

STRATEGIES FOR INTEGRATING SUPPLY CHAIN IN NEW PRODUCT DEVELOPMENT OF GENERIC PHARMACEUTICAL COMPANIES: A STUDY

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ABSTRACT

The success of knowledge based industry like pharmaceutical mainly depends on speed of the process development. The speed of process development, in turn, depends majorly on the integration and coordination between the functions in the development area and the integration between process development teams and supply chain. The integrations is vital for enhancing the speed of process development and there by introducing the new product to the market. In this research work I have initially focused on group discussions and conducted personal interviews with key leaders based on the predesigned questionnaire and the data has been collected and thoroughly analyzed. I have ensured to include various types of players in the fifteen companies by selecting five companies each from small, medium and large size. The research was conducted on a sample of 565 employees from 15 different pharmaceutical companies. This research reveals the factors to integrate supply chain in new product development of generic pharmaceutical companies.

KEYWORDS: *Supply Chain, New Product Development, Generic Pharmaceuticals, Outsourcing.*

Introduction

The world is just being an onlooker while all the sectors are marching towards remarkable expansion in fact, the last decade has witnessed a tremendous growth and change in the world pharmaceutical industry. Apart from intensive globalization which reinforces the consolidation of the world pharmaceutical industry, increased competitiveness and the fight for global market shares also creates new challenges in this industry. The Indian Pharmaceutical Industry currently is in the front rank of science-based industries in India with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian Pharma Industry is worth of \$ 35.9 billion in 2016, growing at about 16 to 18 percent annually (Ministry of external affairs, Government of India). It ranks high in the world, in terms of technology, quality and range of medicines manufactured. The pharmaceutical industry in India has shown tremendous growth in terms of infrastructure technology, development and a wide range of production. Even while undergoing restructuring, the industry established its presence and flourishing in the changing environment. The industry currently produces bulk drugs belonging to all major therapeutic groups. The different divisions of Pharmaceutical drug development are new drug discovery, Product Development of generic drugs, Active Pharmaceutical Ingredients, Custom Pharmaceutical services and Biotechnology. All of these divisions falls under multi projects environment and project management team is responsible for project integration, cost, quality, scope, time, human resource, risk, communication and procurement for more than one project at the same time.

Generic Drug Business

A generic drug is a cost- effective alternative to a branded drug. The Innovator (original manufacture) receives a patent on his invention to prevent others from using it. Once the patent expires,

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other manufacturers may produce and sell the drug, these manufacturers may produce and sell the drug. A generic drug must have the same active ingredient(s), dosage form, quality, labeled strength, and performance, route of administration, intended use and labeling as that of the approved original branded drug. Generic drug company must show that the generic drug is 'Bioequivalent' to the branded drug, it must have full documentation of the generic drug's chemistry and manufacturing steps, and the generic drug maintains stability as labeled before it can be sold. The raw materials and the finished product must meet pharmacopoeia specifications, if these have been set.

Generic drugs are generally less expensive because generic manufacturers don't have the investment costs of new drug. Once generic drugs are entered to market, there are greater competition, which keeps the price down. Today, almost half of all prescriptions are filled with generic drugs. For the generic companies the year 1984 is considered to be an important year as Hatch-Waxman Act was introduced in this year which standardized U.S. procedures for recognition of generic drugs. The Act has been established Abbreviated New Drug Application (ANDA) process where in the applicant files ANDA with USFDA and proposes USFDA to approve Generic drug applications of Branded drugs without repeating the safety and effectiveness studies of the drugs. As per this act of United States, the Food and Drug Administration offers exclusivity of 180 days period to a generic drug manufacturers in specific cases. During this period only one (or sometimes a few) generic manufacturers can produce the generic version of a drug. This exclusivity period is only offered when the generic manufacturer argues that the granted patent is invalid or is not infringing the generic production of a drug. This attracts many Generic pharmaceutical companies to file in the ANDA process.

