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**Research Paper**

# India and the Global Generic Drug Market: Growth and Challenges Ahead

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***ABSTRACT***: *India is one of the leading manufacturers of pharmaceutical products globally and is the third-largest drug producer by volume. India accounts for 20 percent of the global export of generic medicines and is the world's pharmacy. Affordable and low-cost quality drugs make India the largest exporter of generic drugs. Even during the Covid -19 phase, India opened its hand as a vaccine supplier to the world. Though known as the medical superpower of the world, the Active Pharmaceutical Ingredients (API) for the production of various drugs are mainly imported from China, and this has become a matter of grave concern which questions the health security of the nation. Besides that, rising competition from other countries like Bangladesh looks to expand high-volume commodity manufacturing for generic drugs. The present paper examines the rise of India as a pharmaceutical giant in generic drug production over the entire world and explores the challenges faced by the Indian pharmaceutical industry.*

***KEYWORDS:*** *Pharmaceutical products; Generic drugs; Health security; Drugs*

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## I.INTRODUCTION

Trade plays a crucial role in the international order. It acts as a mighty hand in the exchange of goods and services between countries [1]. The interdependence of nations in trade helps provide order to international society. No nation is self-sufficient in the production of goods. They need to depend on other nations to consume goods that remain insufficient in their nation. Each nation specializes in producing the commodity of its comparative advantage and exchanges parts of its output for the commodity of the other nation's comparative disadvantage through trade [2]. As a result, both countries consume more of both commodities than they would if they didn't trade. India joined the World Trade Organization (WTO) and the TRIPS Agreement in 1994. Liberalized policy reforms over the trade of drugs and pharmaceuticals in post-1991 created tensions in India. The adoption of the TRIPS agreement harms pharmaceutical exports. Despite the negative consequences of the TRIPS agreement, India overcame its insecurities and maintained a trade balance in the next decade. India's pharmaceutical trade has both upsides and downsides. Even though it exports generic medicine to many countries, it relies on other countries, most notably China, for pharmaceutical components, posing a security risk to the country. India's reliance on China is a risky relationship since it can be abused at any time.

## II. Trade based on absolute advantage and comparative cost advantage

Adam Smith indicated that trade is based on absolute advantage and benefits both nations. According to him, nation X may have an absolute advantage in the production of commodity A, whereas country Y may have an absolute advantage in the production of commodity B. However, Country X has a disadvantage in the production of Commodity B, whereas Country Y has a disadvantage in the production of Commodity A. As a result, both nations exchange a portion of their output of the commodity in which they have an advantage, allowing both nations' resources to be used more efficiently and the output of both commodities to grow. The theory advocated the policy of laissez- fair as free trade between nations with minimum government interference take part. The theory explains the greater efficiency that one nation may have over another nation in the production of a commodity [3]. Thus the theory explains a small part of world trade, especially between developed and developing nations. Most governments currently place several constraints on the free flow of international trade,

which appears contradictory. Invariably, trade restrictions are justified in terms of national benefit. In actuality, they are supported by a few sectors and their employees who profit from the restriction, while consumers suffer as a result of having to pay more for rival domestic goods.

David Ricardo's "principles of Political economy and Taxation" presented the law of comparative advantage. This is one of economics' most significant and undisputed rules, with practical application [4]. This hypothesis states that even if one nation is less efficient in producing both commodities than the other, there is still a basis for mutually beneficial trade. The less efficient nation should focus on producing and exporting the commodity with the lowest absolute disadvantage. However, Ricardo articulated the law of comparative advantage in terms of the labor theory of value, which is inaccurate. Despite this, when represented in terms of relative labor productivity, the Ricardian trade model is experimentally supported.

## III. India – pharmacy of the world

Nearly USD 995.8 billion has been contributed globally for the sale of pharmaceutical globally. This stands nearly 16 % of global merchandise export of 2019 [5]. The Covid 19 pandemic surged the growth of pharmaceutical industry as the supply of medicines worldwide rely as the key target. The reduction in trade restrictions, including tariffs, has been argued to promote trade in medical goods and ensure equitable access.

The steep trade of pharmaceutical products, especially generic medicine, made India pharmacy of the world. In the whole world, India ranked 3rd in pharmaceutical production by volume. It is indisputable that India's pharmaceutical manufacturing is rising [6]. Despite being rated 14th in terms of pharmaceutical product value, India's reputation is enhanced by other countries (developed, developing, and underdeveloped) relying on pharmaceutical products. The low labor as well as production cost boosts India to achieve its development. The achievements of the Indian pharmaceutical industry mainly lie in the domestic market with a network of 3000 drug companies and ~10,500 manufacturing units. India exports a high number of generic drugs globally. The Indian pharmaceutical sector contributes about 2 percent to India's GDP and around 8 percent to the country's total merchandise exports [7]. India provides affordable health care for HIV therapy, supplying 80 percent of all antiretroviral drugs worldwide [8]. India's domestic pharmaceutical industry is one of the world's largest, and it is expected to triple in the next years.

