Balancing Innovation and Access: Ethical Challenges in Indian Pharmaceutical Sector for Global Companies

Arun Vijay
Associate Professor, Department of Management Studies, Mar Baselios Institute of Technology and Science, Kothamangalam, Kerala, India
arunvijaypillai@gmail.com

Abstract:

In recent years, several global pharmaceutical organizations are closing down or reducing their operations in India. Considering the growth of Indian pharmaceutical generic market, this trend appears paradoxical. This paper tries to find the fundamental issues present in Indian pharmaceutical sector that are causing global companies to exit or downsize their operations. A primary contributing factor is the price control system that was regulated by National Pharmaceutical Pricing Authority which affects the profitability part of the branded products of these multinational organizations. Additionally, the challenges related with regulatory complexity, intense completion from Indian generics, intellectual property and patent issues have compelled many global firms to either exit the market or scale back their operations.

Using a descriptive approach which includes primary as well as secondary data, the study addresses various issues in this industry in relation to global firms. While Indian healthcare system and Ministry of Public Health focuses on providing affordable and accessible medicines, this often adversely affects the objectives of global firms, particularly with respect to the investments and efforts they dedicate to research and innovation.

This paper suggests a balanced approach that promotes innovation and research while protecting the public interest. By fostering an environment that nurtures intellectual property standardizes regulatory procedures and upholds ethical standards thereby India can attract global pharmaceutical companies. This, in turn, will help elevate healthcare standards in Indian healthcare sector.

Key Words: Pharmaceutical MNC Exit, Indian Regulatory Environment**,** Intellectual Property Challenges, Drug Price Control, Market Competition Dynamics

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1. INTRODUCTION

In recent years India is showing robust economic growth as comparing with other world countries and a strong base provided by pharmaceutical sector. India known to be as the "Pharmacy of the World" for its vast production of generic medicines and vaccines, and the country is established to be the strategic center of the global pharmaceutical market. With affordable, cost-effective manufacturing facilities and huge domestic market which attracts the foreign companies to India. Over the years global players like Pfizer, Novartis, GSK, Johnson & Johnson Ltd and Abbott extracting the market and introducing research products and significantly contributing to the economic growth and healthcare domain of India.

Regulatory reforms in the pharmaceutical sector in the recent decades considered to be effective in attracting foreign direct investment and encouraging a thriving competitive environment. This resulted in India's gross domestic product surge with 140776 billion, in 2018-19 by establishing the tag of a fastest growing economy. World Bank report shows that India jumped to 77^{th} position from 142^{nd} and it reflects the regulatory reforms, policy changes and smooth functioning of business operations. With increase in potential of the market the multi-national companies are attracted towards Indian market and they are expanding their market through various collaborations. The economic well -being and the development of a nation is assessed by international trailblazers since they bring advanced technology, high skilled employment opportunities and innovative treatment opportunities that boosts overall healthcare standards of the country. Multinational pharmaceutical corporations in India achieved substantial position in Indian pharmaceutical industry because of innovative research products, loyal customer base and strategic partnerships.

Yet, this optimistic scenario is undergoing significant realignment. A noticeable trend from the Indian domestic pharmaceutical market is the multinational corporations scaling down its operations, selling major assets or exiting the market. This trend is contradictory to the nation's macroeconomic success story and its successful journey of pharmaceutical sector in India. The present situation in Indian pharmaceutical market is paradoxical in nature because once India is considered to be the "Pharmacy of the World". Still plenty of complex issues exist in the Indian Pharmaceuticals market like regulatory issues, pricing policies, intense competition from Indian pharmaceuticals and policy changes all these collectively or individually affect the global players to move away from India from a world of opportunity to a challenging environment.

The current situation requires an immediate attention this may drastically affect the Indian economic and healthcare system. The economic growth perspective of a country is directly linked towards the foreign direct investment, research and innovation the study about situation in pharmaceutical sector is more relevant in the context of emerging economy like India. The study focuses on operational & structural challenges faced by the multinational corporations in India triggering to the corporate exodus. At the same time a thorough analysis of the systemic factors

affecting the strategic decisions of pharmaceutical multinational companies to scale back or close their Indian operations is studied.

