



The Opportunities Challenges and Performance of India's Drugs and Pharmaceutical Sector

Dr. Javaid Ahmad Bhat¹
Basharat Hussain Bhat²

Abstract

The Indian economy has overcome several challenges, achieved numerous milestones, and is steadily making its way towards the magnificent USD5 trillion mark. Indian economy will inevitably face many challenges in the future due to internal and external factors since its path has always been tumultuous. However, it is a feast to see how specific sectors of the economy, after receiving impetus from policy initiatives and the availability of favourable domestic factors, have grown and overcome insuperable challenges in terms of domestic socioeconomic and external issues of grave importance. It is pertinent to mention that numerous sectors of the Indian economy are hatching or have already begun to roost. Infrastructure and investments are necessary to turn these sectors into delicacies for the economy. The pharmaceutical industry is one of these sectors and is strong enough to deal with the issues faced by the Indian health sector in the domestic market. Additionally, it can ensure that India becomes the net exporter of drugs and medicinal equipment while enhancing its export outreach and elevating its position in the Generic Drugs section to cater to the pharmaceutical needs of emerging economies. Specifically, the paper will examine how the Drugs and Pharmaceutical sector of the Indian economy can contribute to the health of the Indian economy by providing efficient and effective health care.

Key Words; Health Care, Generic Medicine, Drugs, Pharmaceuticals, Indian Economy,

Received 12 Sep., 2022; Revised 25 Sep., 2022; Accepted 28 Sep., 2022 © The author(s) 2022.

Published with open access at www.questjournals.org

I. Introduction

Any economy's backbone rests on various operational and marginal factors across its quadrants. Health and its associated subsectors, like drugs and the pharmaceutical industry, fuel the growth and development of any economy and ensure the well-being of the masses and the health of all. Health care is essential to every country's socioeconomic development, and sound healthcare policies are an indispensable prerequisite for effective health systems. The pharmaceutical industry is vital in developing an effective and efficient health care system. Several sectors with backward and forward links to the drugs and pharmaceutical industry contribute generously to employment and output growth directly and indirectly. According to QuintilesIMS Institute, the global drug market will reach nearly USD 1485 billion by 2022, an increase of USD 350-380 billion from USD 1105 billion in 2016. Demographic trends drive much of this growth, as pharmaceutical markets expand in developing countries and populations age in developed countries. In emerging economies, most of the change will be driven by the increase in generic drugs.

The pharmaceutical market in India ranked third in volume and fourteenth in value in 2020. Roughly 20 percent of generic pharmaceuticals and 62 percent of vaccines are supplied by the business worldwide. There are 300 pharmaceutical firms and 10500 factories in the country. The pharmaceutical sector has been crucial in India's economic development and public health results. Estimates for 2022 indicate that 3.4 million people will be directly and indirectly employed in the industry in highly skilled roles such as research and development (R&D) and manufacturing. The industry is one of the top five contributors to lowering India's trade deficit,

¹Academic Arrangement Lecturer Govt. Degree College Gool, Jammu and Kashmir

Email: Javaid.scholar@kashmiruniversity.net

²Assistant Professor Department of Higher Education, Govt. of Jammu and Kashmir

generating an annual export surplus of USD 11 billion (IBEF, 2021). The first Indian pharmaceutical company was founded in Kolkata in the twentieth century, marking the beginning of the industry's rapid development. From its inception until the 1970s, the market was controlled by foreign firms, with only a handful of domestic competitors (IBEF, 2021). The advent of domestic manufacturers in India may be traced back to the passage of the "Patents Act 1970," which allowed domestic pharmaceutical firms to reverse engineering medication production techniques without paying royalties to the original patent holders. Several Indian pharmaceutical firms entered the export market between 1990 and 2000, capitalizing on their expertise in generic drug production to expand their capabilities and establish a global presence and on the country's economic liberalization policies, which opened the country's economy to privatization and globalization and subsequently sped up pharma exports (IBEF, 2021).