Active Pharmaceutical Ingredients (API)

Active Pharmaceutical Ingredients (API) or bulk drugs are the principal ingredients for finished pharmaceutical products. APIs cannot be directly administered to the patient, to stabilize the mixture inactive substances called excipients are added to API. The drug product, which includes API and the excipient, is referred to as a formulated product. Formulated products are the pharmaceutical products administered to patients which can take the form of capsules, tablets, ointments, syrups, creams, injectable, etc.

New Product Development

Generic pharmaceutical companies tend to enhance their market position by making them self-first in the market when a patent on an original product elapses. Time-to-market of new products is the key strategy for generic companies to get their competitive advantages. Process development is the core function of generic pharmaceutical industry which involves a series of lengthy steps that determine the degree of success for every drug brought to the market. The process development of Active pharmaceutical ingredients (API) is the heart of generic pharmaceutical company. In general the process development of API happens in the following five phases:

- Define Phase- literature survey
- Research Phase- Select the Route of synthesis
- Design Phase- optimizing the process
- Develop Phase- Executing trials and validation batches
- Implement Phase- Regulatory filing

Supply chain management

Supply chain management comprehends the planning and management of all activities in sourcing, procurement, contract manufacturing, and all logistics management activities. Importantly, it also includes coordination and collaboration with vendors and channel partners, which can be suppliers, third party service providers, and customers. In essence, supply chain management integrates Demand and supply management within and across companies. Increasingly the management of relationships across the supply chain is being referred to as Supply Chain Management (SCM). The supply chain is a network of businesses and relationships which offers the opportunity to capture the synergy of intra- and inter-company integration and management. Supply Chain Management integrates key business processes from end user through original manufactures that provides products, services, and information that add value for stakeholders and other customers.

Problem Statement

Developing strategies for integrating supply chain in new product development of generic pharmaceutical companies.

Importance of the Study

The financial cost of a product that is six months late to market could miss out on one-third of the potential profit over the product's lifetime (McKinsey & Co, 1991). This could be due to competitor companies being first to market, capturing the market share and dictating the price, as well as the loss of effective patent life. There is a clear need for pharmaceutical companies to speed up delivery of new products to the market to maintain a competitive effectiveness. In the generic pharmaceutical companies the speed of development is the key factor for success for getting 180 days exclusivity. This will give tremendous amount of profit. In conclusion, the process development for Drug Substance and Drug Product is critical for successful and timely market launch. The aim is to get to market quickly with the development of a drug and product of the appropriate quality and to "do it right first time, every time". Supply chain management plays a vital role to achieve the same.

Despite the importance of the efficiency of the new product development, (which is also called as process development) in the generic pharmaceutical industry and despite the fact that time-to-market has been extensively discussed in the literature, there is very little research in this area directly relating to the generic pharmaceutical industry (J.Prasnikar, T.Skerlj, August, 2006) especially in the area of Active pharmaceutical ingredients (API). Timing of the new product introduction and therefore the speed to market become a key issue for all manufacturers in this industry. If new products are the lifeblood of a corporation, then new product development division is the lifeblood of a company's new products. Supply chain management processes must be integrated into the product development process in order to reduce time to market. As product life cycles shorten, the right products must be developed and successfully launched in ever shorter timeframes in order to remain competitive (D.M. Lambert, M.C. Cooper, 2000). One of the most significant paradigm shifts of modern business management is that individual businesses no longer compete as solely autonomous entities, but rather within supply chains. Business management has entered the era of inter-network competition. In this emerging competitive environment, the ultimate success of the single business will depend on management's ability to integrate the company's intricate network of business relationships thus creating a seamlessly coordinated supply chain that is a potential source of competitive advantage. Hence this study is very important to analyze the gaps and identifying the strategies to integrate supply chain with new product development of generic pharmaceutical company.

Challenges

The following are some of the supply chain management challenges in the new product development of active pharmaceutical ingredients (API) of a generic pharmaceutical company.

Source Identification: When the product is a newly approved one then identifying the sources for API starting material or advanced intermediate is very difficult. Managers need to take a "Make or Buy" decision based on many factors.

