SMART

Journal of Business Management Studies

(A Professional, Refereed, International and Indexed Journal)

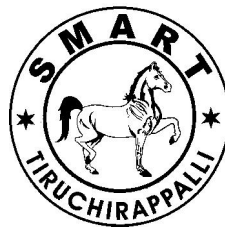Professor **MURUGESAN SELVAM, M.Com, MBA, Ph.D, D.Litt**
Founder - Publisher and Chief Editor

MAJOR DRIVING FORCES FOR INDIAN SME PHARMACEUTICAL INDUSTRY

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Abstract

The study examined the major driving forces, that affect the operational efficiency of the Indian pharmaceutical industry, with special reference to the SME pharmaceutical companies in India. Porter's Five Force Model was used as a frame of reference, to gauge the effect of various environmental and regulatory forces, that affect the working of Indian SME pharmaceutical industry, using regression analysis, as the main tool. The reliability and the regression equation, derived from the Regression Analysis, showed that competitive rivalry, among existing firms, was the strongest force, followed by bargaining power of buyers, threat of new entrants, bargaining power of suppliers and the threat of substitute products, in that order. This study applied the Porter Model on Indian pharma industry, with special reference to the SME units. The industry would find this research to be of practical value, especially for SME industries, for devising their strategies for the growth and competition assessment.

Keywords: *SME, Pharmaceutical Industry, Porter's Five Force Framework,*

JEL Code : *L6 & L70*

Paper Received : *29.10.2023*   ***Revised :*** *09.04.2024*   ***Accepted :*** *10.05.2024*

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1. Introduction

The global pharmaceutical industry, that is spread over North American, European, Asian & African markets, is continuously growing over the past five years, with CAGR ranging from 4 – 12% over the period, with US and European markets maintaining their lead over the Asian markets. USA is the global leader of the pharmaceutical industry as most of the large companies belong to that country. Pfizer is the world's biggest pharmaceutical company, with USD 53.6 bn in pure pharmaceutical sales, followed by other leading names like Johnson & Johnson, Merck, AbbVie. The biggest five of Europe are spread over Switzerland, United Kingdom and France. Like every other industry, pharma is also facing the emerging Chinese giants, with the Chinese pharmaceutical industry growing fast over the past few years **(Statistical, 2019)**. The pharmaceutical industry is one of the fastest growing industries in India, with the total size of this industry pegged at USD 38.2 bn in 2018-19. This industry has seen a compound annual growth rate of 15.4% in the last four years, i.e., 2014-2018 **(E&Y EMIS Report, 2019)** and is expected to grow at CAGR of 22.4% over the period 2015-20, to reach USD 55 bn **(Invest India, GOI Report, 2019)**. Indian pharmaceutical industry is the third largest in the world on volume, and 13th largest by value **(Invest India, GOI Report, 2019)**. The biotechnology sector and the pharmaceutical industry overlap to a large extent. India remains a strong attraction as market for the generic R&D and manufacturing of pharmaceutical drugs, as the macro-factors related to this industry are very strong here **(Trends & Opportunities for Indian Pharma Report, FICCI, 2018)**. Indian pharmaceutical companies are also proving to be the world leaders in the manufacturing of generic drugs **(Invest India, GOI Report, 2019)** and vaccines, by being the source for 50% of the global vaccine supply **(Invest India, GOI Report, 2019)**, with exports to more than 200 countries, at a total value of USD 13.94 bn in the fiscal year 2018-19 (upto December 2018), with USA as the primary export market for the Indian firms. India is the world's largest producer of generic drugs, with generic drugs' export accounting for 20% of global exports in generics **(Asia Pacific Pharmaceuticals Report, Ernst & Young, 2019)**. Because it is a highly fragmented industry, consolidation has become a very important feature of the Indian pharmaceutical market. Pharma is a dynamic industry with rapid development and high profit potential. Best-selling drugs have annual sales of over $ 1 billion. There are also strict legal requirements for the approval of new medicines, which present a major barrier. In addition, there are various other challenges, such as developing appropriate distribution strategies, selecting the right products and anticipating restrictions of competition, including the emergence of new market barriers.

