Investigation of Supply Chain Risk in the Indian Pharmaceutical Industry: A Case Study

Haresh Mahendran, Karthik Narasimhan, Nakul Nagarajan and Gopinath S

Abstract **-The pharmaceutical industry is faced with the challenge of surviving and succeeding in an environment that has become more complicated and uncertain, and one that is characterized by rapid developments in science and technology, and organizational change. The pharmaceutical industry faces relentless change and fluctuating demand which creates immense challenges in anticipating best sellers and predicting volume. Like the high-technology industry, pharmaceutical industry also suffers from many supply chain ailments including raw material shortages, short product life, quality of the product, and seasonal demand. Though India is growing with Information technology, Communication systems, infrastructure, the industry is facing various supply chain risk and uncertainty and hence Supply Chain Risk Management (SCRM) has become a vital part of this industry. We propose to investigate the types and management of risks faced within the supply chain functions of an Indian pharmaceutical company. The research was done through a case study approach. The results presented in the paper would be the outcome of a research study that was conducted in the operations of a medium scale pharmaceutical company. The paper highlights the risks faced in the pharmaceutical company and also identifies the critical point in each section of the supply chain and also investigates mitigation strategies for dealing with these risks. The critical points at different stages of the supply chain have been identified through a survey and the main reason for the risk has also been investigated.**

Index Terms- **case study, critical point, mitigation strategies, pharmaceutical industry, supply chain risk management**

Manuscript received March 06, 2011; revised July 15, 2011

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I. INTRODUCTION

Risk is defined as:
"The combination of the probability of occurrence of harm and severity of that harm."
Risk Management has now become an integral part of every aspect of business operations. Most businesses are ill-prepared to handle the rising risk levels, caused by more global and complex supply chains that are increasing supplier disruptions, logistics delays, and product recalls and safety issues. Globalisation and the quest for ever more cost effective means of supply have greatly increased the complexity of the supply chain which can often reduce both the knowledge and understanding of the exposure to risk.
Increasing threat due to competition, quality concerns, and scarcity of natural resources are major concerns for supply chain managers. In order to insulate business operations from unpredictable, uncontrollable events that can potentially hamper material supply, production and distribution, more and more supply chain managers are turning towards risk management in SCM. Management of risk across the supply chain is key to business sustenance and continued profitability.
Risk Management can help organisations safeguard the quality and supply of product to customers and ultimately the end user. It is about anticipating hazards and controlling risk through an ongoing process of risk awareness, reduction and / or acceptance, and review. The pharmaceutical industry in some senses may be considered unique in that as it has a fiducial responsibility in management and production functions. The stated goals of the pharmaceutical industry are to manufacture products with the highest quality, safety and efficacy, at the lowest possible cost. In order to achieve these goals the industry has to focus on eradicating risks in every step of the supply chain process.
Supply chain risk management (SCRM) is a new and novel methodology that captures both the operations as well as the financial aspects of decision-making. Supply chain management, in general, is still a relatively new concept in most developing countries, more so in India; and many companies have not even begun to consider the formal management of their supply chain.

II. PROBLEM STATEMENT

The main objective of this paper is to define the risks involved in the implementation of successful supply chain in a medium scale Indian pharmaceutical company. The main research questions are:

- What are the different types of risks or potential risks in a pharmaceutical supply chain?

ISBN: 978-988-18210-6-5
ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)

- What are the possible mitigation strategies required to manage these risks?

III. METHODOLOGY USED

A case study research approach was chosen as the research strategy for investigating the research questions.
The case study approach consists of detailed investigations alongside data collection, with a view of providing an analysis of the context and processes involved in the phenomenon under study. Based on the findings from an exploratory quantitative survey and qualitative focus group discussions with supply chain managers, some issues of SCRM are derived.

A. Data Collection

Data was collected through visits to the factory and interviews were conducted with the top level executives as well as working labourers in Purchase, Inventory, Production, quality control, supply chain management and sales departments.
To gain an understanding of the phenomenon of supply chain risk management, an in-depth semi-structured interview technique was used to probe informants regarding the type of risks that the organization and the entire supply chain have been exposed to or perceived as potential risks and the mitigation strategies that are in place to cope with those risks. We also sought to find out the impacts of risks that the organization and the supply chain have experienced in the past.

