DOI : 10.18843/ijms/v5i2(3)/14
DOI URL :http://dx.doi.org/10.18843/ijms/v5i2(3)/14

Speed of New Product Development-Enhancement through Supply Chain Management in a Generic Pharmaceutical Company

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ABSTRACT

Drugs and pharmaceutical industry plays a vital role in the economic development of a nation. Generic pharmaceutical industry is one of the largest and the most advanced sectors in the world, acting as a source for various drugs, medicines and their intermediates as well as other pharmaceutical formulations to meet the patient needs. Given the increasing competition in the world, the sustainability of generic pharmaceutical industry in global footprint is challenging. The key to success of generic pharmaceutical company is the development of new products in a speedy manner with affordable price and introducing them first in to market at the right time is crucial to gain a competitive edge. In this context, to meet the growing complexity of the industry and the varying demands of their business segments, developing strategies for enhancing speed of process development through supply chain in new product development is accomplished to improve the health status of the individuals as well as the society as a whole, so that positive contributions could be made to the economic growth and regional development of a country.

Keywords: Supply chain, integrating supply chain, new product development, Generic Pharmaceuticals, speed of product development.

INTRODUCTION:

The Indian pharmaceutical companies are currently leading top rank in India's science based industry. The Indian Pharmaceutical Industry today ranks very high in the world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenous. And not only that, now the Indian pharmaceutical industry is also exposed to the world of generic drugs where they are doing exceptionally well as they give a tough competition to its various counterparts globally in the field of generic drugs.

Generic Drug Business:

A generic drug is a cost- effective alternative to a branded drug (Innovator drug), generic drugs are considered as identical in dose, strength, route of administration, safety, efficacy, and intended use. Generic drugs are available only after patent protection of the original developer has expired or invalidated. This will increase the number of generic drugs in the market from various manufacturers which will reduce the cost of the drug product. An approved generic drug must have the same active ingredient(s), labeled strength, dosage form, quality, performance, intended use, route of administration and labeling as that of the approved brand name drug.

As per this act the United States, the Food and Drug Administration (USFDA) offers a 180 day exclusivity period to 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 used when a generic manufacturer argues that a patent is invalid or is not violated in the generic production of a drug, and the period acts as a reward for the generic manufacturer who is willing to risk liability in court and the cost of patent court litigation. 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 main active ingredients for finished pharmaceutical products which cannot be administered directly to the patients. During the formulation process, the active ingredient is formulated with suitable excipients to get the drug product in the form of tablets, capsules, syrups, ointments, creams, injections, etc. for intended use.

The global API market can broadly be divided into regulated and semi regulated markets. The semi regulated markets offer low entry barriers in terms of regulatory requirements and intellectual property rights. The highly regulated markets, like the United States and Europe, have stringent criteria in terms of intellectual property rights and regulatory requirements, including facility approvals. As a result, there is a premium for quality and regulatory compliance along with relatively greater stability for both volumes and prices.

The regulatory process by which API manufacturers generally register their products for commercial sale in the U.S. and other similarly regulated countries is via the filing of a Drug Master File (DMF). DMFs are confidential documents containing information on the manufacturing facility and processes used in the manufacture, characterization, quality control, packaging and storage of an API. The DMF is reviewed for completeness by the FDA, or other similar regulatory agencies in other countries, in conjunction with applications filed by finished dosage formulation manufacturers, requesting approval to use the given API in the production of their drug products. For European markets, companies need to submit a European Drug Master File (EDMF) and, where applicable, obtain a Certificate of Suitability (CoS) from the European Directorate for the Quality of Medicines.

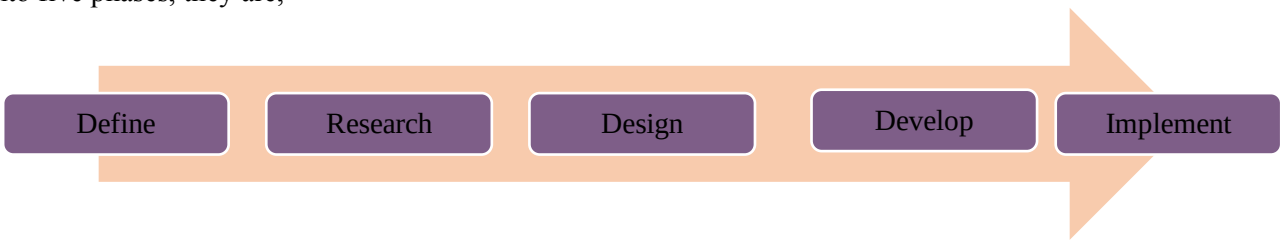
New product development:

Generic pharmaceutical companies tend to improve their market position by being first in the market when a patent on an original product expires. Introducing new products to market gives competitive edge to the generic pharmaceutical companies.

