

THE IMPACT OF REGULATORY CHANGES IN PHARMACEUTICAL MARKET ACCESS AND PRICING: A COMPARATIVE ANALYSIS

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By

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Abstract

- The study examines **THE IMPACT OF REGULATORY CHANGES IN PHARMACEUTICAL MARKET ACCESS AND PRICING**, as well as the connection between regulatory settings and pharmaceutical innovation.
 - The present study employed secondary data gathering methods to ensure a thorough investigation of the influence of regulatory changes on the pharmaceutical business.
 - The findings highlight the nuanced effects of regulatory interventions on the availability, price, and progress of medications, providing useful insights into how different regulatory approaches impact market dynamics and the welfare of patients.
 - Ultimately, this comparative research combines information from several regulatory contexts to offer insights into the intricate relationship between regulatory changes, pharmaceutical market entry, and pricing tactics.
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Introduction

- The pharmaceutical sector serves a crucial role in the healthcare system, as it is responsible for manufacturing and advertising medications, biological products, and medical equipment. These products are employed in the detection and treatment of ailments, and the industry also conducts research to create new products for the improvement of human welfare.
- The correlation between regulatory compliance and the concept of change control is indissoluble. Lack of adequate change control procedures poses a substantial danger of non-compliance within a pharmaceutical company's quality management system (Ugvekar, et al., 2021).
- Pharmaceutical markets are characterized by a lack of responsiveness to price changes, primarily because of widespread medical insurance coverage. Additionally, the patent system grants market strength to pharmaceutical companies by preventing the replication of novel chemical compounds for a specific duration. This combination has prompted most countries to employ diverse methods to regulate the increase in medical expenses (Brekke, et al., 2009).

➤ Regulatory Changes in Pharmaceutical

- The regulatory framework in the Indian pharmaceutical business is of utmost importance due to the swift and continuous changes occurring at the international level, particularly in relation to “good manufacturing practices (GMP)”, “good clinical practices (GCP)”, and “good laboratory practices (GLP)”.
- The Indian pharmaceutical industry is experiencing continuous growth and intensifying competition. As a result, regulatory bodies have been created to ensure the safety, efficacy and quality of pharmaceutical, as well as the accuracy and appropriateness of drug information available to the public (Chatterjee, et al., 2021).
- The oversight of medical items has been progressively broadening since the early 20th century. The pharmaceutical, biotechnology, and medical devices sectors are subject to extensive regulations, making them some of the most tightly regulated industries globally. Regulatory affairs (RA) experts work in several sectors such as the pharmaceutical industry, government, academic research, and clinical facilities (Philip and Philip, 2010).

➤ **Impact of Regulatory Changes on Drug Pricing**

- In 1993, reference pricing was introduced as a reimbursement system where patients receive a partial refund of the retail price when purchasing prescription drugs. Before “April 1, 2005” the reference price was determined by taking the lower value between the list price of a product’s own substitution group and the average price of the corresponding European market (Kaiser, et al., 2014).
- The Supreme Court of India has lately criticized the price restriction, labeling it as "unreasonable and irrational", and has requested the government to review the pricing policy. The DPCO faced scrutiny for included 108 non-scheduled formulations in price control for public benefit, but later reversed its decision.
- The pricing for individual units of all oral formulations and injections were considered, as the DPCO also establishes maximum prices for a single unit. Formulations with specific characteristics such as extended release, dispersible tablets, and controlled release were not included. The ceiling prices specified in the compendium of notified ceiling prices 2015 were observed (Atal, et al., 2016).

➤ **Relationship Between Regulatory Environments and Pharmaceutical Innovation**

- Social laws play a crucial role in influencing innovative efforts towards environmental and health protection. Companies often need to provide novel solutions to meet these challenges, often requiring substantial breakthroughs.
- In the pharmaceutical sector, innovation is essential for firms' performance and reputation. International pharmaceutical patent law encourages innovation through patents and exclusivity, promoting public welfare. R&D is vital in the pharmaceutical industry, driving the development of new drugs.
- The approval of these drugs is the most significant outcome of innovation. Implementing new regulatory regimes for the lifecycle of pharmaceuticals can improve public health services by allowing new treatments to be introduced earlier.
- However, insufficient monitoring and supervision can diminish the effectiveness of this approach, leading pharmaceutical companies to exploit existing patented technologies instead of investing in new technologies (Bouchard, et al., 2009).