IV. RISK CATEGORIZATION AND MITIGATION STRATEGIES

Analysis reveals that a pharmaceutical supply chain potentially faces different types of risks. In response, supply chains tend to have plans in place that are capable of mitigating these risks. In the following discussion we intend to identify and summarize the different types of risks a medium scale Indian pharmaceutical supply chain faces as well as the strategies that are employed to mitigate the risks. The risks are broadly classified as supply related, cost related demand related, production related and miscellaneous risks.

A. Supply Risk

These are risks that could potentially affect or disrupt the supply of products or services that the pharmaceutical supply chain offers its customers. Our analysis reveals that the pharmaceutical supply chain could potentially be affected by the following supply risks:

1. Imports
The company imports its raw materials from a number of countries including China, Japan, Germany etc. The imports are subjected to fluctuation due to various reasons. There could be delay in arrival of vessel/flight at destination port, delay in Customs, and delay in movement of cargo or handing over of cargo to customs or delay in processing documents due to system error at Seaport/Airport. Also certain times, due to continuous holidays, strike by labourers customs may delay clearances.
The mitigation strategy suggested is to make sure the company accounts for this time from their previous experiences and book their supplies a bit in advance with sufficient lead time to overcome this delay.

2. Inferior Quality of supply
Certain raw materials are found to be of inferior quality. These raw materials could be either the imported products or the locally bought products. Since the pharmaceutical products directly affect the lives of people, the company cannot afford to entertain supplies with inferior quality. The mitigation strategy adopted is establishment of high standard quality protocols and strict enforcement of these standards. Vendor auditing should be done regularly following very strict measures of checking. Implementation of Statistical quality control will enhance the consistency and step towards six sigma implementation.

3. Non-Availability of resources
- Raw Materials

The main supplier could suddenly become unavailable due to various reasons such as internal management problems; inability to meet high quality standards, suppliers going out of business, malfunctioning of machinery etc, in such a situation the company would face a shortage of raw material supply. The mitigation strategy adopted is to have secondary suppliers provide the necessary raw material to meet demand when required. For example the company has to have alternate suppliers for the different raw materials.

- Packaging Materials

Packaging materials are an integral part of the finished product. Every company has its own design for the packaging materials such as bottles, etc. and can not to afford to compromise on quality. In case of loss of supplier of the packing materials, a replacement satisfying the specific needs without much compromise on quality is hard to find. To tackle this risk we suggest the company to share a good rapport with the packaging material supplier, prompt settling of bills and also having adequate stock since it's to a large extent a non-perishable commodity

4. Natural Disasters
Sudden occurrence of natural disasters such as floods, earthquakes could disrupt supply.
The mitigation strategies involve understanding the vulnerability points and their impact in the supply chain and developing and testing contingency plans. For Example the company faces a risk of losing key supplies during the monsoon season in India, since most of the transport is by road. Also the recent tsunami in Japan has affected the company.

5. Man-made Disasters
The major source of man-made disasters that could disrupt the supply is terrorism. Regional insurgency in some parts of India leads to delay or in some cases even the loss of supply. These are low frequency events, political rallies and protests could also lead to delay in the supply.

6. Selection of Supplier
The selection of supplier by the company for its raw materials is not only based on the cost and quality but also

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ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)

on other factors. One major factor affecting the selection of supplier is the life of the raw material. Since pharmaceutical products especially the tablets and syrups have a short product life it is required to buy the raw material which can provide a greater life span. The purchasing of the optimum raw material requires extensive research on the part of the company.

7. Cost Risk
The main reason for cost risks include the increase in freight charges due to increase in fuel prices. The increase in government taxes/duty will also impact the costs of supplies. When the cost of production of raw material/packaging material increases, the cost risk increases. One other reason for increase in the cost supplies is due to the increase in demand of supplies.

B. Production Risks

Production risks are those that could potentially affect or disrupt the production of the pharmaceutical products.
We discovered the possibility that the following production risks that could occur in the company:

1. Malfunctioning of Machinery
Since almost the entire process of manufacturing of the pharmaceutical product is automated, optimum performance of the machinery is essential. Any malfunctioning of the machinery can lead to lengthy disruptions in the manufacturing procedure. This increases the cost of production. Also the manufacturing of the products involves the mixing of the chemicals with high precision. Hence the machines are required to be checked and calibrated at regular intervals through preventive maintenance program in order to prevent any problems during the manufacturing stage. Moreover, they should have spare parts at their disposal and qualified personnel to tackle such a situation. Selection of correct machinery will reduce this risk in a large way.