The export statistics from FY 2017–18 to 2022–23 substantiate India's designation as the "Pharmacy of the World," with drug formulations and biologicals continually prevailing, increasing from USD 12,747.9 million in 2017–18 to USD 19,021.1 million in 2022–23, although a little fall of -0.11% in the preceding year. Bulk drugs and intermediates had a modest increase (+0.96%) in 2022–23, indicating a continued reliance on Chinese imports for APIs—a strategic weakness. Surgical and Ayush/herbal items had significant growth in 2022–23, with increases of +18.68% and +13.50%, respectively, indicating a burgeoning worldwide interest in wellness and traditional treatment. Despite a deceleration in overall export growth to 0.72% in 2022–23 following a pandemic-driven increase, the data highlights India's resilience and preeminence in generic pharmaceuticals, even as it confronts challenges such as supply chain reliance and the necessity for diversification to maintain enduring global competitiveness (Table 1).

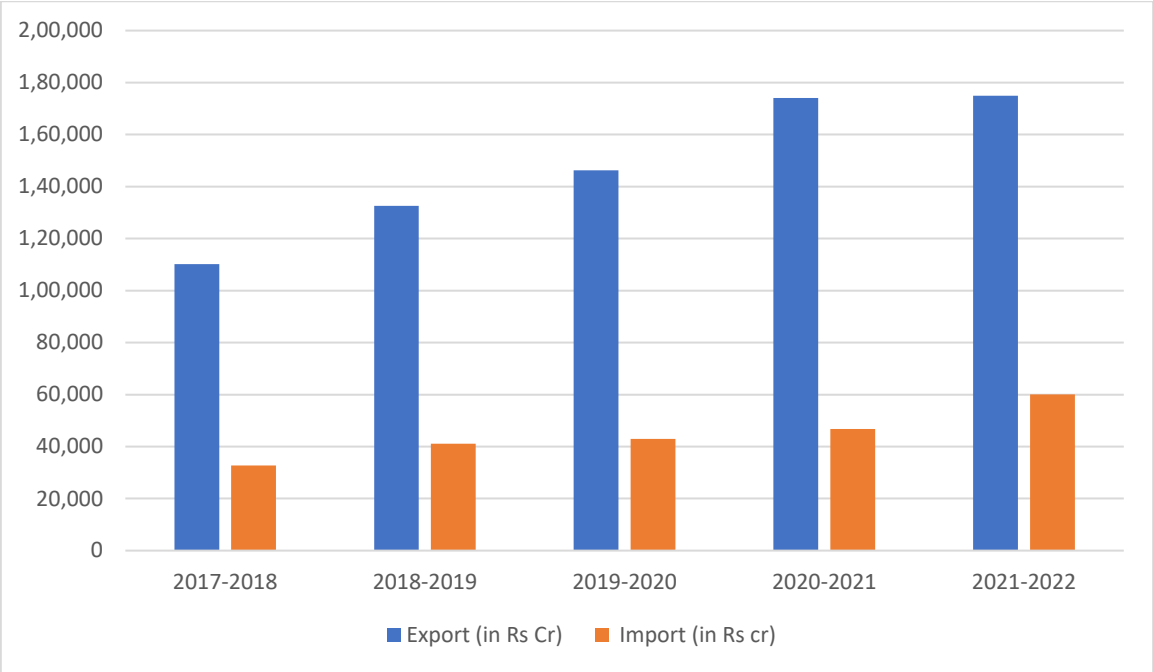
**Table 1: India's category wise export value in USD million** [9]

| Category | 2017-18 | 2018-19 | 2019-20 | 2021–22 | 2022–23 | Growth % |
|---|---|---|---|---|---|---|
| Drug formulations & Biologicals | 12747.9 | 14223.5 | 15826.64 | 19,042.2 | 19,021.1 | -0.11% |
| Bulk Drugs & Drug intermediates | 3525.65 | 3895.14 | 3882.87 | 4,429.7 | 4,472.1 | +0.96% |
| Surgicals | 552.16 | 569.77 | 448.29 | 432.3 | 512.9 | +18.68% |
| Ayush and Herbal Products | 456.12 | 446.12 | 428.09 | 539.9 | 512.9 | +18.68% |
| Grand Total | 17281.81 | 19134 | 20585.89 | 24,444.0 | 24,618.8 | +0.72% |