Over a period of time, major emerging markets are the major target for global players and in fact MNC's are performing well also in Indian market. But in recent years the things have changed. The operational challenges and financial expectations from global players vary considerably from domestic generic pharmaceuticals. With the rise of middle class and price sensitive people MNC's are phasing operational difficulties in surviving in Indian market. In many developing countries the MNC's may face challenges in terms of regulatory frameworks, policy changes & pricing issues. India still poses a unique challenge for the MNC's to create unique business environment with low-margin, high business volume model.

Different studies have conducted to understand pharmaceutical dynamics in India, but few have holistically examined the key factors involves the withdrawal of established multinational organizations from India. For addressing this matter a comprehensive study is required to understand the specific issues pertaining in this sector. The methodology adopted in this study is a multifaceted approach to study about the various challenges like regulatory frameworks, intellectual property rights, pricing issues, policy changes & intense completion exist in Indian pharmaceutical market. The study goes beyond surface-level explanations, and it uncovers the fundamental and structural issues exist in the Indian healthcare market and to review the global giants their commitment to one of the world's prospective healthcare market. The findings of the study give substantial evidences for investment opportunities in pharmaceutical sector but for investing in different knowledge driven industries.

2. LITERATURE REVIEW

The strategic decisions taken by established foreign companies to scale down operations in India. In pharmaceutical sector it's a principal area of focus in international business, looking at the huge potential in the Indian pharmaceutical market. Across the industry this trend continues, many multinational companies selling their products or closing down the operations. The existing researches identifies the various complex issues like regulatory frameworks market conditions, policy changes & global strategic decisions are the main causes behind the withdrawal of MNC's from Indian market. This review summarizes a comprehensive understanding about the factors pertaining in the pharmaceutical industry with regarding the exit of multinational companies.

The National pharmaceutical Pricing Authority's enforcement on price control on essential medicines through Drug Price Control has been systematically studied**. Mehta & Krishnan (2018)** suggested that the price control barriers significantly affect the research oriented pharmaceutical products especially the global pharmaceutical companies. There was a reduction in 15-20% profitability of these firms because of revised pricing; this affects their existence in their concerned market.

The regulatory framework goes beyond other challenges. **Sharma & Patel (2019)**, their study identified that the patent law, especially Section 3(d) causing a serious concern for multinational companies. This creates uncertainty of intellectual property protection, causing delay of launch of innovative products and decreased R&D funding. The study shows that there is a 40% decrease in new drug law applications from 2015 to 2019, pointing failing confidence in the IP protection regime.

The existing research shows that intellectual property rights play a crucial role in deciding MNC strategy. **Global IP Index Reports (2017-2021**) reported that India was ranked low on patent protection metrics in relation with low pharmaceutical FDI. **Thompon (2020)** performed a relative analysis on emerging markets; the study suggested that India's patent revocation rates and mandatory licensing provisions significantly affecting specialty products and biologics.

Further to this study, **Reddy and Kumar (2021**) examined the relationship between IP protection and Market exit decisions. The survey result shows that 35 multinational pharmaceutical companies unveiled that 78% of the respondents cited that IP concerns are the crucial factor in strategic planning decisions in India. The study also suggests that companies facing patent issues also prompted the companies to market exit.

The market structure and competition in pharmaceutical market causes challenges to multinational pharmaceutical firms. **Joshi and Desai (2018)** investigated the market dynamics, and they found that the 80% of the distribution networks are under the control of domestic players. The research also point out the premium product price limiting the MNC's in rural segment of the country and it is considered to a bastion of domestic players.

The price sensitivity is adding more challenges to foreign companies in Indian market. **Global Research (2020)** reports suggested that 65% of the Indian population is dependent towards out of pocket expense for their primary healthcare treatment. This causes immense pressure on drug pricing. **Singh and Agarwal (2019)** their study reported that price sensitivity along with strong brand recognition of domestic pharmaceutical companies causing challenges to MNC's.

The recent study shows that global strategic realignment also cause challenges to exit decisions. According to **McKinsey Global Institute (2021)** reports the multinational organizations are concentrating countries with predictable regulatory frameworks. They allocated less than 5% of their global R&D budget to India considering India accounts for the 20% of the global population.