The issue of Harvard Business Review, in 1979, carried a new model being proposed by a professor in the field of strategic management from Harvard University, Prof. Michael E. Porter. The model proposed was termed the 'Five Forces Model'. This model was primarily based on the 'structure – conduct – perform' paradigm in the Industrial Organization Economics, that helped the companies to assess the profitability potential of the industry in which they operate, along with the analysis of the various competitive and regulatory forces that may affect their functioning in particular. Porter, while proposing this model, built on the earlier work done by industrial economists like Bain, Mason and Scherer. Where Porter differed from these economists was that he maintained that the competition in an industry is not only an outcome of the behavior of the existing firms,

but it is also modified by the overall industry structure **(Pecotich A, Hattie J, Li P-L, 1999)**. These factors were categorized into five points and introduced as five forces that affect any industry's competitiveness and profitability. These are threat of new entrants, power of suppliers, power of buyers, availability of substitutes, and competitive rivalry in the industry. How these five forces interact, provides a decent image of the sector's dynamics and whether an individual organization is appropriately positioned for survival in the sector.

This model could explain the reasons for every industry's maintenance of different levels of profitability, determine its strengths and weaknesses. In fact, a careful study and implementation of this model can also lead a company to search for imperfect markets where more opportunities can be created in order to make superior returns and create better shareholders' value for everybody associated with the firm. Once proposed, this model was extensively used by various organizations for their strategic management purposes.

2. Review of Literature

During the 1980s, majority of works in the field of strategic management were related to the effect of external environment and its link with the strategies. Porter's model and a few other models were the products of this era. As the time progressed, the strategists and the management thinkers started exploring the relationship between strategy and a firm's inner resources and skills **(Grant R. M., 1991)**. During these studies, it was often seen that the companies got into intense competition with each other. **Dyer and Singh, (1998)** studied the strategic portfolio of the pharmaceutical companies and recommended that the best course of action for the smaller pharma companies is to develop collaborative competitive advantage, with other companies, rather than trying to build their own competitive advantage which may consume too much time and resources of the organization. However, all collaborations in any industry, including pharmaceutical industry, do not give equal benefits to all the companies entering into the collaboration. **Hoang & Rothaermal, (2005)** studied the strategic alliances between pharma companies and small biotech companies to understand who gets more advantage out of these alliances, and concluded that the small biotech firms are at a greater advantage because of the agility that comes along with the smaller management size and faster decision making. Even when large organizations do acquire smaller organizations in the pharmaceutical business, it is not a guarantee that they would be able to extract the complete advantage out of these acquisitions. **Schweizer (2005)** studied a host of acquisitions done by large pharmaceutical companies where they acquired the smaller biotech companies for gaining access to their R&D facilities and found that these large organizations were not able to take full advantage due to merging issues. While studying various issues faced by new pharmaceutical companies entering into the business, **Lemley and Feldman (2018)** concluded that the exclusivity rights that come along with any patent grant, should be reconsidered since most of these exclusivity rights are used to stop other companies from working in that field, rather than developing any innovative products during that time period. Patents have been a bone of contention in this industry as many observers believe many companies use patents as blockages for the new entrants and smaller companies, rather than for innovation processes. **Rathore (2023)** delved further into the relevance of patents for a pharma company and concluded that after acquisition of small or new pharma companies, patents and other plans did

not yield any financial value. The holding companies of the patents have, over a period of time, developed special mechanisms for affecting and controlling the prices of the drugs using these patents. **Duggan, Garthwaite and Goyal, (2016)** found that the patented drugs, in India, had enjoyed only a very minuscule 3% rise in the prices, which was almost negligible compared to the American markets. This was due to the monitoring by the drugs pricing authority, along with the fear of invoking of the anti – profiteering measures by the competition.