➤ **Problem of the study**

This study examines the impact of regulatory changes on pharmaceutical market access and pricing across different jurisdictions. It aims to analyze the effects of these changes on market entry and pricing tactics in specific nations, providing insights into how regulatory frameworks change market dynamics and healthcare outcomes globally.

➤ **Importance of the study**

The study "The impact of Regulatory Changes in Pharmaceutical Market Access and Pricing: A Comparative Analysis" examines variations in regulatory frameworks across different regions or countries, providing insights into effective strategies and potential challenges. It is timely as healthcare systems worldwide grapple with rising pharmaceutical costs and the need for fair access. The findings can guide governments, pharmaceutical companies, and healthcare providers in developing regulatory strategies that balance innovation, pricing, and accessibility.

➤ **Research Objectives**

- i. To Analyze the Impact of Regulatory Changes on Market Access.
- ii. To Assess the Influence of price regulation “(Drug Price Control Order 2013)” on Drug Affordability and Availability, 2008–2018:
- iii. To investigate the Relationship Between Regulatory Environments and Pharmaceutical Innovation:
- iv. To provide Policy Recommendations for Optimizing Market Access and Pricing Strategies.

Aim of the study

The study examines the impact of regulatory changes on pharmaceutical accessibility and pricing, comparing different approaches globally. It seeks to identify patterns, differences, and similarities, providing insights for stakeholders like pharmaceutical companies, healthcare providers, and patients, and enhancing understanding of the complex relationship between rules, market dynamics, and pricing strategies.

Review of Literature

Author	Title	Findings
Grünwald, F., & Stargardt, T. (2024)	Harmonizing regulatory market approval of products with high safety requirements: Evidence from the European pharmaceutical market.	The findings indicated that countries observed an average reduction in launch delay of 10.9 months ($p = 0.004$) following their accession to the European Union.
Rathore, A. S., et al., (2023)	FDA warning letters: a retrospective analysis of letters issued to pharmaceutical companies from 2010–2020.	The study compiled warning letters issued by the FDA between 2010 and 2020, obtaining data such as the issuance date, company name, and nature of the violations from the FDA website.
Janjal, V. S., et al., (2021)	Recent drug regulatory affair and CTD module progress review for submission of pharmaceuticals product.	It stated that Pharmaceutical regulatory issues are concerned with the procedure of obtaining official approval for pharmaceutical products.

Mensa Sorato, M., et al., (2020)	Why healthcare market needs government intervention to improve access to essential medicines and healthcare efficiency: a scoping review from pharmaceutical price regulation perspective.	It ensured that individuals in the healthcare market have inexpensive access to high-quality critical medicines is a key objective of “universal health coverage and health-related sustainable development goals”.
Mary, D., et al., (2017)	Evaluation of Pharmaceutical Regulatory System & present scenario of Indian pharmaceutical industry.	The study concluded that the regulatory landscape is of utmost importance as well as the responsibility placed on regulatory authorities to guarantee a sufficient availability of high-quality medications at reasonable costs for the Indian population.
Tekiner, H., & Ulu, A. (2015)	The historical evolution of the Turkish pharmaceutical legislation from 1852 to the present.	The analysis found that several issues, such as the credentials required for pharmacists, the prerequisites for establishing a pharmacy, and the national pharmacopoeia.