Capability Sourcing: The latest approved drug products are more complex with respect to Manufacturing process, analytical procedures and handling techniques, which needs expertise and capability in each functional domain. Supply chain managers are facing difficulty for "capability sourcing" as it is not available in house. This study has identified important criteria to do capability sourcing which can improve a company's strategic position by reducing costs, streamlining the organization, and improving quality. Finding more-qualified partners to provide critical functions usually allows companies to enhance the core capabilities that drive competitive advantage in the industry (Mark Gottfredson, Rudy Puryear, 2005).

Manufacturing Partners: Out sourcing or third party management is one of the challenge areas of supply chain. The role of managing third-party manufacturers/partners is very different from the traditional procurement and manufacturing role.

Speed of Development: Speed of process development is the central part of activity which decides the success of the company, the company who develop the new product fast and come to market first will capture the market.

Research

• **Scope of the study**

The scope of the study is to derive strategies for integrating supply chain in new product development of generic pharmaceutical companies.

Integration: To understand linkages between various departments in the generic pharmaceutical company and analyze the current gaps in the existing system to improve the efficiency by integrating supply chain management. This study is also to identify the methodology of integrating supply chain operations involved in various phases of product development like feasibility studies, optimization studies, validation studies and product launch.

This research studies following strategies for integrating supply chain in new product development of generic pharmaceutical companies,

- Make or Buy strategy
- Partner selection and evaluation
- Outsourcing
- Usage of IT System

This research also study the correlation between Speed for process development and integration of supply chain with new product development.

Research work

In this research work we have initially focused on group discussions and had personal interviews with key leaders to design the questionnaire. The data has been collected from 15 pharmaceutical companies by using the designed questionnaire. Among the fifteen companies five companies are of small size, five companies are of medium size and five companies are of large size. This research focuses on integrating supply chain in new product development work.

The research was conducted with 565 employees of 15 different pharmaceutical companies, the respondents are from different departments like process development, Supply chain, Manufacturing, Business development, Marketing and Top management teams.

During the focus interviews followed by structured questionnaire survey the following outcomes have been derived,

Limitation of the Study

This study involves integration of supply chain in Generic Drug product Development as a model. This study is limited only to Active Pharmaceutical ingredients (API) process Development and will not cover Discovery research and Formulations.

Research Hypothesis

Based on the initial literature studies the following Hypothesis were derived, however, this may be redefined and further hypothesis may also be added in the due course of the research.

- MAKE or BUY decision has no significant impact on Integrating supply chain in new product development
- Partner selection and evaluation has no significant impact on Integrating supply chain in new product development
- Outsourcing is has no significant impact on Integrating supply chain in new product development
- Usage of IT System is has no significant impact on Integrating supply chain in new product development
- Speed for process development has no significant impact on Integrating supply chain in new product development

Analysis of Data

The primary data collected from the samples were analyzed using the statistical tools. Chi-Square Test was used to analyze the data collected from questionnaire.

Hypothesis 1

MAKE or BUY decision has no significant impact on Integrating supply chain in new product development

Table 1: The overall impact of MAKE or BUY decision on Integration is significant

| | Observed N | Expected N | Residual |
|----------------|------------|------------|----------|
| Neurtal | 19 | 188.3 | -169.3 |
| Agree | 292 | 188.3 | 103.7 |
| Strongly Agree | 254 | 188.3 | 65.7 |
| Total | 565 | | |

Table 2: The overall impact of MAKE or BUY decision on Integration is significant**Test Statistics**

| | |
|-------------|----------|
| Chi-Square | 232.209a |
| Df | 2 |
| Asymp. Sig. | .000 |

a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 188.3.

From the above table chi square is significant (chi square sig. value is 0.000 < 0.05), reject null hypothesis. It means that MAKE or BUY decision strategy on has significant impact on Integrating supply chain in new product development

Hypothesis 2

Partner selection and evaluation has no significant impact on Integrating supply chain in new product development

Table 3: The overall impact of Partner selection and evaluation on Integration is significant

| | Observed N | Expected N | Residual |
|----------------|------------|------------|----------|
| Neurtal | 17 | 188.3 | -171.3 |
| Agree | 295 | 188.3 | 106.7 |
| Strongly Agree | 253 | 188.3 | 64.7 |
| Total | 565 | | |

Table 4: The overall impact of Partner selection and evaluation on Integration is significant**Test Statistics**

| | |
|-------------|----------|
| Chi-Square | 238.485a |
| df | 2 |
| Asymp. Sig. | .000 |

a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 188.3.

