrease dependency on China. Though, there was an increase in imports due to Indian pharmaceutical firms producing generic drugs at low prices. During the study period, the share of imports has been stable rate but it has increased during COVID times.

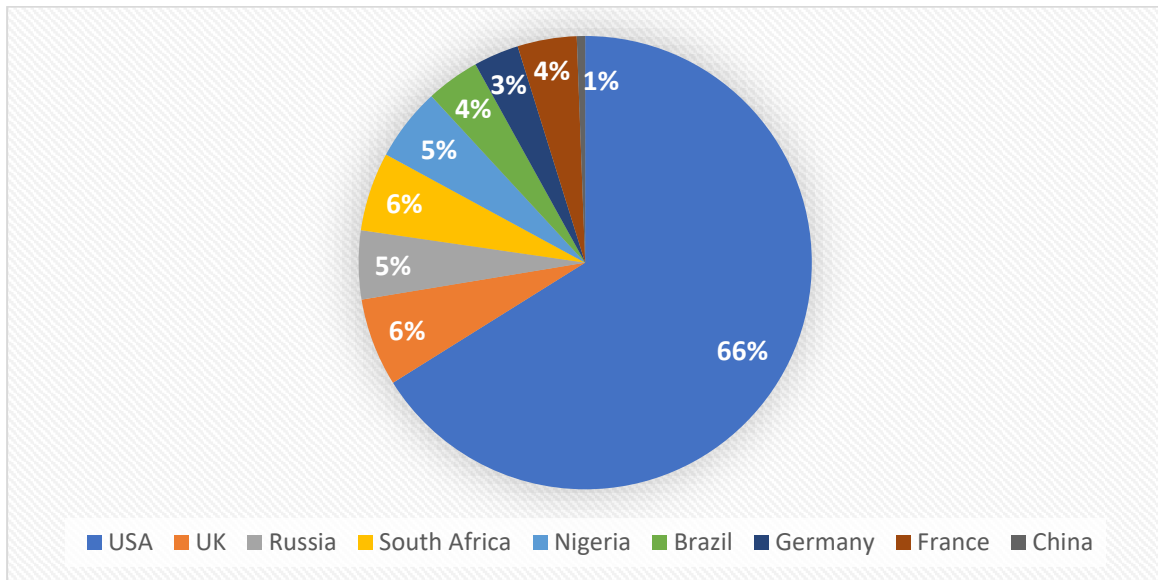


Figure3:Top export destinations of the Indian pharmaceutical industry

Source: Directorate General of Commercial Intelligence & Statistics (DGCIS)

The above figure 3 highlights the top export destinations of drugs from India. The secondary data were employed from the Directorate General of Commercial Intelligence & Statistics. The share of Indian pharmaceutical products in the global market has grown over the years. The USA is the largest place for exporting drugs with 66 percent of Indian pharmaceutical products in 2021-22. The UK stands in second position with 6 percent sharing in Indian pharmaceutical products, followed by Russia at 5 percent, South Africa at 6 percent, Brazil at 4 percent and France also 4 percent.

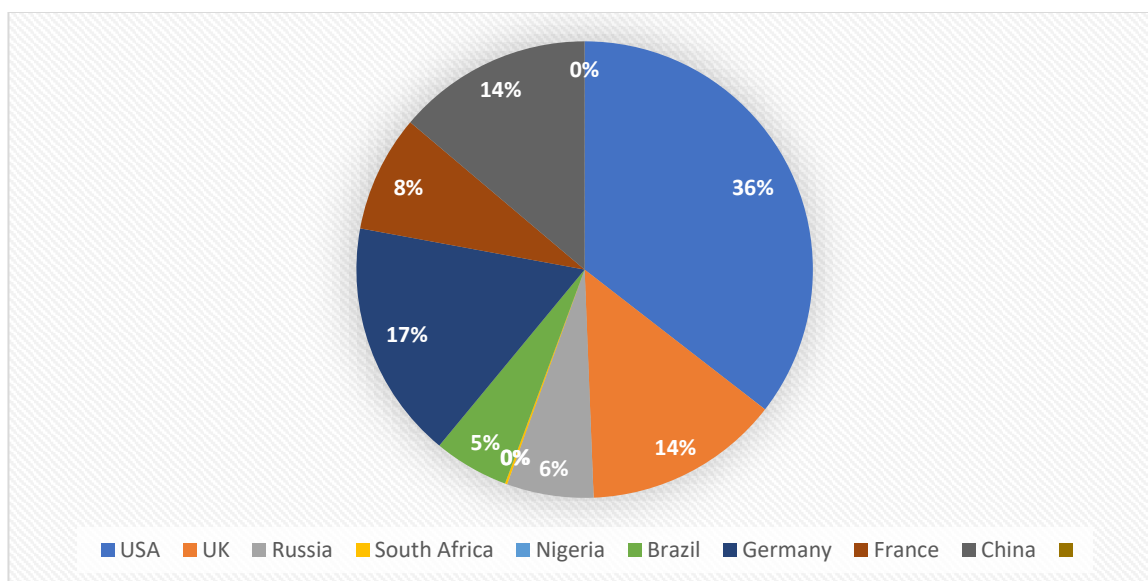


Figure4: Top import destinations of the Indian pharmaceutical industry

Source: Directorate General of Commercial Intelligence & Statistics (DGCIIS)

