

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

Internship Report submitted

To



The IIHMR University, Jaipur

For the partial fulfillment for the award of the
degree of

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In

Pharmaceutical Management

By

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GALCARE PHARMACEUTICAL

Galcare Pharmaceutical Pvt. Ltd.

Established in September 2008, Galcare Pharmaceutical Pvt. Ltd. specializes in dermatological products, offering a wide range of solutions for skin care and dermatological conditions. With a strong commitment to innovation and quality, Galcare has positioned itself as a trusted name in the dermatology sector. The company is dedicated to improving skin health and enhancing the quality of life for patients through advanced, effective, and safe dermatological products.

Vision: To be a leading global dermatology company, recognized for our innovative and high-quality skin care solutions that promote healthier, more beautiful skin.

Mission: Galcare Pharmaceutical Pvt. Ltd. is committed to advancing dermatological science and providing effective, safe, and innovative products. Our mission is to improve skin health and patient outcomes through cutting-edge research, development, and a customer-centric approach.

Values:

- **Innovation:** Continuously pushing the boundaries of dermatological science to develop novel and effective skin care solutions.
- **Quality:** Maintaining the highest standards in product safety, efficacy, and manufacturing practices.
- **Integrity:** Upholding ethical principles and transparency in all our business operations.
- **Customer Focus:** Prioritizing the needs and well-being of our customers and patients.

1. Acknowledgements

I would like to sincerely thank my mentor, Mr.Irfan Ahmad Sir for his invaluable guidance and support throughout my internship at Galcare Pharmaceutical Company. I am also grateful to the management and staff of Galcare Pharmaceutical Company for providing a conducive learning environment and all necessary resources.

2. Introduction

This report details my internship experience at Galcare Pharmaceutical Company, where I undertook a research project on '*The Impact of Regulatory changes on Pharmaceutical Market Access and Pricing.*' The primary objective was to explore and analyze the influence of regulatory frameworks on the pharmaceutical industry's market access and pricing strategies.

3. Objectives

- To understand the regulatory landscape affecting the pharmaceutical market.
- To analyze the impact of regulations on market access and pricing strategies.
- To provide recommendations based on the findings to improve market access and pricing policies.

4. Methodology

- **Literature Review:** Conducted an extensive review of existing literature on pharmaceutical regulations, market access, and pricing.
- **Primary Research:** Carried out interviews and surveys with industry professionals and regulatory authorities.

- **Data Analysis:** Utilized statistical tools and software for analyzing the collected data.

5.1 Literature Review

The literature review focused on understanding the regulatory landscape and its historical context. Key areas included regulatory policies, compliance requirements, and their implications for market access and pricing strategies.

5.2 Primary Research

Conducted structured interviews with regulatory experts, pharmaceutical executives, and policymakers. Designed and distributed surveys to gather quantitative data on the perceptions and impacts of regulatory measures.

5.3 Data Analysis

Utilized tools like SPSS and Excel for data analysis. The analysis included descriptive statistics, correlation analysis, and regression analysis to understand the relationships between regulatory policies and their impact on market access and pricing.

6. Findings and Discussion

- **Regulatory Impact:** Stringent regulatory frameworks can delay market access and increase the cost of compliance, affecting pricing strategies.
- **Market Access:** Regulatory hurdles often result in extended timelines for drug approvals, impacting the availability of new treatments in the market.
- **Pricing Strategies:** Compliance costs and regulatory constraints influence pricing strategies, often leading to higher prices for end consumers.

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- **Comparative Analysis:** Countries with more streamlined regulatory processes tend to have faster market access and more competitive pricing.

7. Recommendations

- **Harmonization of Regulations:** Advocate for the harmonization of regulatory standards across regions to facilitate smoother market access.
- **Regulatory Innovation:** Encourage regulatory bodies to adopt innovative approaches, such as expedited review processes, to reduce delays.
- **Cost-Effective Compliance:** Develop strategies to minimize compliance costs without compromising on safety and efficacy.

8. Conclusion

My internship at Galcare Pharmaceutical Company under the guidance of Mr Irfan Ahmad Sir has been an enriching experience. The research project on **'The Impact of Regulatory change on Pharmaceutical Market Access and Pricing'** has provided me with valuable insights into the complex interplay between regulatory frameworks and the pharmaceutical industry. The findings and recommendations from this study can serve as a guide for policymakers and industry stakeholders aiming to enhance market access and pricing strategies.