Current Status of Drugs and Pharmaceutical Sector in India

The growth of India's pharmaceutical business can be directly attributed to the contributions of the country's many pharma firms, which have a prominent presence in the global supply chain. Key manufacturers include domestic firms like Sun Pharmaceutical Industries, Cipla, Lupin, Dr. Reddy's Laboratories, Aurobindo Pharma, Zydus Cadila, Piramal Enterprises, Glenmark Pharmaceuticals, and Torrent Pharmaceuticals, many of which have independently developed drugs and collaborated with international firms to create others. With a firm grasp on overseas markets like North America and Europe, the Indian pharmaceutical industry could invest USD 41 billion in sales. Because of its ready access to raw materials and skilled labour, India has become a global centre for the production of generic pharmaceuticals (IBEF, 2021). Moreover, India is the only country with the most significant number of USFDA-approved pharma factories, with more than 262 including active pharmaceutical ingredients (APIs), as it produces medications for a third of the price in the US and half the price in Europe.

In India, the pharmaceutical industry is known for being stable and predictable, with a steady growth of 10 to 12 percent per annum (Joshi, 2017). The Indian pharmaceutical market is projected to grow to USD 65 billion by 2024 and USD 130 billion by 2030, as stated in the country's Economic Survey 2020-21. India faces both an opportunity and a dilemma in its pursuit of becoming the world's pharmacy centre in the wake of the recent COVID-19 outbreak. In FY21, India earned USD 24.4 billion from the export of pharmaceuticals, an 18 percent increase over the USD 20.7 billion it reached in FY20 (IBEF, 2021). The US Food and Drug Administration reports that in the last nine months of FY21, Indian pharmaceutical companies received nearly half of all new abbreviated new drug application (ANDA) approvals, which is expected to assist in expanding exports in the future (IBEF, 2021). The domestic pharmaceutical industry is likely to keep growing at the same rate in FY2022, and chronic therapies are likely to be strong growth drivers (Pharma Outlook, 2021). In addition to generic drugs, Indian Biosimilars, which are generic versions of Biological medications, have been growing at a CAGR of 30 percent since 2008. In 2018, this product category picked up speed and was likely to increase significantly in the medium to long term. The Serum Institute of India, founded in 1966, is doing exemplary work by making and supplying affordable and life-saving vaccines. Public health care is improving, but private health care is still the norm. Aside from that, most medical facilities are found in cities. The health care system in India is having trouble meeting the needs of its people.

Outreach and Quantum of Indian Drugs and Pharmaceutical Products

There is no denying that India's pharmaceutical and drug industry has evolved significantly over the past two decades. Branded generic drugs are increasingly present in India's retail market. The country's plethora of active domestic players has increased competition and driven down drug prices, making them more affordable and increasing access to healthcare for the country's population. In addition, it has benefited from developments and innovations in the formulation of drugs and other pharmaceutical products. There has been a decrease in activity in the domestic market. In 2017, the growth rate of domestic pharmaceutical sales hit an eight-year low of 5.5 percent. Still, the exports almost doubled from 2008–09's USD 8.7 billion to 2016–17's USD 16.88 billion, with the United States market being the primary driver of this growth (Patra et al., 2018). About 34.36 percent of Indian exports went to the United States, with Africa taking 18.62 percent. Exports of pharmaceuticals were worth USD 17.27 billion in FY 2018. Products such as biologicals, Ayurvedic medicines, herbal remedies, and surgical instruments are also included in these exports.

In the last decade, the demand for generic drugs in the United States has been the single most important factor in the expansion and success of Indian generic pharmaceutical firms. The US generics market is between 70 and 80 billion dollars, with the country accounting for around 30 percent (by volume) and 10 percent (by value) (Indian Pharmaceutical Industry Report, April 2018). The Indian pharmaceutical industry celebrated a record-breaking year in 2017, with 304 ANDAs approved by the FDA. An estimated USD 100 billion will be generated by 2025 from India's biotechnology sector, which includes biopharmaceuticals, bio-services, bio-agriculture, bioindustry, and bioinformatics. This represents an annual growth rate of approximately 30 percent (v, 2018). The pharmaceutical industry has traditionally prioritized low-value manufacturing activities, such as

active pharmaceutical ingredients (APIs) and generics. Indian pharmaceutical firms have also shown signs of ascending the value chain (Global Pharma looks to India). Research skills are also on the rise, following the pattern seen in manufacturing.