The above figure 4, describes the top import destinations for the Indian pharmaceutical industry. According to the Directorate General of Commercial Intelligence & Statistics the USA, the UK, Russia, South Africa, Nigeria, Brazil, Germany, China and France are top trade partners of India in the year 2021-22. The figure crystal clear the top import partners of India. It exports generic drugs to both developed and developing nations. The US is the biggest destination for importing and exporting generic drugs with 36 percent of Indian generic drugs. Growth in import drugs also has increased during the recent COVID pandemic period. With 14 percent, the UK is at second position and Germany is listed in third position. Although, India import 14 percent of its pharmaceutical products and 60 percent of its bulk drugs from China.

V. COVID-19 and Government Incentives

Indian drugs and pharmaceutical exports stood at US\$ 24.44 billion in 2021. Indian pharma is the 12th largest exporter of drugs in the global market. Indian pharmaceutical sector contributes 6.6 percent to the total merchandise exports (Ministry of Chemicals and Fertilizers Government of India, 2022). Chaudhary (2021) examined that around 70 percent of Active Pharmaceutical Ingredients (APIs) on which India is completely reliant on China for imports because of low prices. Indian pharma industry produced more formulation drugs than bulk drugs. The nature of Indian domestic firms is export-oriented for that reason more dependence on bulk drugs. It transformed into the global generic hub. The share of the Indian pharmaceutical industry is 10 percent of the global market, exporting 60 percent of COVID drugs to more than 200 countries at low prices (Ministry of Chemicals and Fertilizers Government of India, 2022). India must have a strong domestic pharmaceutical sector, including infrastructure, R&D spending and quality medications at reasonable costs and availability. China is the only source of APIs for India. 70% of API imports come from China. Out of 699 APIs, 378 APIs were imported from China and 58 APIs came from a single country on which India was strongly dependent (Joseph, 2022). Dependency on a single country is a big threat to India. Y K Hamied, Chairman of Cipla, the legendary Indian Generic

firm, said that “If China decided one bright day to stop import to India, we would be finished. The pharmaceutical industry is zero both domestic and export and we are looking at the danger objectively” as cited by (Joseph & Kumar, 2021). Last two decades, India’s position was in trade surpluses with other countries but it had been a trading deficit with China for bulk drugs. The government of India is concerned about the emergence of importing bulk drugs from China. The government of India starts a scheme called the Production Linked Incentive Scheme (PLIs) on 20-03-2020 to achieve the main objective of Self-Reliance. The main objective of this scheme is to improve the manufacturing of 41 essential bulk drugs in the domestic market. Also, improves capabilities and investment in Research and Development (R&D) in domestic firms and attain the goal of Self-Reliance (Neogi et al., 2014). Formerly, the Production Linked Incentive Scheme was also introduced in the electronics industry (Vora et al., 2021). Dr V M Katoch's committee recommendations followed for mega API parks, there are 41 pharma parks to improve bulk drug production (Joseph & Kumar, 2021).

VI. Conclusion

The Indian pharmaceutical industry emerging very fast and it has been seen major structural and economic changes in its trade orientation post-TRIPS. In the initial stage, it has been more focused on the repackaging of drugs but now it is focused on generic drugs. The present study analyses the trends in the export and import of the Indian pharmaceutical industry post-TRIPS. After analysing traded data, it is concluded that exports increased because of the replacement of the product patent act with the process patent act. It can be said that the patent act impact trade accordingly because it has increased post-TRIPS. Now, the focus is more on formulation drugs as the share of this category is more than bulk drugs. The amendments in the patent act and the COVID pandemic both affected Indian trade. Some positive and negative phases were faced by the pharmaceutical sector during the pandemic time. The market size also enlarged in USA, UK and other developed countries. The UK, USA, Russia and South Africa are the top destination of Indian industry for trade. The paper also concluded that the exports increased by the Indian pharma industry in the worldwide market due to exporting generic drugs at low prices. Production Linked Incentive Schemes (PLIs) motivated the domestic pharmaceutical industry of India to produce more bulk drugs. The purpose of the PLI schemes is to reduce the dependency of bulk drugs on a single country and to become self-reliant at the global level.

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