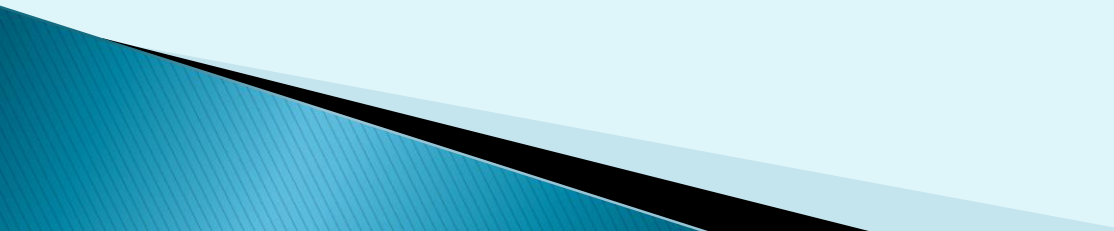
Murteira, S., et al., (2014)	Drug reformulations and repositioning in the pharmaceutical industry and their impact on market access: regulatory implications.	It study found that repurposing has become a widely used approach in medication development, although it encounters various obstacles, including the growing and constantly evolving regulatory framework.
Boscaljon, B. L. (2013)	Regulatory changes in the pharmaceutical industry.	The study evaluated the market response of pharmaceutical companies' stock prices after the release of new advertising guidelines by the FDA. The pharmaceutical business experiences positive effects after the FDA announcement.
Tabibi, S. J., et al., (2012)	Challenges & opportunities facing the pharmaceutical industry in Iran: A qualitative approach.	It determined the primary organizational elements that have the greatest impact on the distribution system of pharmaceutical medications in Iran. The study marked defined participant selection criteria and utilized deliberate sampling, followed by snowball sampling.

Research Gap

The study aims to address the lack of research on the impact of regulatory changes on pharmaceutical markets by examining regulatory frameworks in specific countries or regions.

It will provide detailed insights into how different regulatory methods affect drug accessibility, pricing tactics, and patient outcomes by analyzing variances in regulatory settings.

Current research often focuses on individual national viewpoints or lacks analysis of market entry and pricing tactics across different regions or nations.



Research Methodology

- The study used a robust methodology focused on gathering secondary data to examine the effects of regulatory changes on the pharmaceutical business and their effect on the affordability, accessibility, and innovation of drugs.
- The research goals were achieved using a diverse strategy combining quantitative and qualitative data sources. This technique allowed for a thorough understanding of the regulatory environment and its impacts.
- Descriptive statistics were used to assess the impact of price control, specifically the “Drug Price Control Order (DPCO)” 2013, on the affordability and availability of drugs between 2008 and 2018.
- Market analysis reports were used to collect data on the overall sales of medicine, sales of antibiotics, and sales of price-regulated antibiotics.
- The impact of the “DPCO 2013” intervention on medicine sales and market dynamics was evaluated using interrupted time series analysis.

Results and Discussion

Objective 1: To analyze the Impact of Regulatory Changes on pharmaceutical industry.

- The pharmaceutical industry is in a perpetual state of change, as new breakthroughs in medicine and technology influence the delivery of healthcare. Regulatory changes have a substantial influence on the industry.
- The pharmaceutical business has experienced a rise in the complexity and dynamism of regulatory reforms. Governments worldwide are implementing new laws and regulations to enhance patient safety and bolster healthcare systems, which have an impact on pharmaceutical businesses.
- The regulatory changes have a multifaceted influence. Pharmaceutical businesses should allocate additional time and resources to ensure compliance with new rules, which might potentially result in delays in the release of new products and higher expenses.
- Ultimately, alterations in regulations exert a substantial influence on the pharmaceutical sector. Pharmaceutical businesses are now required to allocate additional time, money, and expertise to ensure compliance due to the implementation of tougher rules for clinical trials, more stringent approval processes, and higher pharmacovigilance requirements.

Objective 2: To Assess the Influence of price regulation, “(Drug Price Control Order 2013)” on Drug Affordability and Availability, 2008–2018.

Table 1: Descriptive Statistics

Market	2008	2013	2018
Total Medicine Sales (INR Billions)	410	790	1290
Antibiotics Sales (INR Billions)	74	113	140
Price Regulated Antibiotics Sales (Value INR Billions; % in parentheses)	26.2 (35%)	36.3 (32%)	40.6 (29%)
Price Regulated Antibiotics Sales (Volume in million SUs; % in parentheses)	4495 (45%)	5873 (46%)	5855 (49%)
Number of Companies Selling Antibiotics	535	401	535

The Indian pharmaceuticals market experienced significant growth from 2008 to 2018, with total medicine sales increasing from 410 INR billion to 1290 INR billion.