When the competitive and other forces are discussed in order to understand their impact on the pharmaceutical industry, Porter's Five Force Model is commonly used. However, a big drawback with the same is that Porter views all the interactions between different players in an industry as hostile in nature, while completely ignoring the role of cooperation and collaborations among these industry players **(Aktouf et al, 2004).** There is also a growing concern that this model is not connected to other models or theories in the strategic business management area like PEST or SWOT. Another major criticism of the model is the lack of connectivity of the individual forces mentioned in the model. The model puts these forces as unaffected by each other, while that cannot be the case. These forces would work along with each other also, while affecting any industry **(Grundy, 2006).** Another drawback of this model is the disconnect of this model with 'Internet' and 'Innovation', that are two very crucial factors affecting the businesses today. However, it is very important to understand that these two are not some separate or individual forces that may change the way businesses are transacted. At best, these can be classified as 'enabling factors' that will act on the current forces prevalent in the businesses and change the way those forces affect the business as a

whole **(Karagiannopoulos et al, 2005).** Porter and his co-writers answered the applicability issues of the model regarding positioning of products, shifting industry structures, and the rise of complementary products as a new force. They broke up these factors and detailed the break up and applicability of these issues in the current business scenario. Despite these flaws, this model still remains one of the most suitable models, that can be applied to all the industries and under any kind of circumstances **(Porter et al, 2008)**.

Thus, it is clear that the pharmaceutical industry is a unique industry in itself that balances its profitability along with its social responsibilities, its innovation and R&D needs, along with the huge financing needs of the same and free market practices along with the government controls under which they operate. Understanding these various factors, whether external or internal, that affect this industry, is important to understand the nature of this industry and the success formula for the same. Most of the research done in this field has looked at one or the other factor at a time for explaining the same, which is not enough, according to the authors' view. There is a need to study the impact of all the factors together working in this industry, and only then, we would be able to understand the true nature of this industry and creation of a viable business model would be possible. Taking the help of Porter's Five Force Model is imperative here, since no other model envisages all the possible factors that impact a business simultaneously and devise a framework for this study that encompasses the evaluation of all these factors or forces that are working in this industry at the same time from the point of view of the insiders of this industry, i.e. the people employed in this industry involved in managerial and decision making roles.

3. Statement of the Problem

The pharmaceutical sector, which is distinguished by ever-changing competitive environments and dynamic market conditions, encounters the difficulty of maximizing operational efficiency in order to achieve long-term expansion. Although the importance of elements such as substitute threats, bargaining power of buyers and suppliers, threat of new entrants, and competitive rivalry is recognized, there is still a lack of comprehension regarding the intricate effects that these forces have on the operational efficiency of small and medium pharmaceutical enterprises. The primary objective of this study is to fill this void by an exhaustive examination, which will yield practical conclusions that help guide strategic decision-making and improve operational effectiveness in this critical industry.

4. Need of the Study

The pharmaceutical sector, being an essential participant in worldwide healthcare, functions within an intricate milieu influenced by a multitude of external factors. Pharmaceutical firms, and medium and small enterprises (SMEs) in particular, must comprehend the precise dynamics of the threat of substitutes, bargaining power of consumers and suppliers, the threat of new entrants, and competitive competition in order to establish and maintain a successful business. Conducting this research is crucial to address the current lack of understanding and offer industry participants a comprehensive understanding of how these variables affect operational effectiveness. The knowledge gained from this study will provide pharmaceutical industry leaders with the potential to develop strategic initiatives that promote growth, resilience, and sustainability.

5 Objectives of the Study

I. To understand the unique characteristics and dynamics of pharmaceutical industry.

II. To understand the intensity of different forces acting upon pharmaceutical industry, with specific focus on SMEs.

III. To determine the relative impact of these forces on the operational efficiency of these SME pharmaceutical companies.

6. Hypotheses of the Study

In order to fulfill the earlier mentioned objectives, a framework of hypotheses was devised, keeping the five forces proposed by Michael Porter as the frame of reference.

H1: There is a statistically significant impact of the threat of new entrants on the operational efficiency

H2: There is a statistically significant impact of the bargaining power of the suppliers on the operational efficiency

H3: There is a statistically significant impact of the bargaining power of buyers on the operational efficiency

H4: There is a statistically significant impact of the threat of substitute products on the operational efficiency

H5: There is a statistically significant impact of the threat of competitive rivalry on the operational efficiency

7. Research Methodology

7.1 Sample Selection

The study employed a purposive sampling strategy. Sample was mainly collected from Hyderabad based firms as it is a center for pharmaceutical raw material supply. The entire data were collected from 150 industry people, spanning Production Managers, Marketing Managers, and Operations Managers across

diverse pharmaceutical organizations. **Table-1** shows the Description of Respondent Profile.