Growth Predictions of India's Drugs and Pharmaceutical Sector

In 2020, the Indian pharmaceutical market was projected to be worth USD 55 billion, up from USD 12.6 billion in 2009. In a high-growth scenario, this number was expected to rise to USD 70 billion and USD 35 Billion in a worst-case scenario where restrictive regulations and a slowing economy have depressed the industry (Bhadoria et al., 2020). Key growth drivers were identified in the McKinsey Report, India Pharma 2020 and classified into four categories (Epidemiological factors, Increasing Affordability, Enhanced Accessibility, and Rising acceptability). The following points were outlined in the report mentioned above:

- By 2020, the number of patients will have increased by nearly 40 percent due to epidemiological factors such as the growing population and the steadily rising disease prevalence.

- Rising incomes and expanded insurance will make pharmaceuticals more affordable. About 380 million people are projected to be covered by government-sponsored health programs for the masses by 2020.

- Increased government spending on healthcare, new medical infrastructure development, patentable products that fuel expansion in specific therapeutic areas, and rising drug prices will contribute to greater drug accessibility. Over the next ten years, over USD 200 billion will be invested in developing and improving healthcare facilities.

- Pharmaceuticals will benefit from the government's USD 4.5 billion in healthcare costs. The competitive market created by numerous actors in action will increase the acceptance of modern medicine and newer therapies. Increases in diagnostic and treatment rates can be expected from investments in raising patients' awareness and education levels. People's openness to biologics and preventative medicines is expected to increase.

Uncatered Markets and Pharma needs of Emerging Economies

Millions of individuals in low and middle-income nations die yearly due to preventable diseases for which they lack access to effective immunizations, medications, and diagnostic tests. The report claims that only four businesses (Glaxo Smith Kline, Johnson & Johnson, France's Sanofi, and Germany's Merck) are responsible for 63 percent of the important R&D initiatives (Kollewe, 2018). Furthermore, the "Access to medicine Foundation" reports that the world's largest pharmaceutical firms have failed to develop two-thirds of the 139 urgently needed treatments (drugs, vaccines, diagnostic tests, or devices) in developing nations (Kollewe, 2018).

Rising Demand for Drugs and Pharma in lieu of Climate Change, Rising Population, and Environmental Pollution

Waterborne and vector-borne diseases, in particular, are expected to surge due to climate change. Malnutrition, malaria, diarrhea, and heat stress are all anticipated to claim an additional 250,000 lives annually between 2030 and 2050 due to climate change (Salt, 2013). This makes it even harder for low and middle-income nations to provide even the most fundamental health care services to their citizens. Changes in India's epidemiology are occurring alongside those in nearly every other developing country. A projected 199 million Indians will be 60 or older by 2028. (Salt, 2013). This is in addition to the many other variables that will increase demand for both generic and specialty pharmaceuticals and medical care services. Given the location of India, demographic makeup, and other socioeconomic challenges, all of these factors will have equal, if not more significant, impact. Moreover, environmental contamination will raise both mortality and disease rates. These factors highlight the need for a potent drugs and pharmaceuticals industry, which can serve as a cash cow and meet the needs of expanding markets, as well as meet the domestic demands for pharmaceuticals and guarantee citizens' access to healthcare.

Generic Medicines and India

Indian pharmaceutical firms have long argued that they can make a difference in the fight for easier access to low-cost generic pharmaceuticals. Cipla shocked the pharmaceutical industry in 2001 by offering to sell anti-AIDS medications at a fraction of the price charged by multinational drug companies in Africa. Further, it improved the quality of life for millions of people throughout Africa (Sharma, 2018). Therefore, there is good reason to believe that Generics can assist in expanding patient access to essential drugs. Yet, India's home market is highly disorganized, with many manufacturers focusing solely on making generics. India produces about 20 percent of all generic prescriptions (Global Pharma looks to India). The government permitted local manufacturers to create patented medications beginning in the 1970s, and the Generics industry has benefited from this trend. As of February 2009, 35 percent of accelerated approvals for new drugs by the US Food and Drug Administration (FDA) went to companies based in India (Global Pharma looks to India). Domestic generic

manufacturers are expanding their relationships with multinational corporations to bolster their product lines. Indian pharmaceuticals have become even more consolidated due to mergers and acquisitions.