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 following are the steps involved in the process development in the Generic pharmaceutical company.

Process development cycle:

The entire process development of a new generic product (Active pharmaceutical Ingredient) can be divided into five phases, they are,



Define phase of the process development involves the collection of all the available literature information for the identified drug candidate which include, collection of product details, literature review, identification of best possible synthetic route based on safety, environmental, legal, economical and throughput evaluation. Upon successful identification of synthetic route, development team conduct the feasibility studies in the research phase of the development to check whether the synthetic transformation or reagent or conditions employed in the process is feasible for the next stage of development or not. In the design phase of the development, team identifies the optimal process conditions in terms of identification of suitable reaction medium, mole equivalent of reaction partner, addition rate of reagent, agitation, temperature and time for the reaction, solvent for extraction, distillation temperature, solvent for recrystallion and drying temperature, suitable control strategy etc., using QbD principles and design of experiments (DoE). After identification of optimal process conditions from lab, the process will be transferred to manufacturing unit for trial purpose to understand the scale-up behavior of each unit operations. Based on the trail batch observations and recommendations, the process will be validated in the development phase of the product development. After this phase of the development, all technical documents pertaining to process development and scale-up would be submitted to regulatory agencies for seeking the completeness of the development. Finally, in the implement phase, the process will be scaled up with the finalized process for commercialization of active pharmaceutical ingredients based on the needs of customer requirements.

Supply chain management:
Supply chain management encompasses the planning and management of all activities involved in sourcing and procurement, conversion, and all logistics management activities. Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers, and customers. In essence, supply chain management integrates the supply and demand management within and across companies (Flynn,B.B., Huo,B., & Zhao ,X.(2010))
The management of relationships across the value chain of the company is being referred to as Supply Chain Management (SCM). Strictly speaking, the supply chain is not a chain of businesses with one-to-one, business-to-business relationships, but a network of businesses and relationships. SCM offers the synergy between the companies and also with in the companies. In that sense, SCM deals with business process excellence and represents a new way of managing the business and relationships with other members of the supply chain(Koçoglu,I., Mamolu,S.Z., Ince,H., & Keskin,H.,.(2011)).
Supply Chain Management is the integration of key business processes from end user through original suppliers that provides products, services, and information that add value for customers and other stakeholders.

PROBLEM STATEMENT:

Developing strategies for enhancing speed of process development through supply chain in new product development of generic pharmaceutical companies.

IMPORTANCE OF THE STUDY:

The financial value 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. This is basically because the competitor companies are entering, capturing market and dictating the price, and also because of the loss of effective patent life. In today's scenario the speed of process development is the success deciding factor for any generic pharmaceutical companies. All the generic pharmaceutical companies target for achieving 180 days exclusivity which will yield them the tremendous amount of economic growth, only the companies who can achieve the speed of process development can achieve this target (Petersen K.J., Handfield R.B., & Ragatz G. L. (2005).
In spite of the importance to achieve the efficiency of the new product development, (which is also called as process development) in generic pharmaceutical companies and despite the fact that early to market have been extensively discussed in the literature, there is very little research in this area directly relating to the generic pharmaceutical industry 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 (Shah,N.(2004)).
In many cases the supply chain managers are not completely familiar with the strategic drivers of new product development like, regulatory requirements, intellectual property (IP) requirements and target cost requirements. Yet without understanding they will have to manage the situation effectively. It's little wonder that the process development team (R&D) many times express disappointment that their supply chain professionals are not providing more approaches to achieve excellence in process development (Petersen K.J., Handfield R.B., & Ragatz G. L. (2003).
At the same time, supply chain professionals are often frustrated by R&D people's lack of understanding and support to achieve excellence. In total, there is a disconnection between the supply chain managers and the R&D managers to achieve excellence and moreover there is a lack of common goal for them (Presutti Jr,W.D.,& Mawhinney,J.R. 2007).
Hence this study is important to analyze and develop the strategies to enhance the speed of process development through supply chain.