Antibiotics sales also rose from 74 INR billion to 140 INR billion, though growth slowed in the latter five years. The value of price-regulated antibiotics sales increased in absolute terms but decreased in percentage terms, suggesting a lesser relative impact of price regulation over time.

However, the volume of price-regulated antibiotics sales rose, suggesting a higher quantity being sold under regulation. The number of companies selling antibiotics fluctuated, dropping from 535 in 2008 to 401 in 2013, before returning to 535 in 2018, indicating market consolidation followed by re-expansion. Overall, the data reflects a growing pharmaceuticals market with dynamic regulatory impacts and changing market participation.

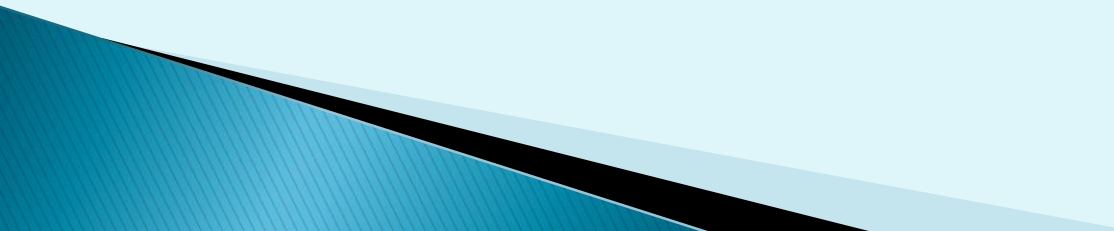
Objective 3: To investigate the Relationship between Regulatory Environments and Pharmaceutical Innovation.

Table 3: Regulation Effects on Pharmaceutical Innovation

Objective	Aspect	Positive Effects	Negative Effects
Economic	Competition	Increases and guarantees incentives for innovation	Reduces income for investors, hindering R&D cooperation
	Antitrust	Allows competitors to enter the market and push leading companies	The leading companies in innovation are limited by the incentives to invest in R&D.
	Mergers and Acquisitions	Allows the efficient acquisition of innovative companies.	Limits absorption strategies and innovation incentives.
	Market Access	Reduces competition for companies that are already in the market	Hinders the entry of potential innovative companies.
	Pricing	Minimum prices reduce risks and guarantee a minimum volume of sales. Fully free prices lead to monopolistic prices	Maximum prices reduce incentives to innovate.
	Public Corporations and Natural Monopolies	Promotes progress in productivity by regulating the rate of return.	Marginal pricing discourages R&D investment.
Social	Environmental Protection	Encourages the development of new ecofriendly processes and products by setting temporary barriers to market entry.	Limits innovation and creates compliance costs.
	Occupational Health and Safety	Encourages the development of safer processes by setting temporary barriers to market entry and to monopoly profits.	Limits innovation and creates compliance costs.
	Consumer and Producer Safety	Increases the acceptance of new products among consumers and promotes their use, encouraging innovation.	Limits innovation and creates compliance costs.

Institutional	Employment Protection	Job security	High adjustment costs.
	Bankruptcy Laws	Greater creditor confidence to invest in innovation	Restrictions to obtain external funds for risky investments.
	Intellectual Property Rights	Creates additional incentives to invest in R&D through the temporary appropriation of monopolistic rights.	Limits the development and diffusion of new technologies and products.
	Liability Rights	Increases the acceptance of new products among consumers and promotes their use, encouraging innovation.	Very high liability risks reduce incentives to develop and market innovative products.
	Immigration	Immigration of foreign workers increases pressure on local workers.	Integration costs

- Pharmaceutical innovation is significantly influenced by various economic, social, and institutional factors. Economic factors like competition, antitrust legislation, mergers and acquisitions, market access, pricing, and public enterprises play a crucial role in this process. Competition can stimulate innovation but may limit investor revenue, while antitrust regulations encourage new competitors.
- Mergers and acquisitions can facilitate the acquisition of innovative enterprises but may restrict internal incentives.. Enforcing regulations on public enterprises and natural monopolies enhances productivity but hinders investment in research and development.