Challenges to India's Drugs and Pharmaceutical Sector

Regarding total volume produced, India is the third-largest manufacturer of pharmaceutical products. There is a myriad of variables that have contributed to the sector's ability to carve out a place for itself; nevertheless, there is also a multitude of problems that hinder its flight and outreach. The Indian pharmaceutical market is unstable, volatile, and unclear because of the industry's widespread fragmentation. Increasing operational prowess and adaptability is a priority (Sharma, 2015). The Export environment for Indian pharmaceuticals has changed in recent years due to warnings from the USFDA and rapidly expanding regulatory hurdles for Indian producers, along with escalating rivalry in that market and the consolidation of channel partners in the US. Indian factories were the target of 272 FDA inspections in 2015, and the country received half of all FDA warning letters issued that year (Das, 2018). The percentage of FDA inspections and warning letters dropped to 192 and 29 percent, respectively, in 2017. Government pricing policies have led to a low-profit margin. Slowing pharmaceutical sales growth might be attributed to price constraints and lengthy product approval processes. In April 2016, the Indian government began regulating the prices of 18 percent of the pharmaceutical market in the country based on the value of drugs sold. While this method may discourage investment, achieving the broader goal of making health care more accessible at lower costs is necessary. Drug prices in India are relatively low because of the country's robust generic competition, as noted in the McKinsey Report, Indian Pharma 2020. Additional regulations would have a detrimental effect on the industry's viability and discourage investment.

Contrary to what you may have experienced in the United States, not all generic medicines in India are inexpensive. Accurate generic models reduce medicine prices and more value for the end user. The coming decade will shift towards the US generic model, compelling many to switch to an accurate generic approach (Joshi, 2018). This will reduce their fair share of profits and pressure company resources. Raw materials and APIs (active pharmaceutical ingredients) rely heavily on imports from other nations, particularly China. Too few incubators for the number of raw materials that need to be produced. The absence of state-level functional testing laboratories to validate and ascertain quality criteria. The urban parts of India are dominated by for-profit hospitals, whereas the country's outlying regions lack medical infrastructure. Currently, participation in the Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) is optional; the code's goal is to create a market ecology that is both ethical and legally compliant. A more robust, thorough, and accountable legal and compliance structure will be required once UCPMP is codified into law (Joshi, 2018). High-threat pathogens include Zika, Nipah, Ebola, Middle East Respiratory Syndrome coronavirus (MERS-Cov), Severe Acute Respiratory Syndrome (SARS), Disease X, an unknown pathogen that could cause a severe epidemic, and antimicrobial resistance, which is the most important of all, are all on the rise ((World Health Organisation, 2019)). Medical devices have a lot of untapped potential but are held back by a lack of regulatory and research & development support and intense competition from Europe and China (Global Pharma looks to India). Low-end medical supplies and disposables are typically produced domestically, while high-end medical equipment is commonly imported (Global Pharma looks to India).

Ways to do away with Challenges

A holistic and multi-pronged strategy is required to ensure that the efficacy of India's Drugs & Pharmaceutical industry soars high and meets the problems faced by the said sector. Firstly, the diseases and pathogens that potentially cause a public health emergency but don't have the proper treatments or vaccines must be identified and prioritized for research. Additionally, increased investments and funding; release of more and more patented products; strengthening of medical infrastructure; expanding and deepening of health insurance; upgrading of both mass and super specialty treatment procedures; gaining ground in rural markets; meeting the needs and rising demands of Tier 1 and Tier 2 cities; more partnerships between domestic players and international manufacturers to get into new markets should be promoted. Focus on Nephrology, Urology, and Oncology, which make up most of the Super-Speciality therapeutics, has to be sharpened. Introducing New Molecular Entities (NMEs) in these therapeutic areas and increasing private insurance coverage will help make high-cost therapies, like biologics, more affordable.

Moreover, research works should be incentivized to improve the national health research system and build up research capacity. As the size and variety of the Indian pharmaceutical market grow, several opportunities will reach their full potential. These include patented products, consumer healthcare, biologics, vaccines, and public health, all of which are under-penetrated or don't work as well as they could. Creating a market will require working with a broader range of partners to improve diagnosis rates and patient compliance, which will change the very nature of the patient funnel (India Pharma, 2020). Moreover, attention should be paid to both output production and production quality of drugs and pharmaceuticals, along with the increased expenditure on health care.

