

AN EMPIRICAL STUDY OF THE INDIAN PHARMACEUTICAL SECTOR

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Abstract

The empirical research presented here examines the main dynamics, obstacles, and possibilities facing the Indian pharmaceutical industry. The report clarifies the complexities of this important business by means of a thorough examination of empirical data, market trends, and regulatory frameworks. The study intends to offer useful insights for scholars, industry stakeholders, and policymakers by revealing empirical facts. It provides a thorough grasp of the industry's present situation as well as possible future development routes. The study's conclusions support strategic planning and well-informed decision-making, which in turn promotes innovation and sustainability in the Indian pharmaceutical industry.

Keywords: *Pharmaceutical Industry, Bulk Drugs, Contract Research, Patent.*

1. INTRODUCTION

Following India's 1947 declaration of independence, its authorities made the creation of a national patent system that catered to its particular requirements a top priority. The relevant patent law issues were handled by committees chaired by Justices Bakshi Tek Chand and Rajagopal Iyengar, which resulted in the National Patents Act being enacted in 1970. This law sought to balance the public interest and expedite industrialization. In 1970, a new Patents Act was passed with the intention of supporting India's independence in drug manufacture by excluding agrochemicals and pharmaceuticals from patent eligibility. Following the balance of payments crisis of 1991, economic liberalisation became necessary and led to a change in policy towards neoliberal policies that emphasised support for the private sector and an export-oriented approach. By bringing India into line with international norms, the Patents Act amendments of 2005 put an end to the process patent era and made patents for novel medications possible. The Indian pharmaceutical sector was greatly affected by this shift, which led to a reevaluation of its dynamics in areas including contract research, bulk drug export, and formulation export. This essay aims to offer a thorough examination of

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the Indian pharmaceutical industry following amendments, highlighting developments and difficulties.

1.1. Formulation Export

To make a finished therapeutic product, a pharmaceutical formulation combines several substances, including active medicines. The pharmaceutical industry in India is positioned to lead the country's manufacturing sector, being the second largest in the world by volume. Nine billion dollars' worth of formulations and bulk pharmaceuticals were sold in India in 2023 by more than 20,000 licenced pharmaceutical businesses. Although over 60% of these bulk medications were shipped, with the US and Russia being the main destinations, only 85% of these formulations were used locally. This highlights India's important place in the world's supply networks for pharmaceuticals.

1.2. Bulk Drug Export

These constituents comprise pharmaceutical raw materials, intermediates, medication additives, and gelatin capsules (also known as active pharmaceutical ingredients, or APIs). The industry faced more competition as it expanded beyond bulk pharmaceuticals after regulatory reforms. Among the pioneers, Dr. Reddy's was aware of the ramifications from the start and gradually shifted its emphasis to formulations. In the wake of the WTO, lesser-known companies such as Divi's Laboratories, Matrix, Suven Pharma, and Neuland Laboratories developed survival strategies, despite the focus being on Dr. Reddy's and Aurobindo. Data analysis, however, shows that diversification hasn't impeded the bulk medicine industry's expansion. This development highlights the Indian pharmaceutical industry's flexibility and resilience in the face of shifting market conditions.

2. LITERATURE REVIEW

Sharma and Modgil (2020) investigated the relationship between Total Quality Management (TQM), Supply Chain Management (SCM), and operational performance within the Indian pharmaceutical industry. Their study, published in the Business Process Management Journal, delves into the intricate dynamics of quality management and supply chain operations, shedding light on how these factors influence overall performance. By conducting empirical analysis, Sharma and Modgil provide valuable insights into the strategies and practices that enhance operational efficiency and effectiveness in the pharmaceutical sector.

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Ganguly and Chatterjee (2020) explored the role of social capital, knowledge quality, knowledge sharing, and innovation capability in the context of the Indian pharmaceutical sector. Their study, published in *Knowledge and Process Management*, examines the interplay between social relationships, knowledge management processes, and innovation outcomes. Through empirical investigation, the authors elucidate the mechanisms through which social capital and knowledge sharing contribute to innovation capability within pharmaceutical firms. This research offers important implications for fostering a culture of innovation and collaboration in the industry.

Farhan et.al (2020) focused on board composition and its impact on firms' profitability in the Indian pharmaceutical industry. Published work from Farhan and colleagues provides empirical evidence on the relationship between board structure and financial performance, particularly within the Indian pharmaceutical context. By analyzing board composition and its implications for profitability, the study sheds light on corporate governance practices and their influence on firm-level outcomes. The findings contribute to the ongoing discourse on governance mechanisms and their role in enhancing financial performance in the pharmaceutical sector.

3. RESEARCH METHODOLOGY

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4. DATA ANALYSIS

We have employed the least squares method, a mathematical tool, to determine the growth of different segments of the Indian pharmaceutical industry following changes to the country's patent laws. The graphs below display the study's findings.