7.2 Period of Study

The data were collected between December 2022 and March 2023.

7.3 Sources of Data

The data collected were primary in nature and the study carried out among the group of indenting agents and other diverse people, who managed the import of pharmacological raw resources from China. The sample population consisted of these people, who handled the logistics and procurement aspects of pharmaceutical raw materials in India.

7.4 Tools used in the Study

In this paper, the authors used the Regression Analysis, to assess the impact of the chosen forces (based on the Porter Model), on the operational efficiency of these companies. To complete this task, the study designed a structured questionnaire, which was first validated through a pilot study of 25 respondents and a reliability test along with the test, for one-dimensionality.

8 Data Analysis & Interpretation Regarding Major Driving Forces for Indian SME Pharmaceutical Industry

Table 1 describes the respondent profile of the survey, that targeted production managers, marketing managers, and operations managers from pharmaceutical companies. A total of 150 respondents was targeted, and 98 responses were received, resulting in an overall response rate of 65.33%. **Table 2** examines the reliability of Porter's Five Forces Model analysis, a tool used to evaluate the competitive landscape of an industry. The study examined internal consistency, ensuring the measurements used to assess each force, are aligned. The five forces analyzed were the traditional threats of new entrants, substitutes, and buyer and supplier bargaining power, along with competitive rivalry. The analysis also considered "Operational Efficiency" as a factor influencing industry dynamics. For each force, a value between 0.738 and 0.913 was fixed. These values represented the Cronbach's Alpha coefficient, a measure of how consistently the measures used to assess each force, were related. Generally, a value above 0.7 is considered acceptable, with higher values indicating stronger internal consistency. The analysis revealed some interesting insights. The bargaining power of buyers reported the highest reliability score (0.913), suggesting a strong alignment in the way this force was measured. Conversely, operational efficiency recorded the lowest score (0.738), indicating the method used to evaluate this factor might require further refinement to ensure consistent measurement. The overall reliability score of 0.852 indicated a moderate to good level of internal consistency within the analysis. **Table-3** explores the results of the regression analysis, conducted to understand the factors influencing operational efficiency. The analysis examined the strength of the relationship between these factors and operational efficiency. Regression Model Summary revealed a moderately strong positive correlation (Multiple R = 0.821) between the predicted and actual operational efficiency scores. In other words, the model did a reasonable job of capturing the factors, that influenced the operational efficiency. Further, the model explained a substantial portion of the variance in operational efficiency scores (R Square = 0.675). In simpler terms, over two-thirds (67.5%) of the variability in operational efficiency can be attributed to the factors, included in the model. The adjusted R Square (0.628) reinforced this notion, providing a more reliable estimate of the model's explanatory power.

Table-4 (ANOVA for Operational Efficiency Model) displays the statistical significance of the model. The F-statistic (43.22) and its associated significance level (0.000) paint a clear picture. This statistically significant result (p-value < 0.001) indicated a strong relationship between the predictor variables and operational efficiency. In other words, the model was effective in predicting operational efficiency based on the variables it considered. The coefficient for the threat of new entrants was 0.074, with a p-value of 0.479. Since the p-value was greater than the conventional significance level of 0.05, the null hypothesis (H1) was not rejected. For the second hypothesis, the coefficient for the bargaining power of suppliers was 0.003, with a p-value of 0.982. As the p-value was much greater than 0.05, the null hypothesis (H2) was not rejected. As far as third hypothesis was concerned, the coefficient for the bargaining power of buyers was 0.055 with a p-value of 0.287. Since the p-value exceeded 0.05, the null hypothesis (H3) was not rejected. Regarding the fourth hypothesis, the coefficient for the threat of substitute products was 0.53, with a p-value of 0.000. Since the p-value was less than 0.05, the null hypothesis (H4) was rejected. Regarding the last hypothesis, the coefficient for competitive rivalry was 0.036, with a p-value of 0.000. Since the p-value was less than 0.05, the null hypothesis (H5) was rejected. Utilizing the regression coefficients in **Table 5**, the study formulated a regression equation, that established the relative strength of variables on the operational efficiency of small and medium pharmaceutical businesses: Operational Efficiency = 0.037 × threat of substitute products + 0.069 × threat of new entrants + 0.446 × competitive rivalry + 0.059 × bargaining power of suppliers + 0.247 × bargaining power of buyers