- Environmental regulations promote sustainable innovation but impose compliance costs, while health and safety rules guarantee safer work conditions. Institutional variables like employment protection, bankruptcy rules, intellectual property rights (IPR), liability rights, and immigration also influence innovation. A well-balanced strategy is needed to foster continuous and efficient innovation in the pharmaceutical sector while protecting broader economic, social, and institutional objectives.
 - Social factors like environmental protection, occupational health and safety, and consumer and producer safety also influence innovation
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Future Scope of the study

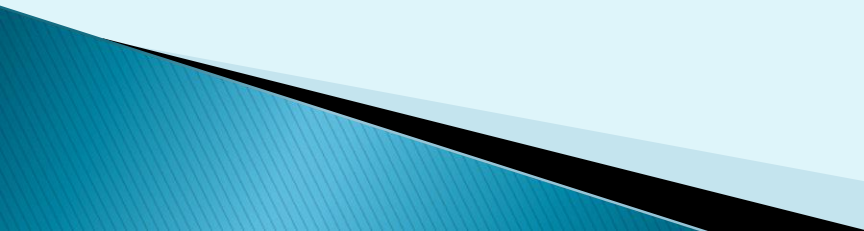
Finally, the dissertation will suggest potential areas for future research to delve deeper into the changing regulatory environment and its effects on pharmaceutical markets. Possible subjects encompass developing regulatory patterns, digital healthcare advancements, and the impact of worldwide health emergencies on regulatory structures.

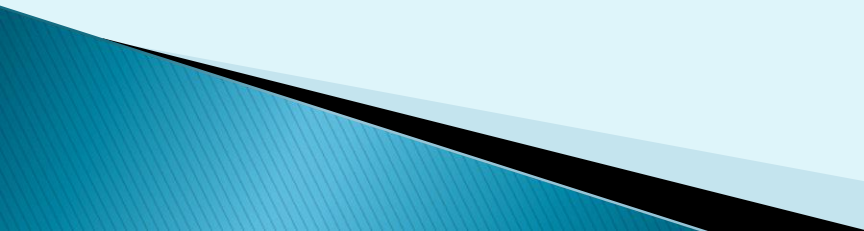
Implications of the study

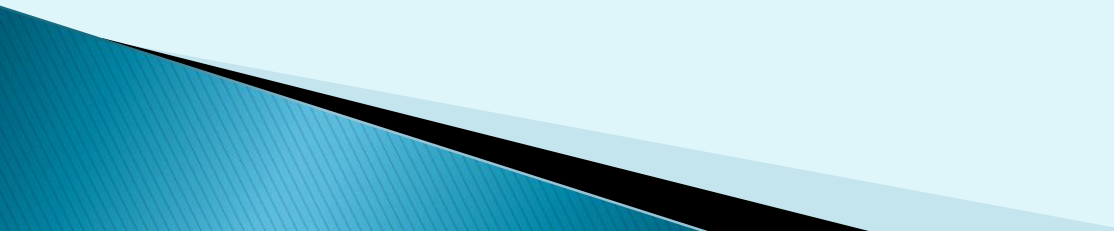
The study explores the impact of regulatory changes on pharmaceutical market access and cost, highlighting the importance of understanding the regulatory environment for policymakers, pharmaceutical firms, healthcare practitioners, and patients. It highlights the need for informed decisions regarding pricing strategies and market entry, as well as the potential benefits for patients, such as increased transparency and potentially reduced medication costs. The analysis highlights the intricate relationship between legislation, market dynamics, and healthcare outcomes, guiding the development of informed policies and strategic plans in the pharmaceutical industry. By understanding these factors, stakeholders can gain a competitive edge and improve patient access to drugs.

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THANK YOU!