The graph (1)depicts a steady and substantial increase in India's pharmaceutical exports from 2017–18 to 2021–22, with exports significantly exceeding imports throughout this timeframe—a notable exception from India's general trade pattern, which usually has a trade deficit. Imports rose progressively from around ₹32,796 crore in 2017–18 to ₹60,000 crore in 2021–22, while exports escalated from ₹1,10,195 crore to almost ₹1,80,000 crore, illustrating India's expanding prominence in global pharmaceutical supply chains. This robust export performance underscores India's strategic role as the "Pharmacy of the World," bolstered by its extensive production infrastructure, USFDA-compliant facilities, and capacity to fulfil global vaccination requirements. The pharmaceutical sector in India is vital for both national health security and the global public health framework, as seen during the COVID-19 pandemic when it provided key vaccinations globally. The sector's strong export

growth throughout global disruptions highlights its crucial role in India's economic development and its ability to grow from a US$42 billion market in 2021 to over US$120 billion by 2030.

**Graph 1: Trade of Pharmaceuticals** [10]




## IV. Challenges ahead

### 4.1 India's universal access to health care – yet to achieve

In the world 2nd most populated country, the idea of health for all is still at risk. There are many people who do not have access to health care. Economic disparities among the people are the major reason behind it. Access to and cost of health care has become unaffordable for common people. In the case of India, its GDP spend over health sector is about 1 percent compared to 2.5 to 3 percent of other developing nations. Other than that, only about 29 skilled health workers are available for every 10,000 people in India compared to about 41 in China, and about 111 in the United States [11].

### 4.2 Patent burdens

Since 1995, an agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been established in member countries of WTO, where India is a signatory. In India, Patent law is compulsory at all levels- executive, legislative, and judiciary. The implementation of Patent Rights by 2005 in India initiated several burdens to Indian Pharmaceutical Sector, significantly changing the favorable conditions enjoyed by the generic industry. Drug reverse engineering was prominent still that period and it get stopped due to implementation of patent regulations in India.

During the COVID 19 pandemics, India and Africa proposed for TRIPS waiver. The proposal is to waive a vital provision of the TRIPS agreement on Covid- 19 vaccines, drugs, therapeutics, and related technologies. The agreement gives legal relaxation for the member country during the pandemic period. But, although the USA has vocally supported India for the proposal, no further support has been received. Like developed nations, especially the EU openly rejected the proposal [12]. As a result, pressure from wealthy countries, particularly those with a well-established healthcare system, is restrained on developing and underdeveloped countries, posing severe difficulties to pharmaceutical industries worldwide.

### 4.3 Overdependence on API import

Though India is known as the world's pharmacy, the Active Pharmaceutical Ingredients (API) (primary raw material) used to produce finished medicine is mainly imported from China. China supplies up to 70% of the APIs used in India. In other circumstances, such as life-saving pharmaceuticals, the reliability on Chinese imports might be as high as 80 to 100 percent. This is especially true in the case of fermentation-based APIs like penicillin and erythromycin, which rely virtually entirely on a Chinese import. In the year 2021 API segment witnessed a substantial decline with overall sales degrowth at 6.2% year over year to 4,300. This happens in the same period

when the higher base and opportunities stemming from the Chinese vacuum [13]. Chinese supplied API at a cheap cost, which made the Indian pharmaceutical Industry purchase more from China. The Indian pharmaceuticals use this as an opportunity to supply medicine at an affordable price. However, on the other hand, this stands as a security concern while any diplomatic failure with China will stop each nation's trade. India cannot seize the API due to inadequate infrastructure facilities like the uninterrupted supply of water and electricity and the lack of scale in 'Special Economic Zones'[14]. The sudden stoppage of API supply will inversely create a major health crisis in India.

**4.4 Protectionist policies of developed nations**

Nowadays, developed nations try to seek drug security of their nation. During the period of Donald Trump, he has issued an executive order to eliminate drug import. Germany and France have issued a similar decision. India contributes 40% of generic drugs to the US and a quarter of all drugs to the UK (Table 2). USA imports from India account for 2.3% of overall USA imports in 2019[15]. The USA imported $7.6 billion in pharmaceuticals in the year 2019. However, the US is one of the critical importers of Indian pharmaceutical drugs, implementation of a protectionist policy like this will affect the balance of trade. While most nations adopt the protectionist policy, India offers a wiliness hand to help other nations during the pandemic. Other than that, while US President Trump announced that his country is stopping the financial assistance given to WHO while India showed support for WHO.