Improved focus on the Drugs and Pharmaceutical Sector will aid the Health of the Indian Economy

According to the 2030 Agenda for Sustainable Development, "from a health perspective, development can be said to be sustainable when resources-natural and manmade are managed by and for all individuals in ways that enhance the health and welfare of present and future generations." Specifically, the 2030 Agenda presents an opportunity to improve health systems by bolstering health systems to achieve Universal Health Coverage and by acknowledging that health depends on and, in turn, supports productivity in other vital sectors like agriculture, education, employment, energy, the environment, and the economy (World Health Statistics, 2017). According to the 2013 World Health Organization (WHO) Health Report, scientific investigation is crucial to enhancing people's health. The importance of research in creating the infrastructure, tools, and services essential for achieving universal health care was reaffirmed.

The emergence of "BIG DATA" is just one-factor inspiring efforts to connect databases across disciplines, increase data accessibility, and create novel analytical approaches that will shed light on the condition at hand and pave the way for therapeutic advancements (World Health Statistics, 2017). All other sectors of the economy will benefit from innovations and advances in the health care system and the pharmaceutical industry that goes hand in hand with it. As a result, poverty will be alleviated because people will have less need to pay for expensive medical care out of their pockets, but it will also raise people's living standards. Moreover, it will improve the welfare of the masses, boost their disposable income, savings, and job opportunities, encourage investment, and boost the country's pharmaceutical industry's ability to export to countries with growing middle classes. In addition, with sharper attention, India would be better able to tackle the severe health problems that are draining the country's most valuable resource: its people.

II. Conclusion and Suggestions

A million-dollar question—how drugs and the pharmaceutical sector in India will become a potent health supplement—requires the attention and actions of all players, including government pharmaceutical companies, World organizations, private investors, angel investors, and other lending bodies. To ensure emergency preparation and an early response system, practical policy efforts and enough funding and investment in critical areas, together with a favourable taxation system, are necessary. Compared to traditional oral solids, attention should be paid to complex generics and super specialty drugs. Compliance with standards and quality assurance of the medicines and medical equipment, upgrading facilities, and tweaking production procedures should be prioritized. The drug industry is getting bigger and better and demands adequate facilities in the supply chain, such as cold chains, to prevent shocks during the distribution process.

Moreover, spreading the country's medical infrastructure far and wide, focusing on rural areas and super-specialty hospitals, is the need of the hour. Thus, emphasis should be paid to high-end medical equipment, primarily made in Europe and China, to cut down on imports and make more of them at home. More attention should be given to Biotech, Biosimilars, Biologics, and Bioinformatics to promote better medical facilities that will meet the high-tech demands of potential customers, provide a natural boost to medical tourism, and promote the growth of the country as a whole. In addition, promoting the cosmetics industry, especially the organic cosmetics industry, which has been growing over the past five years, will offer more shine to this sector. Furthermore, more significant investments, infrastructural development, and research should be promoted to care for and eliminate medical waste according to standards and rules and minimize environmental costs. In conclusion, we can state that the field mentioned above has sufficient evidence to deduce that a boost to the Drugs and Pharmaceutical Sector will bestow good health to the Indian economy and as such will act as a potent health supplement, which, together with other sectors of the economy, will ensure India's journey towards USD 5 Trillion economies are secure and sound. However, what is necessary is sector-friendly regulatory procedures, an increase in funding for scientific research, and the implementation of proper policy measures.