2. Human Risks
Human risks are mainly caused due to negligence on part of the employee. Although most of the production processes are automated, steps are present which can lead to disruptions due to the human risk. These risks can be avoided by providing proper training to the employees. Another human risk is labour unrest. This is handled by the company by setting up unions to look after the employees and paying heed to all their requirements.

3. Wrong Packaging:
The company produces a number of products. One particular risk the company faces is handling the criteria to be met while exporting its products to other countries or selling it to the hospitals domestically. Every institution has its own requirement in terms of packaging and labelling. The company must make sure these requirements are met before shipping of the products as any fault in the packaging could lead to rejection of the entire batch. More so, there are norms to follow strictly in the pharmaceutical industry. Certain chemicals should not be exposed to sun light, and thus packing these products in transparent bottles will lead to the chemical disintegration the product will lose its quality. These situations can be prevented by careful inspection, packing slips and extensive quality control checks before shipping the product.

4. Power Shutdown
In developing countries such as India, continuous power supply is still a dream! Regular power shutdowns halt the production and create a huge stress on the production department.
The company must have full power back up systems to make sure production is not halted in such a situation

C. Demand Risks

Demand-related risks could potentially affect the ability of the company to make products available to its customers. Our analysis reveals that the supply chain could be affected by a number of demand-related risks such as ban of a product will have an adverse effect on the company with the demand plunging to zero. In such a scenario, other products with similar functions will come in as replacement to the banned product. This will lead to increase in demand of the substitute products. News about new side-effects though in-frequent, can lead to sudden drop in demand, more so in the case of pharmaceutical products. An Epidemic outbreak will also lead to a sudden increase in demand. Successful marketing campaigns will also lead to rise in demand of the product. Competition from rival companies plays a huge role in demand fluctuation.

1. Forecasting Errors

Forecasting errors could aggravate the demand unpredictability. Factors that affect forecast accuracy include long lead times, short life cycle products, orders placed by intermediaries within the supply chain that creates the bullwhip effect, sudden outbreak of an epidemic and not incorporating the impact of promotions in forecast calculations. These are frequently occurring risks and the impact includes significant misallocation of resources in inventory, facilities, transportation, sourcing, pricing and information management.

The mitigation strategies that the company should follow to tackle these demand risks are forming collaboration between the company and its suppliers, this can ensure that the customer requirements are met successfully. To collaborate on demand planning successfully, business partners need to share and modify each other's demand plans and forecasts. Importantly, each partner needs to understand and electronically share its promotional plans. Once demand plans and forecasts are in place, replenishment plans designed to assume adequate product availability would be jointly developed. Introduction of e to e business model will eliminate the forecasting error.

ISBN: 978-988-18210-6-5
ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)

D. Miscellaneous Risks

1. Transportation Risk

There are 3 main types of risks to consider when transporting a shipment at different stages in the supply chain network:

- The risk that the shipment is delayed.
- The risk that the shipment does not reach its destination.
- The risk of hazardous material.

The reason for the first two cases could be caused due to natural causes such as cyclones, earthquakes, heavy rainfall etc. Contingency plans have to be made before hand to deal with such risks. The third case that is the risk of hazardous material is caused when the transported substance is contaminated due to exposure to harmful substances while transporting. This can be prevented by using right material of construction containers to prevent exposure.

2. Quality Risks

Since the pharmaceutical products directly affect the health of the customer it is extremely necessary to produce products of the highest quality. This can only be achieved by following strict quality protocols at each stage of the supply chain. Proper quality inspections have to be done.

3. Storage Risk

All suppliers will use warehouse facilities (and also quarantines) to store materials and they may not have the same standard of pest control processes as their customers. The warehouses in which either the raw materials or the finished goods are stored could be contaminated. Regardless of the value of the product, the accountable organisation still needs to consider potential hazards within the supply chain and apply Risk Management.

4. Information Sharing Risks

Information is crucial and key to success in supply chain performance because it is the foundation on which supply chain processes execute transactions. Without information a manager cannot know what customers want, how much inventory is in stock and when more products should be produced or shipped. He is forced to make decisions blindly. This is where IT comes into play. Using IT systems to capture and analyse information can have a significant impact on firm performance. The company under consideration does not use any Enterprise based software (ERP).

We suggest use of ERP software such as SAP and ORACLE to improve efficiency. They provide transactional tracking and global visibility of information from within a company. This helps the company to improve the quality of its operational decisions. Other information sharing risks include attack by viruses, hackers etc.