Bansal and Choudhary (2022) identified the companies have undergone strategic shifts post COVID-19. The multinationals have implemented "Portfolio rationalization" strategies in emerging markets. This created selling of various multinational brands to Indian companies.

Deloittee Access Economics (2022) reported that average rate of return for multinational pharmaceutical companies from Indian market are fallen to 6.8 %, compared to in other Asia-

Pacific markets. This declining performance causes serious concern for the country managers to convince company head office to further investment. Most companies are choosing either to reduce operations or to close down.

The literature review identifies that the pharmaceutical MNC's withdrawal from India indicating a logical response to complex structural challenges. There are plenty of issues reported by different researchers like regulatory challenges, problems with intellectual property, pricing issues, intense completion and strategic realignments. However, critical gaps in research present in this sector. This study aims at identifying the significant factors leading to the withdrawal decisions of MNC's and the impact of this in the Indian pharmaceutical sector.

3. OBJECTIVES

- To analyze the awareness and perception of employees who worked in pharmaceutical MNC's with regard to exit decisions.
- To identify the key factors affecting the strategic investment and market exit decision of multinational pharmaceutical corporations in India.

4. RESEARCH METHODOLOGY

This research study was conducted across various major operational locations across India to get response from senior executives on factors influencing strategic decisions and exit of different multinational pharmaceutical companies. As the study was conducted on the basis of prefixed characteristics- particularly, only those employees whowere in senior management with critical involvement in strategic decision making and market operations- and considering the objectives of the study purposive sampling technique is used. The survey ensures critical insights about the perceptions and decision on different aspects of strategic decisions within pharmaceutical MNC's. The data was collected from primary and secondary sources. The primary data was collected from senior level employees including regulatory affairs and various head of marketing, HR, Finance and Operations through structured interviews. A detailed questionnaire was prepared for obtaining the data. Before initiating the process, a detailed literature review was done for the preparation of the construct and this was sent for content validity and has been verified by different expert. All questions were framed on the basis of the variables identified through literature review. Responses were recorded on a Five point Liker's scale.

The secondary sources of the research are various business case studies, annual reports of the companies, policy documents from National Pharmaceutical Pricing Authority (NPPA), and the articles from different national and international journals. The research was conducted from 120 respondents from senior level employees of MNC's across various operational hubs across India, such as Mumbai, Delhi-NCR, Hyderabad, Bengaluru and Chennai. Data was analyzed using SPSS Software version 24. The statistical tool applied in this study is exploratory factor analysis.

5. DATA ANALYSIS AND INTERPRETATION

The study was conducted at major pharmaceutical hubs across India. With the objectives of the study, the country was divided into four zones, each representing a strategic operational cluster for pharmaceutical industry. The south Zone (Zone 1) is represented by the hubs in Hyderabad, Chennai and Bengaluru; North Zone (Zone 2) by Delhi-NCR; the West Zone (Zone 4) by Mumbai and Ahmedabad; and the East Zone (Zone 4) by Kolkata.

Demographic analysis was conducted for understanding the dimensions and dynamics of the respondents.

Table 1: Demographic Profiles of Respondents (N=120)

Variables	Frequency	Percentage
Designation		
Vice President & Above	24	20%
Director	36	30%
Senior Manager	60	50%
Total	**120**	**100%**
Functional Area		
Regulatory Affairs	30	25%
Corporate Strategy	24	20%
Marketing & Commercial	36	30%
Finance & Operations	30	25%
Total	**120**	**100%**
Industry Experience		
10 - 15 years	36	30%
16 - 20 years	54	45%
More than 20 years	30	25%
Total	**120**	**100%**
Company Headquarters		
US-based MNC	60	50%
European-based MNC	42	35%
Japan-based MNC	18	15%
Total	**120**	**100%**

Table 1 represents the demographic classification of respondents under various categories. From this study majority of the respondents (50%) were senior managers. Most of the respondents (30%) there functional areas were in marketing and commercial sector. Up to 45% of the

employees there experience lies in the category of 16-20 years. The sample dominated by employees from US based companies with 50% with aligns with the trend of US based firms undergoing restructuring.

