

Synopsis for Dissertation



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By

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Title: *Procurement Related Challenges in Emerging Injectable Firms In India.*

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Synopsis of Dissertation

Introduction

The injectable pharmaceutical industry in India is a rapidly growing and vital segment of the global healthcare ecosystem. While marked by significant advancements, this sector, especially its emerging firms, faces a complex array of procurement-related challenges. These challenges are crucial to address as they can significantly limit growth and operational efficiencies, particularly for smaller companies that lack the infrastructure and resources of larger, more established players. The dissertation emphasizes the critical role of a robust procurement process in ensuring product quality, regulatory compliance, cost management, and overall competitiveness within this dynamic landscape.

Objectives of the Study

The primary objectives of this study are:

- To explore the intricate landscape of procurement challenges related to injectable pharmaceuticals, specifically focusing on emerging firms in India.
- To synthesize existing literature to elucidate the complexities influencing procurement dynamics.
- To identify best practices and strategies that can enhance the operational efficiency and competitiveness of emerging companies.
- To contribute to the discourse on the future of the injectable pharmaceutical industry in India and its role in global healthcare.

Problem Statement

Emerging injectable pharmaceutical firms in India encounter multifaceted procurement challenges that can limit their growth and operational efficiencies. Unlike larger firms with established processes and supplier relationships, smaller companies often lack access to sufficient resources, know-how, and market intelligence. These hurdles include difficulties in sourcing high-quality raw materials, navigating complex regulatory requirements, managing cold-chain logistics, facing cost pressures from raw material shortages and import dependence, and effectively managing overall costs. This often leads to production delays, increased costs, and potential quality issues.

Research Questions

While not explicitly listed as numbered questions, the dissertation implicitly seeks to answer:

- What are the unique procurement challenges faced by emerging injectable pharmaceutical firms in India?
- How do supplier reliability issues impact these firms, and what strategies can mitigate these risks?
- What are the complexities of regulatory compliance for emerging firms, and how can they ensure adherence?

- What are the critical cold-chain logistics challenges, and how can these be optimized?
- How do cost pressures, raw material shortages, and import dependence affect emerging firms, and what strategies can mitigate these impacts?
- What is the role of technology and collaborative approaches in enhancing procurement processes for these firms?
- What strategic pathways can enhance the resilience and sustainability of emerging injectable pharmaceutical companies in India?

Important Elements of the Study

- **Methodology:** The study employs a **secondary research methodology**, analyzing data already collected and published by researchers, organizations, and regulatory bodies. This approach is chosen due to the wealth of existing literature in the pharmaceutical sector and the challenges of primary data collection.
- **Data Sources:** Primary databases consulted include **PubMed and Scopus**, using keywords like "pharmaceutical procurement," "injectable drugs," "supply chain management," and "regulatory compliance."
- **Inclusion/Exclusion Criteria:** Focused on recent studies (within the last five years), empirical data, case studies, or comprehensive analyses specific to the Indian context. Outdated or irrelevant studies were excluded.
- **Thematic Analysis Approach:** A qualitative method involving familiarization with data, generating initial codes, searching for and reviewing themes, and defining/naming them.
- **Key Themes Identified:** Regulatory Compliance, Supply Chain Disruptions, Cost Management, Technological Advancements, and Stakeholder Collaboration.
- **Theoretical Frameworks:** Discusses Transaction Cost Economics (TCE), Just-In-Time (JIT) principles, and Strategic Sourcing theory to analyze procurement dynamics.

Key Insights

The dissertation provides several key insights into the procurement challenges:

- **Supplier Reliability:** Emerging firms often struggle with inconsistent quality and availability of raw materials due to limited bargaining power and lack of established relationships, necessitating investment in supplier relationship management and diversification.
- **Regulatory Compliance:** The complex and evolving regulatory environment (e.g., GMP, quality control) poses a significant financial and human resource burden, requiring proactive strategies like staff training and leveraging technology.
- **Cold-Chain Logistics:** Maintaining product integrity requires strict temperature control, which is costly and complex, especially for firms in remote areas. Innovations like IoT-enabled monitoring and strategic partnerships with logistics providers are crucial.

- **Cost Pressures:** Fluctuations in raw material prices, import dependence, and market volatility create financial strain. Strategies include diversifying suppliers, strategic sourcing, lean procurement, and R&D for cost-effective production methods.
- **Raw Material Shortages:** Disruptions (e.g., natural calamities, geopolitical tensions, pandemics) highlight the vulnerability of supply chains, emphasizing the need for diversified supplier bases and alternative sources.
- **Import Dependence:** Heavy reliance on imported raw materials exposes firms to price volatility, currency fluctuations, and trade policies, advocating for local sourcing and robust domestic supply chains.
- **Technological Integration:** Digital tools (AI, ML, blockchain) are underutilized but can revolutionize procurement by improving visibility, streamlining operations, facilitating data-driven decision-making, and enhancing compliance tracking.

Recommendations for Action with Conclusion

The dissertation proposes strategic pathways for resilience:

- **Supplier Diversification:** Expand supplier networks across different geographical regions to mitigate risks from single-source reliance and foster competitive pricing.
- **Investment in Digital Tools:** Leverage digital procurement platforms, AI, ML, and blockchain to enhance efficiency, visibility, predictive analytics, and transparency.
- **Collaborative Sourcing Approaches:** Form alliances (joint ventures, partnerships, consortiums) with other firms to pool resources, negotiate better terms, share risks, and foster innovation.
- **Regulatory Training and Compliance Programs:** Invest in comprehensive training for staff on GMP, GDP, and other regulations, fostering a culture of compliance and continuous engagement with regulatory bodies.
- **Cold-Chain Innovations:** Explore and implement IoT-enabled monitoring systems and advanced packaging solutions to ensure product integrity and optimize logistics.
- **Strengthening Supply Chain Resilience:** Implement dual-sourcing strategies and invest in supply chain visibility tools.
- **Enhancing Regulatory Knowledge:** Collaborate with regulatory experts and establish dedicated regulatory affairs teams.
- **Prioritizing Quality Assurance:** Implement robust Quality Management Systems (QMS) and conduct regular audits.
- **Adopting Cost-Effective Procurement Strategies:** Explore group purchasing organizations (GPOs) and collaborative buying, and conduct regular market analyses.
- **Embracing Technological Advancements:** Invest in and train personnel on AI, ML, and blockchain for data-driven decision-making.

Final Conclusion

The dissertation concludes that the procurement challenges faced by emerging injectable pharmaceutical companies in India are multifaceted and necessitate strategic interventions. By understanding these challenges and implementing the recommended strategies—such as supplier diversification, investment in digital tools, collaborative sourcing, robust regulatory training, and cold-chain innovations—firms can significantly enhance their resilience and operational efficiency. The future of the injectable pharmaceutical sector in India is promising, but its success hinges on the ability of emerging companies to adapt, innovate, and maintain agility in a dynamic and competitive market. Continuous research, collaboration between academia and industry, talent development, and engagement in industry networks are crucial for shaping a robust and sustainable future for this vital sector.