

A STUDY ON SUPPLY CHAIN PRACTICES IN PHARMACEUTICAL INDUSTRY WITH REFERENCE TO ESSENTIAL DRUGS IN INDIA

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ABSTRACT

Worldwide pharmaceutical companies are working day and night to supply the drugs and medicines to hospitals and retails due to rise in demand of such goods. In India, the essential drugs are consumed at a high rate which keeps its demands always high and to meet such high demand, pharma companies need to have an effective and advanced supply chain which can meet such high demands of every Indian. The ever growing country of 1.3 Billion people need medicines for priority needs in their hands at right quantity and superior quality. The supply chain while providing these needs faces a lot of issues due to socio-economic structure of Indian economy and poor infrastructure facilities. The real problem lies in deciding the right drug to be produced at the right quantity. Quantification of the essential drugs is a task and the new technologies have been developed to make the pharmaceutical supply chain more efficient. The main objective is to reduce the time taken to make the drugs available in the market and also to make sure that there is no wastage or overproduction of drugs while keeping in mind the affordability of the majority of the patients as India is a developing country and is highly prone to becoming victims of drug counterfeit. With gradual development these issues will be resolved as new trends and technologies specially made to provide tailor made solutions to pharma companies are coming up. An overall study about these topics is presented in the paper as it takes into account the study of many past research.

Keyword: - *Pharmaceutical, Supply Chain Management, Essential Drugs, Counterfeit, Regulations.*

1. INTRODUCTION

1.1 Background

Supply chain is referred to as a network of people, technology, places and resources which leads to the delivery of raw materials from vendors to manufacturing units and till the end consumer of the product. It is like an optimization process between vendors, manufactures, consumers and other stakeholders. Supply chain is responsible for even the minutest of details, from balancing cost between the smallest of material to having regular flow of goods at right time, right price to right people. Pharmaceutical supply chains have to provide the right mix of drugs in right quantity at right time to manufacturer with optimum cost, keeping in mind the regulatory authorities and cost for customers. These supply chains can be a core part of the company's work or can be outsourced to a third party for more effective and efficient work. The supply chain department has to work hand in hand with the Research and development department and the TQM department so as to maintain the quality of drugs as they have to work under the Central Drugs Standard Control Organization (CDSCO). Supply chain let's have a balance between different works in the organization and lead to efficient working and better results. These companies get a lot of benefits from efficient supply chains, like greater productivity, shorter lead time, better customer satisfaction rate and fewer people involved which results in better fulfilment rates. (Kapoor D, 2018)

1.2 Purpose of Study

The purpose of this paper is to study and evaluate the supply chain system in pharma industry with reference to essential drugs with focus on India, essentially about the distribution of medicines and the issues related to it. Currently the modern medicine trend is changing and to meet current demand of these drugs the new technology and related gaps in service is unaddressed.

1.3 Method of Study

Being a conceptual paper, the paper is solely based on the articles published, books and different websites on search engine Google. It is a secondary data collection method, where Google Scholars, JSTOR and other places are used to get the literature and material for study. Key words like “Pharma industry supply chain”, “Medicine control” where used to search and review literature.

1.4 Scope of Study

The study explains the supply chain in pharma industry in India and the way it supplies essential drugs to clients and end users in an effective way. The study also aims to analyze the challenges and provide for some solutions for these problems with the analysis of newest trends in the supply chain operations and how pharma sector can adopt them. The study also explains the regulatory bodies in India which governs the movement and processing of drugs, chemicals and pharmaceutical products.

2. LITERATURE REVIEW

(Schwarz, 2011) explains the effects of information sharing on Pharmaceutical Supply Chain. The study also throws light on investment buying which is made to earn at times of bullish prices in market. Investment buying also helps distributors to stock essential goods when needed and continuous sales for manufacturers. They also brought in the impact of inventory management agreement which significantly reduced the inventories. The agreement is monitored by proper regulatory bodies, which ensures proper flow of goods.

(Brain, 2004) This study highlights the key points of patent use in essential drug manufacturing, where it leaves little or no chance for competition from others, which creates more profit in the hands of manufacturers as the cost of these drugs are very cheap. The article also explores how big firms existing in the market work on regional strategies to expand market throughout a region, which determines the sales of the product.