**Table 2: India's** Pharma Exports Region Wise Value in USD Million

| Region | 2017-18 | 2018-19 | 2019-20 | Growth% |
|---|---|---|---|---|
| North America | 5348.00 | 6145.67 | 7073.97 | 15.10% |
| Africa | 3346.97 | 3436.44 | 3513.64 | 2.25% |
| EU | 2752 | 3003.91 | 3140.76 | 4.56% |
| ASEAN | 1181.45 | 1310.30 | 1292.16 | -1.37% |
| LAC | 1135.15 | 1308.30 | 1341.37 | 2.53% |
| Middle East | 869.05 | 1074.11 | 1068.22 | -0.55% |
| South Asia | 764.33 | 812.84 | 873.36 | 7.44% |
| CIS | 733.17 | 788.27 | 905.23 | 14.84% |
| ASIA (Exclude Middle East) | 627.30 | 693.62 | 772.87 | 11.43% |
| Oceania | 320.25 | 340.84 | 343.41 | 0.76% |
| Other European Countries | 150.99 | 162.86 | 202.99 | 24.64% |
| US Minor Outlying Islands | 0.00 | 0.10 | 0.07 | -34.97% |
| Others | 0.02 | 0.00 | 0.02 | |
| Grand Total | 17281.81 | 19134.49 | 20585.89 | 7.59% |

Source: DGCIS

**4.5India's emerging neighbors'**

In the current policy of China, it has identified pharmaceutical such as one of its strategic industries. China is planning to focus its pharmaceutical sector on the drug formulation sector. In 2009 China's share in the global formulation was 0.4%, while it increased in 2018 to 1.2%. Though India has doubled this global share of formulation from 1.5% to 3.6%, there is still tension in the growth of China which has a history of massive growth in the past. Other than that, most of the Chinese export is to the EU and North America, and there is a huge growth variation of trade compared to 19% of 2009 to 36% in 2019 [16]. The Chinese government has issued proper guideline to ensure the quality of the medicine exported. It has enhanced it standard by using Artificial Intelligence and genetics to develop medicines.

B.R. Sikri, president of the federation of Pharma Entrepreneurs said that, "Bangladesh is a small country compared to India. However, their presence in the global scenario in formulations as well as in API industry is phenomenal. In a short span of a couple of years, they have started exporting to more than 80 countries. If this tempo continues, it will be a big competition to India [17]. Bangladesh has increased its pharmaceutical exports due to a patent waiver that will last until 2032 for least developed nations. Thus, Bangladesh emerges as a future threat.

4.6Supply chain disruption

The outbreak of corona leads to a slowdown in production in the pharmaceutical sector. Lack of workforce, low supply of raw materials, difficulties in logistics disrupted the supply chain. The Government of India has initiated different methods to overcome Corona Crisis. Several control rooms have been set up to look after the smooth transportation flow and delivery of essential commodities. The state drug controllers were

instructed from Drug Controller General (DCGI) to provide data daily. However, India as a critical player in the global generic industry, a minor emergency in the society will affect the stability of the balance of trade.

**4.7 Insufficient new innovations**

Indian Pharmaceutical companies have been slow to grow in the innovation space (e.g., new molecular entities, complex generics), with a limited government supported Research System. Though India has a massive amount of generic medicine production, an innovation in the pharmaceutical sector is low. This happens because India has a weak infrastructure and inadequate Research and Development (R&D) in the pharmaceutical field. Pharmaceutical companies are not interested in conducting R&D in India due to the low incentives and infrastructure provided by the Indian Government. The policies of DPCO stand as one of the examples for the situation, as DPCO establishes various pricing parameter that creates an uncertain environment and thus reduce the profitability of the companies. R&D requires huge capital, which has been received from the profit. Without profit, none of the companies initiate establishing companies in India for creating innovations.

**4.8 Increased scrutiny in quality compliance**

Since 2009, India has had the highest number of Food and Drug Administration (FDA) inspections; as a result, continued investment in improving quality standards will divert profits away from other areas of development, reducing growth. The success of generic export to the United States has begun to plateau due to price attrition. But meanwhile nearly 20% of all pharmaceutical goods sold in the Indian market are counterfeit (times of India) which threaten the reputation of India as "pharmacy of the world". This market is beginning to diminish due to growing buyer consolidation, and increased competition has also become a key concern of India.