5. Safety regulations by government agencies may impose more stringent requirements on the company and increases the cost of doing business. Again implementing cost reduction strategies in its operations and supply chain has to be done in such cases.

V. OBSERVATION

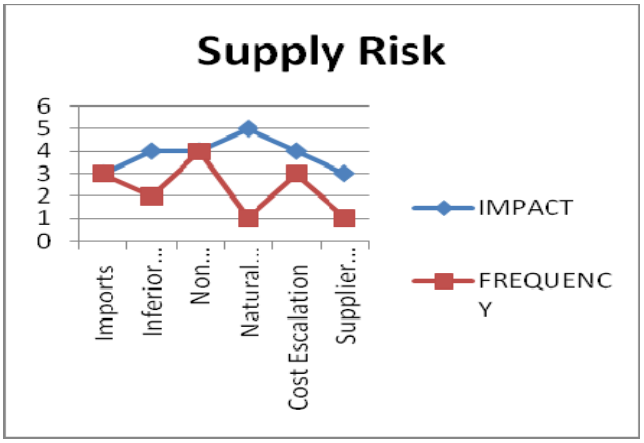

Figure 1: Deals with the various risks in the supply department and shows its impact and frequency.

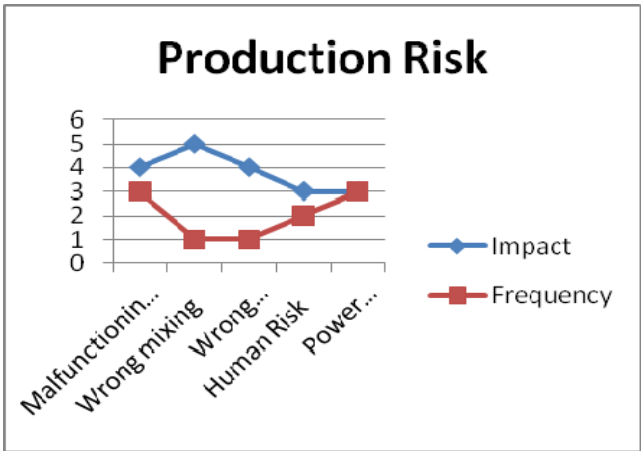

Figure 2: Deals with the various risks in the production department and shows its impact and frequency.

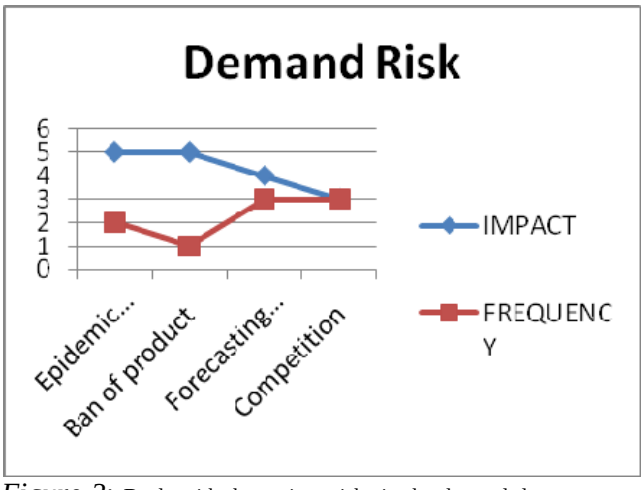

Figure 3: Deals with the various risks in the demand department and shows its impact and frequency.

The three graphs plotted above (Figure 1, Figure 2 and Figure 3) deals with the various risks at the various stages of the Supply chain such as supply, production and demand and the values are derived from the response of the employees. From each graph, the critical point at each stage can be spotted. Critical point is defined as the risk which

ISBN: 978-988-18210-6-5
ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)

needs to be given highest priority in terms of mitigation strategies and needs to be dealt with great care. The critical point is found with its value of impact and its frequency of occurrence. With '5' being very high, '4'- high, '3'-moderate, '2'-low, '1'-very low, the critical points have been found.

VI. HYPOTHESIS

From the observation graphs the critical points of supply chain at the different stages, that is supply, demand and production have been found. Detailed investigations on the causes for these risks were carried out and the following assumptions were made. This was then verified through a survey conducted among the employees.

A. Hypothesis 1

The main reason for non-availability of raw material/packaging material is due to demand fluctuation of the company.