9. Findings of the Study

The study revealed a robust association between the selected variables and operational efficiency. The adjusted R-squared value of 62.8 percent indicated that the selected factors would account for about 62.8 percent of variance in the operational efficiency. The statistical significance of the model provides more evidence in favour of the proposition that the parameters, being examined together, would enhance the operational efficiency of small to medium-sized pharmaceutical organizations. For the purpose of determining the relative significance of the discovered forces, regression coefficients were analyzed**.** The coefficients offer valuable insights regarding the magnitude and orientation of the influence that each variable has on operational efficiency. By utilizing the regression equation produced from these coefficients, it is possible to quantify the collective impact of the components.

Competitive rivalry was identified as a significant driver among the variables, as indicated by its highest coefficient (0.446), which implied a strong impact on operational efficiency. Significant impacts were also observed from the threat of substitute products (0.037) and the threat of new entrants (0.069). Conversely, the bargaining power of buyers and suppliers reported significantly smaller coefficients, suggesting that their impact on operational efficiency was comparatively weaker.

10. Suggestions

The study suggests an exhaustive examination of the competitive environment in order to pinpoint certain domains of rivalry. One potential approach to attaining a competitive edge is through the implementation of tactics, that distinguish products or services, investigate specialized markets, and improve brand positioning. In order to innovate and diversify

the product portfolio, allocate resources towards research and development, considering the significant influence of substitute items. Constant innovation serves to fortify market presence and discourages the development of prospective substitutes.

11. Conclusion of the Study

The pharmaceutical industry is an example of a unique case, where the market forces and the societal forces, both work together on the industry players. With a high level of government control for the welfare and affordability issues of the medicines and other procedures, the private organizations of this industry do not have the same kind of free will and the actions that other industries may boast of. A major reason for this control from regulators and the governments is due to the nature of the products and services offered by this industry which are critical and life – saving in nature. As the detailed analysis in the previous pages exhibits, the industry analysis, performed by using the Porter Model, can be viewed from two aspects; one related to the industry and the specific analysis related to the SME pharmaceutical industry. As far as the entire pharmaceutical industry is concerned, this industry is marked by very high entry barriers, like large investments required for developing research and development wings, long and often risky clinical trials, and taking care of all the government-directed adherence to the social welfare schemes.

Different from large enterprises, the Porter forces act on SME pharma companies in a different manner, for these companies, the competition from existing players is the toughest to overcome, followed by the threat of new entrants, bargaining power of buyers, suppliers and the threat of substitute products, in that sequence. As depicted in the previous discussion on each force's components, many troubles or

problems for SME pharma companies are primarily, due to their not-so-strong financial position, lesser marketing and advertising budgets and a weaker brand. Due to these issues, the companies are not left with much maneuvering space in acquiring the skills that they lack, while the smaller marketing and advertising budgets lead to a direct loss in terms of OTC drugs sales, and an indirect one, in terms of weaker brand recall and customer trust in the products. This directly affects their brand, which cannot be leveraged while competing against large enterprises. As they are smaller companies with lesser valuations, they are also a ripe target for the bigger companies entering into these markets, looking at key competitive advantage or strength that these SME players might offer.

However, as clear from the earlier discussion, not all is lost for these small companies, who can leverage their own unique strengths, however small those might be, to compete with these large enterprises and carve out a niche for themselves. It is clear that marketing and advertising, along with the brand-building is a weaker part of these organizations. However, there are opportunities for growth for these small players also, specifically in the niche areas where the larger enterprises do not offer their products or services because of the profitability or market size issues. A smaller pharmaceutical company can always tailor their product or offering to suit the requirements of a hitherto unprofitable market segment, which has been left untouched by the large enterprises. A micro-financing model, modified to suit the pharma industry, may be created by SME players to fulfil the needs of these segments. Rural areas of the country provide a vast opportunity to increase the customer base and sales for these SME companies, as large organizations or MNCs tend to concentrate more on the highly profitable urban markets. The biggest challenge