## V. Way forward

According to the Indian Pharmaceutical Alliance report conducted in 2019, the Indian pharma industry can endower on a vision of establishing India's global leadership in life sciences while driving domestic access and affordability. The report states that to achieve USD 120- 130billion by 2030, India has four critical drivers of growth:

- Accelerated growth in India is driven by increased accessibility and affordability.
- Potential breakthroughs in next-generation innovative products.
- Strong growth in the US market by driving higher ANDA share in molecule going off-patent and potential ease in price erosion.
- Increased growth in the large underpenetrated market such as Japan and China.

Archiving these goals means that the Indian pharmaceutical industry can improve its global market share, and India will improve its current 14th ranking in value.

Indian drug industries need to focus more on their R&D, especially in the innovation toward chronic disease, because there is a high demand for specialized diseases, which are more expensive than other drugs. India needs to increase the budgetary allocation in health care, especially in boosting the domestic market, health care insurance, and R&D. Recently State Government of Andhra Pradesh and Uttar Pradesh have announced their intention to set up pharma parks. This is a favorable attraction for welcoming pharma investment.

India needs to reduce the uncertainty around the pricing of medicines. India needs a well-organized pricing policy that touches all stakeholders of the industry. In particular Indian Government need to revive the trust in pharmaceutical stakeholders by reducing the frequency of policy revision; thus, the confusion raised from this will be resolved. The process for regulatory approval should be simplified. Other than that, there is a controversy in the Indian governmental system. The pharmaceutical matter comes under two ministries - the ministry of health and family welfare and the ministry of chemical and fertilizer. The authorizing mechanism is held under the Central Drug Standard Central Organization (CDSCO), which is under the ministry of health and family welfare, whereas prizing is under the pharmaceutical department, which is under the ministry of chemical and Fertilizers. Indian Government needs to create an independent Ministry for Pharmaceuticals, so there will be an ease of flow of pharmaceutical sector.

The Government should initiate proper infrastructure support for the production of API. The major dependence of India for API lies in China and its create a security concern nowadays not because of COVID outbreak but also in the border issues with it. As an immediate effect it can import API from US, Singapore, Italy and Hong Kong but it is not effective as the cost of ingredient from those countries is high compared to China. The Cost of API determines the fluctuation of price of drugs. So, the effective solution for this problem is that achieving self-reliance in production of API. Still 1991 India had its own API production using public sector like Hindustan antibiotics Ltd and Central drug Research Institute. But manufacturing unit get shut down due to environmental concern low profitability. So due to the lack of insufficient API made in India in 2013 V M Katoch Committee has been appointed. The proposal from the committee lies still in papers. So, Government should look forward to self-reliant in API production.

By 2024, the patent for most of the medicine will expire as its period expires. The wise use of expired drugs and creating generic medicines enhance the generic market. As the sector strives to become the world's top provider by volume, increased exports to huge and hitherto under-served countries like Japan, China, Africa, Indonesia, and Latin America might be the next source of development. To adapt to local market requirements, penetration in these markets may necessitate a new business strategy (e.g., partnerships with local manufacturers, distributors, etc.). Government actions and trade relations support will assist Indian pharmaceutical companies in gaining market access in these markets.

Success of Indian pharmaceutical industry has been limited to the success in the production and export of generic medicines. India needs to focus more on new innovation initiating the future, such as gene therapy. Though India launched the first bio similar development in 2007 by India's Dr. Reddy to Rituximab, Reditux, no more new innovations yet happen. (Indian Pharmaceutical Industry, 2021) If India focuses more on the biosimilar market, the future pharma Industry can capture the market. India accounts for the highest human resources in the medical field compared to a developed nation. The wise use of its cost-efficient workforce in clinical research will capitalize its economy in the world.

## VI. Conclusion

Indian industry has established it presence from nowhere in 1970's to everywhere in 2000's today. It's investment in pharmaceutical industry especially heavily on plants, equipment and machineries lie remarkable. But toward capacity building Indian pharmaceutical industries development is not that much sufficient for countries growth. Though Indian pharmaceutical industry has established a strong presence in the international society, its overdependence for API over China remains as a major challenge. Lack of new innovations and in sufficient aid from government make growth of Indian pharmaceutical sterilized.

Indian pharmaceutical sector has an overall positive growth in its economic, social and political levels. Economically, despite its starvation in ingredients for production, the overall balance of trade and supply of generic medicines shows a surge. Socially, Indian generic drugs stand as an effective option due to its low cost and Access for nations, though its quality in dispute. And politically, the present epidemic has once again highlighted global inter – dependencies were the term medical diplomacy enhanced in the international order. India should join the ranks of other global health leaders in order to secure a coordinated global response to the crisis and to establish a global health system that focuses the needs of low- and middle-income nations.

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