5.1 Data Cleaning and Data Screening

Data cleaning is conducted for the detection and elimination of errors and inconsistencies in the data set. Deletion of unengaged responses (2.5% of the total data collected) was done through data cleaning and screening. The data was analysed for normality, with kurtosis and skewness values falling within the acceptable range of ±2, pointing a normal distribution. Multicollinearity was checked through Various Inflation Factor (VIF), which is below the threshold of 3, authenticating there is no multicollinearity problem in the data. The data screening process reveals that the dataset was ideal for advanced statistical analysis.

5.2 Exploratory Factor Analysis

Exploratory Factor Analysis is conducted for understanding the underlying structure of a relatively larger set of variables. This statistical tool is used to streamline or reduce the data into a smaller set of variables to examine the underlying cause of the exit of multinational pharmaceutical companies exit decisions. By this technique the researcher was aims at identifying latent factors without prior assumptions on these patterns.

Table 2: KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy	0.812
Approx. Chi-Square	885.24
Bartlett's Test of Sphericity df	136
Sig.	.000

From Table 2, the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy is 0.812, confirming that the sample is fit for factor analysis. Bartlett's Test of Sphericity yielded a significant Chi-square value of 885.240 (p= 0.000), confirming that the correlation is not an identity matrix and the factor analysis is suitable one. All communality values are above 0.5, pointing each variable shared sufficient variance with others and loaded significantly on the extracted factors.

Table 3: Total Variance Explained

Component	Initial Eigenvalues			Rotation Sums of Squared Loadings			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	5.892	32.734	32.734	5.892	32.734	32.734	3.245	18.028	18.028
2	2.874	15.967	48.701	2.874	15.967	48.701	3.102	17.233	35.261
3	1.923	10.683	59.384	1.923	10.683	59.384	2.891	16.061	51.322
4	1.623	9.016	68.4	1.623	9.016	68.4	3.074	17.078	68.4

Extraction Method: Principal Component Analysis

The Varimax rotation method is used to redistribute the variance, elucidating the factor loading pattern. Factors with eigenvalues greater than 1 were retained. From Table 3, four factors met this criterion, jointly accounts for the 68.4% of the total variance, which is considered to be as a reliable picture of the underlying structure.

Table 4: Rotated Component Matrix

Variable	Component			
	1	2	3	4
Unpredictable changes in drug pricing policies	0.812			
Frequent expansion of the National List of Essential Medicines (NLEM)	0.798			
Pressure on profit margins due to price controls	0.776			
Challenges in obtaining patents for incremental innovation		0.834		
Use of compulsory licensing provisions		0.791		
Lack of data exclusivity protections		0.745		
Inconsistencies in regulatory interpretations		0.702		
Dominance of low-cost domestic generic manufacturers			0.812	
High price sensitivity of the market			0.784	
Difficulty in achieving volume-based targets			0.733	
Delays in new drug approvals				0.815
Infrastructure bottlenecks in logistics				0.782
Complexity of state-level regulatory compliance				0.694

Extraction Method: Principal Component Analysis

Rotation Method: Varimax with Kaiser Normalization

The rotated component matrix, demonstrated in Table 4, shown the factor loadings of each variable. Variables with factor loadings above 0.5 were termed significant. The analysis disclosed four factors, each comprising variables that correlate strongly with the underlying construct.

Table 5: Reliability Statistics

Cronbach's Alpha	N of Items
0.836	13

The study was conducted through self-structured questionnaire testing its reliability is essential, The reliability analysis, shown in Table 5 indicates Cronbach's Alpha value of 0.836 for the 13 items, pointing strong internal consistency and reliability of the scale.