that these SME players would face in the rural areas, would be forging the supply chains for these areas. The main problems for establishing and managing these supply chains would be the lack of infrastructure, skilled manpower, lesser volume of business, resulting in reduced profitability. But these companies can innovate their supply chains and pool their efforts, in order to beat the larger organizations in this field, where they could create their own supply chains, or, explore the possibility of merging their supply chains with other industry players like ITC Chaupal, or Government sanctioned E-Mitras, fertilizer and seed companies' distribution chains. These small SME pharmaceutical companies can beat the MNC players in this game and carve out a profitable and scalable business for themselves, if they innovate and use their strengths to their advantage and target the weaknesses of these MNC pharmaceutical companies.

12. Limitations of the Study

Although this study offers significant contributions to the understanding of the determinants of operational efficiency in small and medium-sized pharmaceutical firms, its lack of generalizability must be acknowledged as an inherent limitation. The research was limited to a particular sector of the business, and discrepancies in organizational frameworks, external circumstances, and regulatory systems could potentially affect the generalizability of the results to more extensive settings. It is advisable to use caution while generalizing the findings to businesses that possess unique attributes. Additionally, it is advisable to conduct additional research across other sectors in order to obtain a thorough grasp of the dynamics of operational efficiency.

13. Future Scope of the Study

Future studies could explore diverse sectors, considering variations in organizational frameworks, external circumstances, and regulatory systems. This approach would provide a more comprehensive understanding of the factors influencing operational efficiency across different business landscapes. Researchers could delve into sectors with unique attributes, thus enriching the knowledge base and ensuring a more nuanced perspective on the subject.

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Table 1: Description of Sample Respondent of SME Pharmaceutical Industry in India

Respondent Category	No of Respondents Targeted	No of Responses Received
Production Managers from Pharmaceutical Companies (Top Executives & Middle Management)	67	44
Marketing Managers from Pharmaceutical Companies (Top Executives & Middle Management)	45	29
Operations Managers from Pharmaceutical Companies (Top Executives & Middle Management)	38	25
Total	150	98

Source: Primary Data Computed using SPSS

Table 2: Reliability Analysis of Porter's Five Forces Model analysis regarding Major Driving Forces for Indian SME Pharmaceutical Industry

Reliability Analysis	
Threat of New Entrants	0.856
Bargaining Power of Buyers	0.913
Bargaining Power of Suppliers	0.869
Threat of Substitutes	0.756
Competitive Rivalry	0.836
Operational Efficiency	0.738
Overall Reliability	0.852

Source: Primary Data Computed using SPSS

Table-3: Regression Model Summary of Operational Efficiency Regarding Major Driving Forces for Indian SME Pharmaceutical Industry

Regression Statistics	
Model	1
Multiple R	0.821
R Square	0.675
Adjusted R Square	0.628
Standard Error	0.24847

Source: Primary Data Computed using SPSS

Table 4: ANOVA for Operational Efficiency Model Regarding Major Driving Forces for Indian SME Pharmaceutical Industry

Model		df	SS	MS	F	Significance F
1	Regression	5	17.524	2.476	43.22	0.000
	Residual	134	8.027	0.056		
	Total	139	23.551			

Source: Primary Data & Computed using SPSS

Table 5: Regression Coefficients for Operational Efficiency Regarding Major Driving Forces for Indian SME Pharmaceutical Industry

		Unstandardized Coefficients		Standardized Coefficients		
Model		B	SE	β	t	Significance
1	(Constant)	0.818	0.21		3.887	0.000
	Threat of Substitute Products	0.037	0.084	0.53	5.503	0.000
	Threat of New Entrants	0.069	0.091	0.074	0.71	0.479
	Competitive Rivalry	0.446	0.087	0.36	3.623	0.000
	Bargaining Power of Suppliers	0.059	0.09	0.003	0.023	0.982
	Bargaining Power of Buyers	0.247	0.049	0.055	1.069	0.287

Source: Primary Data & Computed using SPSS