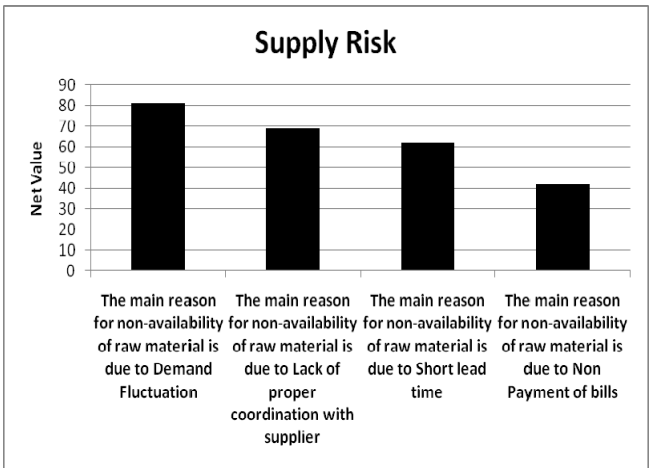

Figure 4: Shows the response from the employees in the supply department.

From the above bar graph it is clear that the main reason for non-availability of raw material is due to demand fluctuation of the company. Thus the hypothesis is accepted.

B. Hypothesis 2

The main reason for malfunctioning of machinery is due to inefficient preventive maintenance technique.
From the bar graph it was found that the main reason for malfunctioning of machinery is due to lack of spare parts or improper/over usage and not due to inefficient preventive maintenance technique. Hence the hypothesis is rejected.

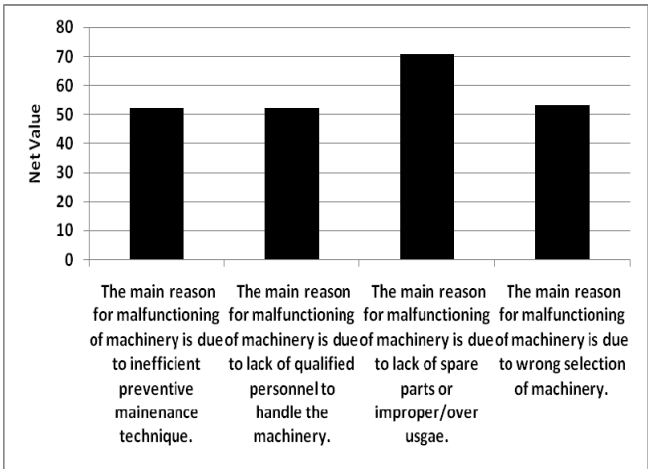

Figure 5: Shows the response from the employees in the production department.

C. Hypothesis 3

The main reason for forecasting errors is due to not using proper demand forecast software.

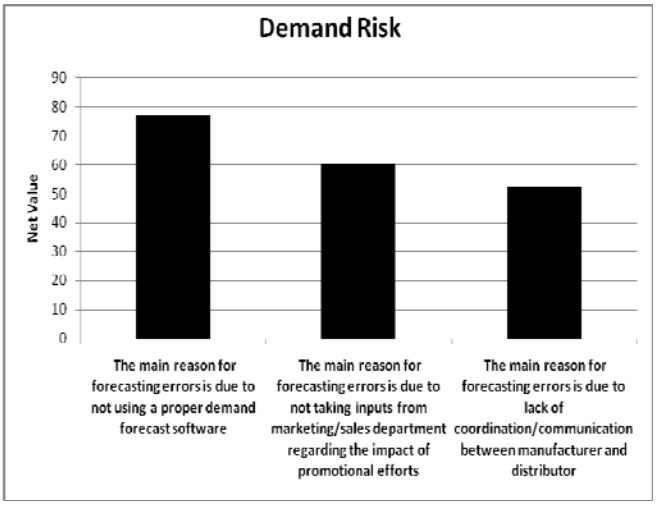

Figure 6: Shows the response from the employees in the demand department.

The bar graph clearly shows that the main reason for forecasting errors is due to not using proper demand forecast software. Therefore the hypothesis has been accepted.

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VII. CONCLUSION

This empirical study concludes different classification of risks and its mitigation strategies. The classifications are supplier risk, demand risk, production risk and miscellaneous risks which include transportation risks, storage risks and information sharing risks. Through a detailed study of this medium scale Indian pharmaceutical company we have been able to identify the risks faced in this industry at different stages of its supply chain. With the help of the graphs, we have also spotted the critical points based on their impact on the supply chain and their frequency of occurrence and they are found to be:

- Supply – Non-availability of raw material/packaging material
- Production – Malfunctioning of machinery
- Demand – Forecasting

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