(Morris, 2019) examined the current situation of excessive outsourcing by the manufacturers for a single product. This requires proper inventory management and effective pipeline to meet the situation of high demand. He brings in how India is becoming a global attraction for pharmaceutical manufacturers. The author also discussed about how the entry of new drug can affect both company and end user if the supply chain is disrupted causing shortages in supply. The study also discussed about how multiple suppliers and low-capacity utilization rates contribute to disruption of Pharma supply chain.

(Kapoor D, Lupin Publishers, 2018) in this article discussed about how pharmaceutical supply chain works, further adding on to the topic they also mentioned about the benefits of supply chain which helps pharma companies make better use of available resources and focus on reducing process time. Furthermore, the main issues and challenges that a pharmaceutical company usually faces while production of essential drugs in India is also discussed and the issues were poor transportation, temperature changes and issue of counterfeiting, lack of adherence, etc. Study majorly focused on providing insights on basic conditions that need to be taken care of, to increase efficiency of the supply chain process.

(Saharia, n.d.) discussed the need of supply chain transformation in the article. They further explained why transformation plays a very important role in the growth expected by the pharma industry. It further reflects the key hurdles faced by supply chain in India and the major factors forcing the process to change. This article also came up with ways to forfeit these hurdles. The study concluded that the supply chain efficiency can be achieved by the pharma industry in India through robust improvements and transformation.

(Bolineni, 2016) Indian pharmaceutical companies spend one-third of their revenue from SCM activities due to inherently poor transportation infrastructure. The pharmaceutical supply chains in developing and developed countries vary in terms of their organization, financing, function, and ideal characteristics of the best performing supply chains.

(Brynjolfsson and Yang, 1996) Reveals that the adoption of e-procurement saves the costs of the preparation and transmission of paper purchase requests and invoices and enables ordering systems to be tied directly to production systems thus eliminating costly, time –consuming errors from manual data entry (Mungu, 2013)

3. WHAT IS ESSENTIAL DRUGS AND HOW THEY ARE PROCURED?

“Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness” (Kar SS, 2010). Essential medicines list is developed by WHO every 2 years. This list includes the dosages for specific common diseases, it also comes with specified quantity required per dosage and it is monitored at every stage of development.

Strict protocol is followed during the production and procurement of these drugs. This also comes with a tight supply chain pipeline where every function should be in regards to the guidelines put up in the “Essential Medicines list” published by WHO.

Essential drugs comes with a tight process of supply chain, starting from raw material procurement to delivery to retailers, which leaves suppliers and manufacturers with less opportunities to cut down on its costs as these medicines need to be provided at effective rates which are easy for consumption even for a common man. Seeing the need of essential drugs in Indian scenario of less affordability of high end medical treatment, state governments are taking initiatives to publish their own list of essential medicines based on clinical guidelines. This list was published firstly in Tamil Nadu, 1994 followed by Delhi based on National list. But this can only be achieved with lowering the supply chain cost involved with them. (Kar SS, 2010)

3.1 THE REGULATORY BODY

Starting from procurement, correct temperature during logistical activities and quick and fast delivery within expiration date, the Government of India has major rules and organization in place to look over the industry work. The government has Ministry of Health and Family welfare and Ministry of Chemicals and Petrochemicals under which we have CDSCO for drugs and NPPA and DCP for chemicals respectively. Now the CDSCO sets standards for safety, quality of drugs and has watches over how the drugs are used and made, whereas the NPPA that is the National Pharmaceutical Pricing Authority which sets price for drugs which are produced in bulks. Lastly the Ministry of Chemicals and Petrochemicals watches over like a guard over the entire industry, the planning, development and other activities related to the chemicals in India. (S.D.Mankar, 2014)

4. SUPPLY CHAIN MANAGEMENT IN PHARMACEUTICAL INDUSTRY

Supply chain as mentioned by (Jayashree Dubey, 2007) “is the network of organization that are involved, through upstream and downstream linkages, in different process and activities that produce value in the form of products and services delivered to the ultimate customers”.

Availability of essential drugs in the right place at the right time can be a matter of one’s life; making of these drugs need a rigid and complex supply chain management practices attached to it. (Kapoor D, Lupin Publishers, 2018) explained in their study how participation of different stakeholders and increasing interest of human life has made this structure complex by demanding more channels of distribution.