Research work:
During this research work initially we had focused on group discussions and had personal interviews with key opinion leaders to design the questionnaire. The data have been collected from 15 pharmaceutical companies by using a designed questionnaire. Among the fifteen companies five companies are from small size, five companies are from medium size and five companies are from large size. Although the research focuses on integrating supply chain in new product development work, in the article we takeout the work which are related to speed of process development. As the research reveals the integrating supply chain is directly proportional to the speed of product development, the research results are interpreted in this paper to speed the process development.
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,

Improve the speed of process development:
There is a clear need for pharmaceutical companies to speed up delivery of new products to the market to maintain a competitive effectiveness. The key to success of generic pharmaceutical company is the "The speed of process development" for getting 180 days exclusivity. The key is to go to the market as early as possible with the developed new product with the appropriate quality. Hence the process development should happen at the fastest possible timeline.
Based on the focused interviews with key opinion leaders followed by discussions and survey, the following factors have been finalized for enhancing the speed of product development. In this study many questions have been designed to identify the factors to enhance the speed of process development. Although many of the points have been identified to improve the speed of process development, the following factors have been shortlisted as important factors. Please find below the factors for enhancing the speed of process development in pharmaceutical companies,

- Capability sourcing (out sourcing the technology which is not available in in-house to get access to new technology or new capability) for R&D by supply chain team will have a significant impact on quick development of the new product.
- Early engagement with the concerned cross functional team will reduce the procurement timelines in new product development
- Early engagement of suppliers/partners in the project will help for enhancing the speed of process development
- Transparent and continuous information between Supplier/partner and SCM team will help to reduce the lead time for procurement which in turn will help to reduce the process development timeline
- Outsourcing less value added activities will reduce the time cycle of the process development
- Engaging more contract manufacturers (strategic business partners) will enhance the speed of project execution

RESEARCH HYPOTHESIS:

Based on the literature studies followed by focus interviews and discussions the following Hypothesis were derived.
Hypothesis-1: There is no significant association between type of Pharma Company and their opinions on Outsourcing to enhance the speed of product development
Hypothesis-2: There is no significant association between type of Pharma Company and opinions on cross functional coordination to enhance the speed of product development.
Hypothesis-3: There is no significant association between type of Pharma Company and their opinions on partner selection and evaluation to enhance the speed of product development.

Analysis of Data:
The primary data collected from the samples were analyzed using the statistical tools. Chi-Square Test, crosstab and Symmetric analysis were used to analyze the data collected from the questionnaire.

Hypothesis-1:
There is no significant association between type of Pharma Company and their opinions on Outsourcing to enhance the speed of product development

Table I

Crosstab							
			Outsourcing to enhance the speed of product development				Total
			Disagree	Neutral	Agree	Strongly Agree	
Type of Pharma Company	Small	Count	3	0	28	5	36
		% within Type of Pharma Company	8.3%	0.0%	77.8%	13.9%	100.0%
	Medium	Count	5	14	84	31	134
		% within Type of Pharma Company	3.7%	10.4%	62.7%	23.1%	100.0%

Crosstab							
			Outsourcing to enhance the speed of product development				Total
			Disagree	Neutral	Agree	Strongly Agree	
	Large	Count	11	37	218	129	395
		% within Type of Pharma Company	2.8%	9.4%	55.2%	32.7%	100.0%
Total		**Count**	**19**	**51**	**330**	**165**	**565**
		% within Type of Pharma Company	**3.4%**	**9.0%**	**58.4%**	**29.2%**	**100.0%**

Table II

Chi-Square Tests			
	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	16.320[a]	6	.012
Likelihood Ratio	19.356	6	.004
Linear-by-Linear Association	5.088	1	.024
No of Valid Cases	565		
a. 3 cells (25.0%) have expected count less than 5. The minimum expected count is 1.21.			

From the above table chi square is significant (Chi-square sig. Value is 0.012 < 0.05), reject null hypothesis. It means that there is a significant association between type of Pharma Company and their opinions on Outsourcing to enhance the speed of product development. It means that impact of Outsourcing on Integration is dependent on type of Pharma Company.

Table III

Symmetric Measures			
		Value	Approx. Sig.
Nominal by Nominal	Phi	.170	.012
	Cramer's V	.120	.012
No of Valid Cases		565	
a. Not assuming the null hypothesis.			
b. Using the asymptotic standard error assuming the null hypothesis.			

The strength of association between type of Pharma Company and their opinions on Outsourcing to enhance the speed of product development is 12.0%.

Hypothesis-2:

There is no significant association between type of Pharma Company and opinions on cross functional coordination to enhance the speed of product development.