4.1. Formulation Export

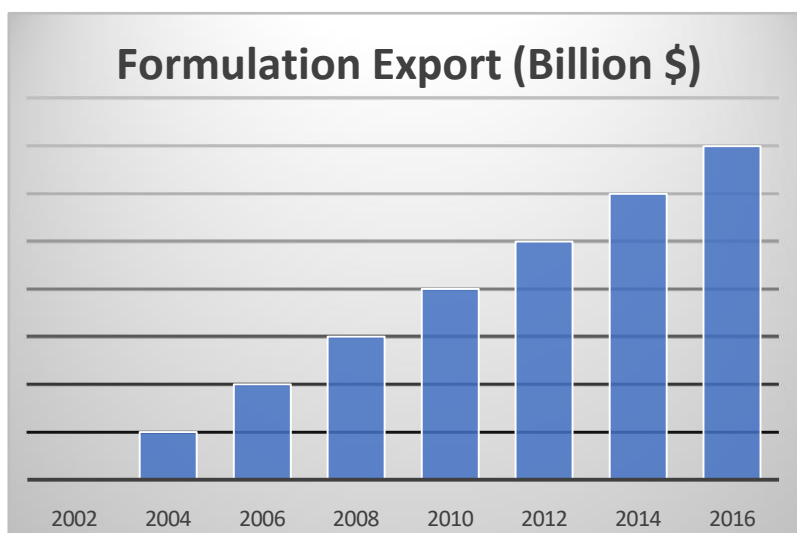


Figure 1: Growth of Indian Formulation Export in Billion \$ Vs Trend

The findings show that Indian formulations are increasing steadily and are unaffected by changes in patent regulations. By 2023, they are expected to reach \$7 billion.

4.2. Bulk Drug Export

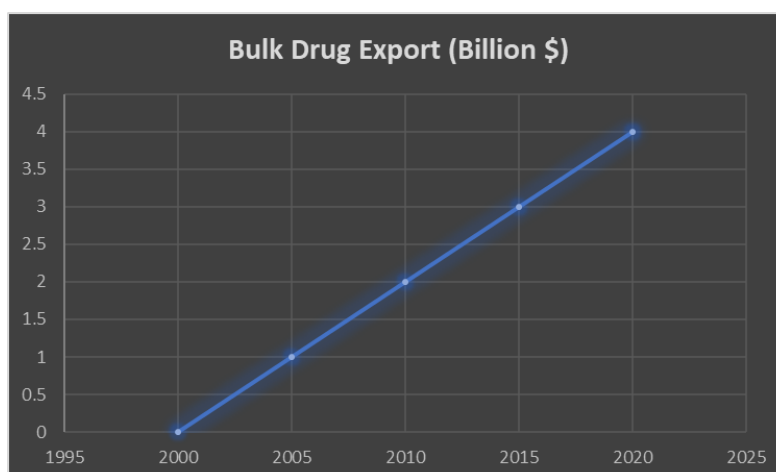


Figure 2: Growth of Indian Pharmaceutical Contract Research Actual Vs Trend

According to the study's findings, the bulk medicine market in India would be valued at 6.5 billion dollars in 2023.

5. CONCLUSION

India began its unique intellectual property journey more than 40 years ago, motivated by

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the need to support the development of the country's pharmaceutical industry and provide for its impoverished people. Nonetheless, recent modifications to India's intellectual property laws demonstrate the country's compliance with global IP norms. This change has had a significant impact on a number of aspects of the Indian pharmaceutical industry. The expiration of patents for well-known pharmaceuticals and the convergence of international patent laws have created a significant opportunity for Indian manufacturers to excel in creating generic copies at competitive pricing. Certain firms have prospered in the generic medication industry by utilising their proficiency in process advancements. However, difficulties still exist, especially in the home market where access to healthcare is restricted and per capita income is low. Several companies have delved into new chemical creation and established strategic alliances with both local and foreign rivals, going beyond standard technology transfer agreements, in an effort to explore multiple growth possibilities. Indian pharmaceutical companies have also proven their strength in exporting formulations and bulk drugs. The industry's adaptability and endurance in the face of shifting patent regulations highlight its forward-thinking outlook and tenacity. Prospects for the industry look good going forward, particularly in the area of contract research, suggesting more growth and success in the years to come.

REFERENCES

1. Farhan, N. H., Tabash, M. I., Almaqtari, F. A., & Yahya, A. T. (2020). *Board composition and firms' profitability: Empirical evidence from pharmaceutical industry in India.*
2. Ganguly, A., Talukdar, A., & Chatterjee, D. (2020). *Social capital, knowledge quality, knowledge sharing, and innovation capability: An empirical study of the Indian pharmaceutical sector. Knowledge and process management, 27(1), 25-42.*
3. Gupta, K., Goel, S., & Bhatia, P. (2020). *Intellectual capital and profitability: Evidence from Indian pharmaceutical sector. Vision, 24(2), 204-216.*
4. Nandy, M. (2020). *Is there any impact of R&D on financial performance? Evidence from Indian pharmaceutical companies. FIIB Business Review, 9(4), 319-334.*
5. Panwar, A., Jain, R., Rathore, A. P. S., Nepal, B., & Lyons, A. C. (2018). *The impact of lean practices on operational performance—an empirical investigation of Indian process industries. Production Planning & Control, 29(2), 158-169.*

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6. Saha, E., Rathore, P., Parida, R., & Rana, N. P. (2022). *The interplay of emerging technologies in pharmaceutical supply chain performance: An empirical investigation for the rise of Pharma 4.0. Technological Forecasting and Social Change*, 181, 121768.
7. Sarwenda, B. (2020). *Intellectual capital, business performance, and competitive advantage: An empirical study for the pharmaceutical companies. QUALITY Access to Success*, 103-106.
8. Sharma, S., & Modgil, S. (2020). *TQM, SCM and operational performance: an empirical study of Indian pharmaceutical industry. Business Process Management Journal*, 26(1), 331-370.
9. Tyagi, S., Nauriyal, D. K., & Gulati, R. (2018). *Firm level R&D intensity: evidence from Indian drugs and pharmaceutical industry. Review of Managerial Science*, 12, 167-202.
10. Yameen, M., Farhan, N. H., & Tabash, M. I. (2019). *The impact of liquidity on firms' performance: Empirical investigation from Indian pharmaceutical companies. Academic journal of interdisciplinary studies*, 8(3), 212-220.