References

- [1]. Bhadoria, V.S., Bhajanka, A., Chakraborty, K., Mitra, P., Bhattacharya, S., Chakraborty, S., Handa, K., Jain, S., Kalyanasundaram, S., Kumar, K.K., Matai, A., Mohan, V., Nayak, G., Sahney, S., Sikri, Y., & Subramanian, S. (2010). India Pharma 2020 Propelling access and acceptance, realizing true potential.
- [2]. Das, P. P., Mugnaioli, E., Nicolopoulos, S., Tossi, C., Gemmi, M., Galanis, A., ... & Pop, M. M. (2018). Crystal structures of two important pharmaceuticals solved by 3D precession electron diffraction tomography. *Organic Process Research & Development*, 22(10), 1365-1372.
- [3]. ET Health World. (2017, August 29). The State of Pharmaceutical Industry in India – An Overview. *ETHealthworld.com*. Retrieved September 24, 2022, from <https://health.economictimes.indiatimes.com/news/pharma/the-state-of-pharmaceutical-industry-in-India-an-overview/60273583>
- [4]. ET Health World. (2018, December 6). Forthcoming challenges and changing skill sets for the Indian pharmaceutical industry in the next decade. *ETHealthworld.com*. Retrieved September 24, 2022, from <https://health.economictimes.indiatimes.com/news/pharma/forthcoming-challenges-and-changing-skill-sets-for-Indian-pharmaceutical-industry-in-next-decade/66966630>
- [5]. Global pharma looks to India: Prospects for growth. (2018). In <https://www.pwc.com/gx/en/pharma-life-sciences/pdf/global-pharma-looks-to-india-final.pdf>.

- [6]. Headquarters, W. (2013, August 15). Research for universal health coverage: World health report 2013. Retrieved September 24, 2022, from <https://www.who.int/publications/i/item/9789240690837>
- [7]. IBEF. (2021, September 1). Indian Pharma Industry To Touch Us\$ 130 Billion By 2030 | IBEF IBEF. India Brand Equity Foundation. Retrieved September 24, 2022, from <https://www.ibef.org/blogs/indian-pharma-industry-to-touch-us-130-billion-by-2030>
- [8]. Joshi, V. K., Joshi, A., & Dhiman, K. S. (2017). The Ayurvedic Pharmacopoeia of India, development, and perspectives. *Journal of ethnopharmacology*, 197, 32-38.
- [9]. Kolleye, J. (2018, November 20). Big pharma "failing to develop urgent drugs for poorest countries." *The Guardian*. Retrieved September 24, 2022, from <https://www.theguardian.com/business/2018/nov/20/big-pharma-who-failing-to-develop-urgent-drugs-for-poorest-countries>
- [10]. McKinsey & Company, Inc. (2020). India Pharma 2020 Propelling access and acceptance, realizing true potential. In https://www.mckinsey.com/~media/mckinsey/dotcom/client_service/Pharma%20and%20Medical%20Products/PMP%20NEW/PDFs/778886_India_Pharma_2020_Propelling_Access_and_Acceptance_Realising_True_Potential.aspx.
- [11]. Patra, J. K., Das, G., Fraceto, L. F., Campos, E. V. R., Rodriguez-Torres, M. D. P., Acosta-Torres, L. S., ... & Shin, H. S. (2018). Nano based drug delivery systems: recent developments and future prospects. *Journal of Nanobiotechnology*, 16(1), 1-33.
- [12]. Pharmaceutical Companies in India, Indian Pharma Industry- IBEF. (2020). India Brand Equity Foundation. Retrieved September 24, 2022, from <https://www.ibef.org/industry/pharmaceutical-india.aspx>
- [13]. Reddy, A. V. J., & Rao, B. M. (2017). Opportunities and challenges for Indian Pharmaceutical companies in overseas markets and need for digital tools for sustainable success. *Indian Journal of Pharmaceutical Education and Research*, 51(2), 226-238.
- [14]. Salt, J. E. (2003). Health and climate change: Implications for the pharmaceutical sector.
- [15]. Sharma, C. (2017, June 2). "5" Challenges faced by the Pharma Industry. IIPTA. Retrieved September 24, 2022, from <https://www.iipta.com/5-challenges-faced-by-the-pharma-industry/>
- [16]. Sharma, K. E. (2018, July 19). Dying to Survive: Indian generic medicines have a tale to tell. *Business Today*. Retrieved September 24, 2022, from <https://www.businesstoday.in/opinion/alchemy/story/dying-to-survive-indian-generic-medicines-have-a-tale-to-tell-108357-2018-07-18>
- [17]. Ten threats to global health in 2019. (2019). Retrieved September 24, 2022, from <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>
- [18]. World Health Organisation. (2019). Ten Threats to Global Health in 2019. www.who.in. Retrieved September 24, 2022, from <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>