Table IV

Crosstab							
			Cross functional coordination to enhance the speed of product development.				Total
			Strongly Disagree	Neutral	Agree	Strongly Agree	
Type of Pharma Company	Small	Count	0	0	19	17	36
		% within Type of Pharma Company	0.0%	0.0%	52.8%	47.2%	100.0%
	Medium	Count	0	8	46	80	134
		% within Type of Pharma Company	0.0%	6.0%	34.3%	59.7%	100.0%
	Large	Count	2	11	187	195	395
		% within Type of Pharma Company	0.5%	2.8%	47.3%	49.4%	100.0%
Total		**Count**	**2**	**19**	**252**	**292**	**565**
		% within Type of Pharma Company	**0.4%**	**3.4%**	**44.6%**	**51.7%**	**100.0%**

Table V

Chi-Square Tests			
	Value	**df**	**Asymp. Sig. (2-sided)**
Pearson Chi-Square	11.764[a]	6	.067
Likelihood Ratio	13.220	6	.040
Linear-by-Linear Association	1.026	1	.311
N of Valid Cases	565		
a. 5 cells (41.7%) have expected count less than 5. The minimum expected count is .13.			

From the above table chi square is not significant (Chi-square sig. Value is 0.067 > 0.05), no evidence to reject null hypothesis. It means that there is no significant association between type of Pharma Company and their opinions on cross functional coordination to enhance the speed of product development. It means that independent on type of Pharma Company the cross functional coordination will help to enhance the product development.

Table VI

Symmetric Measures			
		Value	**Approx. Sig.**
Nominal by Nominal	Phi	.144	.067
	Cramer's V	.102	.067
No of Valid Cases		565	
a. Not assuming the null hypothesis.			
b. Using the asymptotic standard error assuming the null hypothesis.			

The strength of association between type of Pharma Company and their opinions on cross functional coordination to enhance the speed of process development is 10.2%.

Hypothesis-3:
There is no significant association between type of Pharma Company and their opinions on partner selection and evaluation to enhance the speed of product development.

Table VII

Crosstab						
			Partner selection and evaluation to enhance the speed of product development			**Total**
			Neutral	**Agree**	**Strongly Agree**	
Type of Pharma Company	Small	Count	0	19	17	36
		% within Type of Pharma Company	0.0%	52.8%	47.2%	100.0%
	Medium	Count	8	78	48	134
		% within Type of Pharma Company	6.0%	58.2%	35.8%	100.0%
	Large	Count	9	198	188	395
		% within Type of Pharma Company	2.3%	50.1%	47.6%	100.0%
Total		Count	17	295	253	565
		% within Type of Pharma Company	3.0%	52.2%	44.8%	100.0%

Table VIII

Chi-Square Tests			
	Value	**df**	**Asymp. Sig. (2-sided)**
Pearson Chi-Square	10.092[a]	4	.039
Likelihood Ratio	10.496	4	.033
Linear-by-Linear Association	2.353	1	.125
No of Valid Cases	565		
a. 2 cells (22.2%) have expected count less than 5. The minimum expected count is 1.08.			

From the above table chi square is significant (Chi-square sig. Value is 0.039 < 0.05), reject null hypothesis. It means that there is a significant association between type of Pharma Company and their opinions on partner selection and evaluation to enhance the speed of product development. It means that impact of partner selection and evaluation on integration is dependent on type of Pharma Company.

Table IX

Symmetric Measures			
		Value	**Approx. Sig.**
Nominal by Nominal	Phi	.134	.039
	Cramer's V	.095	.039
No of Valid Cases		565	
a. Not assuming the null hypothesis.			
b. Using the asymptotic standard error assuming the null hypothesis.			

The strength of association between type of Pharma Company and their opinions on partner selection and evaluation to enhance the speed of product development is 9.5%

CONCLUSION:

Based on this research it is very evident that supply chain team can enable to accelerate the speed of new product development in generic pharmaceutical companies. The research reveals the following facts,

- There is a significant association between type of Pharma Company and their opinions on outsourcing to enhance the speed of product development.
- There is no significant association between type of Pharma Company and their opinions on cross functional coordination to enhance the speed of product development
- There is a significant association between type of Pharma Company and their opinions on partner selection and evaluation to enhance the speed of product development.

Hence supply chain team to designs the strategies based on the type of Pharmaceutical companies to enhance the speed of process development in new product development of generic pharmaceutical companies.

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