From the above table chi square is significant (chi square sig. value is 0.000 < 0.05), reject null hypothesis. It means that Partner selection and evaluation on Integration has significant impact on Integrating supply chain in new product development

Hypothesis 3

Outsourcing is has no significant impact on Integrating supply chain in new product development

Table 5: The overall impact of Outsourcing on Integration is significant

| | Observed N | Expected N | Residual |
|----------------|------------|------------|----------|
| Disagree | 19 | 141.3 | -122.3 |
| Neurtal | 51 | 141.3 | -90.3 |
| Agree | 330 | 141.3 | 188.8 |
| Strongly Agree | 165 | 141.3 | 23.8 |
| Total | 565 | | |

Table 6: The overall impact of Outsourcing on Integration is significant
Test Statistics

| | |
|--|----------|
| Chi-Square | 419.687a |
| df | 3 |
| Asymp. Sig. | .000 |
| a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 141.3. | |

From the above table chi square is significant (chi square sig. value is 0.000 < 0.05), reject null hypothesis. It means that Outsourcing on Integration has significant impact on Integrating supply chain in new product development

Hypothesis 4

Usage of IT System is has no significant impact on Integrating supply chain in new product development

Table 7: The overall impact of Usage of IT System on Integration is significant

| | Observed N | Expected N | Residual |
|----------------|------------|------------|----------|
| Neurtal | 80 | 188.3 | -108.3 |
| Agree | 312 | 188.3 | 123.7 |
| Strongly Agree | 173 | 188.3 | -15.3 |
| Total | 565 | | |

Table 8: The overall impact of Usage of IT System on Integration is significant
Test Statistics

| | |
|--|----------|
| Chi-Square | 144.768a |
| df | 2 |
| Asymp. Sig. | .000 |
| a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 188.3. | |

From the above table chi square is significant (chi square sig. value is 0.000 < 0.05), reject null hypothesis. It means that Usage of IT System on Integrating supply chain in new product development

Hypothesis 5

Speed for process development has no significant impact on Integrating supply chain in new product development

Table 9: The overall impact of Speed for process development on Integration is significant

| | Observed N | Expected N | Residual |
|----------------|------------|------------|----------|
| Neurtal | 40 | 188.3 | -148.3 |
| Agree | 265 | 188.3 | 76.7 |
| Strongly Agree | 260 | 188.3 | 71.7 |
| Total | 565 | | |

Table 10: The overall impact of Speed for process development on Integration is significant
Test Statistics

| | |
|--|----------|
| Chi-Square | 175.310a |
| Df | 2 |
| Asymp. Sig. | .000 |
| a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 188.3. | |

From the above table chi square is significant (chi square sig. value is 0.000 < 0.05), reject null hypothesis. It means that Speed for process development on Integration has significant impact on Integrating supply chain in new product

Conclusion

In the fast changing generic pharmaceutical industry, generic players need to change their gear in product development to sustain in the competition. The pharmaceutical industry is at a stage where ever technological innovations and advanced information and communication systems are rapidly getting imbibed into the development process. Based on the above study we have identified key areas where each and every player needs to focus in order to have a faster developmental cycle. Our study revealed that Make or Buy strategies, Partner selection and evaluation, Outsourcing strategies and Involvement of IT systems have significant impact for integrating supply chain in new product development area of generic pharmaceutical companies. Based on this study it is also evident that the integration of supply chain in new product development will enhance the speed of process development. Sustainable strategies and robust processes need to be inculcated in the above mentioned areas viz. Make Vs Buy Strategies, Partner selection and evaluation, Outsourcing strategies and Involvement of IT systems, for sustainable growth of the organization.

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