Table 6: Factor Analysis Results

Factor 1: Pricing and Regulatory Pressure (18.028%)*	**Factor 2: Intellectual Property Challenges (17.233%)***	**Factor 3: Market Competition Dynamics (16.061%)***	**Factor 4: Operational and Logistical Hurdles (17.078%)***
Unpredictable pricing policies (0.812)	Patentability challenges (0.834)	Domestic competition (0.812)	Approval delays (0.815)
NLEM expansion (0.798)	Compulsory licensing (0.791)	Price sensitivity (0.784)	Logistics bottlenecks (0.782)
Profit margin pressure (0.776)	Lack of data exclusivity (0.745)	Volume target challenges (0.733)	State-level compliance (0.694)
	Regulatory inconsistencies (0.702)		

Note:* Variance explained

The EFA result confirms that four factors, which collectively demonstrates 68.4% of the variance. These factors along with their underlying variables and factor loadings were summarized in Table 6.

6. FINDINGS

The results from exploratory factor analysis indicate that four critical factors collectively responsible for 68.4 % of the variance in multinational pharmaceutical companies decision to exit from the Indian market. The findings reveal that:

1. Pricing and Regulatory Pressure has appeared as the significant factor, contributing 18.028 % of the variance, with high loadings on unpredictable pricing policies (0.812), frequent NLEM expansion (0.798) and profit margin pressure (0.776).
2. Intellectual Property Challenges emerged as the second major factor, contributing 17.233% of the variance, dominated by patentability challenges (0.834%), compulsory licensing concerns (0.791), and lack of data exclusivity (0.745).
3. Market Competition Dynamics explained 16.061% of the variance, characterized by intense domestic competition (0.812), high price sensitivity (0.784), and difficulty achieving volume targets (0.733).
4. Operational and Logistical Hurdles accounted for 17.078 % of the variance, primarily compromising approval delays (0.815), infrastructure bottlenecks (0.782), and state-level compliance complexity (0.694).

The reliability analysis confirmed the internal consistency of these factors with a Cronbach's Alpha of 0.836, indicating high reliability of measurement scale.

7. DISCUSSION

The findings align with and substantially validate existing literature while providing ne empirical evidence from senior executives. The prominence of Pricing and Regulatory pressure confirms previous observations by Bardhan (2020) regarding the disruptive impact of frequent NLEM expansions and unpredictable pricing policies on long-term strategic planning. The Intellectual Property Challenges factor substantiates the concerns raised in the Novartis vs. Union of India case aftermath, demonstrating that Section 3(d) of the Patents Act and compulsory licensing provisions continue to deter R&D investments. The emergence of Market Competition Dynamics as a significant factor reveals the double-edged nature of India's successful generic pharmaceutical industry. The operational and Logistical Hurdles factor highlights persistent infrastructure and regulatory challenges that increase the cost and complexity of ease of doing business.

8. IMPLICATIONS

This study contributes to the literature by developing a validated four factor framework by explaining pharmaceutical MNC exits from emerging markets. Policymakers will have to develop more predictable and transparent pricing policies with longer implementation timelines. Multinational pharmaceutical companies in need to re-evaluate market strategies focusing on niche therapy areas with less price sensitivity. Domestic pharmaceutical companies have to leverage opportunities to acquire divested MNC assets and brands.

9. FUTURE SCOPE OF THE STUDY

The study offers several avenues for future research like:

1. Longitudinal Analysis: Track how these factors evolve over time as policies change and market dynamics shift.
2. Cross-country Comparison: Compare the Indian experience with other emerging markets like Brazil, China and South Africa to identify common and unique challenges.
3. Sector-specific Studies: Investigate whether these factors affect different therapeutic areas.
4. Stakeholder Perspectives: Include views from government regulators, domestic manufacturers and healthcare providers to develop a more comprehensive understanding

10. CONCLUSION

The study concludes that because various issues pharmaceutical multinational companies are leaving India. The exodus of multinational pharmaceutical companies from India is a rational response to a confluence of critical challenges, primarily unpredictable pricing regulations and intellectual property concerns. This trend is further driven by intense competition from low-cost domestic manufacturers and significant operational hurdles. While aimed at short-term affordability, these conditions create an unsustainable environment for innovation-focused corporations. Reversing this trend requires policy recalibration to balance affordable access with a stable, attractive ecosystem for global investment and medical innovation.The study establishes a foundation for understanding the complex interplay of factors driving pharmaceutical MNC exit from India, providing valuable insights for multiple stakeholders across the industry.

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