What makes the process more complex is interventions from regulatory bodies as there is strict control over the use of raw materials of essential drugs at every stage. This adds more complexities in the process where starting process is raw material procurement as procurement of every material is done through number of suppliers existing in market. As described there are basically two main procurement channels in pharma production of essential goods, (i) raw materials and (ii) packaging materials. (Plumiee, 2017) concluded that stability testing needs to be done for a drug once it has passed FDA approval as it needs to pass the condition in which the drugs can sustain itself. To

ensure long sustainability of the product, manufacturer needs to ensure the use of best quality packaging to increase the shelf life of the product to make supply chain more efficient. Because once the shelf life is increased, the supply chain manager can focus on other variables as the drug can sustain longer providing him more time to add more lines in process.

Following that the supply chain moves to the process of manufacturing as described by (Viglo, 2014) which can be direct or indirect in the form of contract manufacturing. After that the manufacturer process ends and the line shifts to the wholesalers with help of distributors in presence of services contract by manufacturer to wholesalers. The wholesaler category is further divided into Primary and Secondary. Next, the lines further move to retailers who provide essential drugs to final consumer as in most of the supply chains but as mentioned by (Viglo, 2014) and (Fein, 2019) the extra line which is added in this process is through the third-party through formulary agreement. These links are commonly hospitals which provide patient direct delivery of medicines through their operational network.

(Kapoor D, Lupin Publishers, 2018) explains how the whole process has to go through the check of regulatory bodies and government check starting from procurement of raw material by manufacturers to customers. The most important point that needs to be noted when the supply chain of essential drugs is discussed as mentioned by (Plumiee, 2017) and (Fein, 2019) is the presence of agreement and contract at each level. These agreements also restrict the manufacturers to shift its suppliers as they are mostly in a long term contract and changing them constantly can lead to high costs to manufacturers. As breaking contract may be too stressful in terms of legal constraints as well. Hence, for the better and efficient flow of a product, the procurement chains need to remain the same. This helps companies to achieve economies of scale with regular order and a refined packaging.

With the study above we can make the following process flow for supply chain in Pharmaceutical Industry:

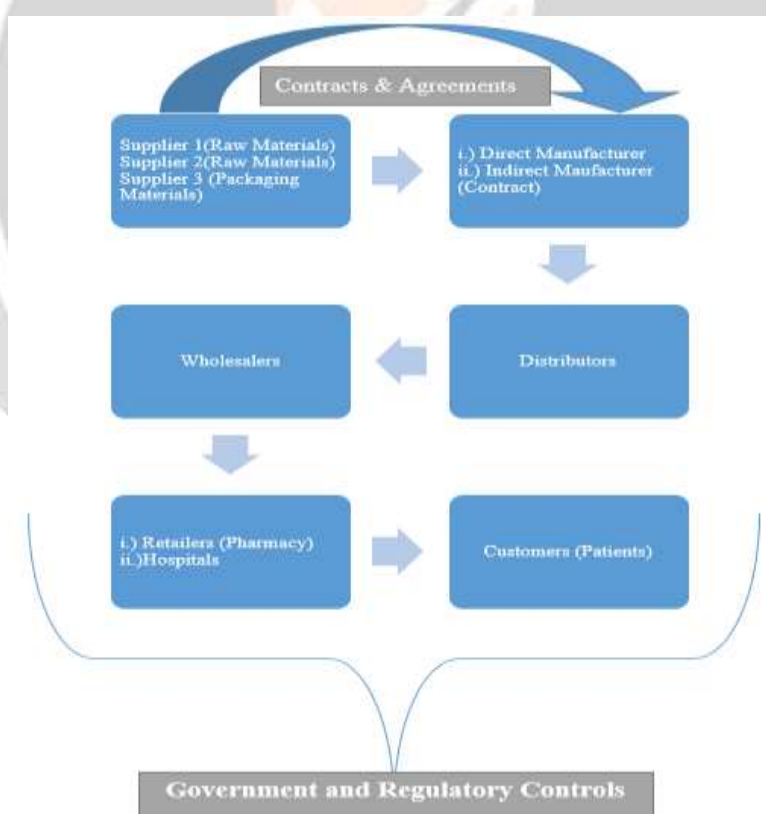


Fig -1: Supply Chain for Pharma Industry of essential drugs

5. PROBLEMS RELATED TO PHARMACEUTICAL SUPPLY CHAIN

(Saharia, n.d.) There is a vast difference between the reality and India's promising growth trajectory in Pharma Sector on paper, where companies are going through tough times in changing their supply chain to current needs. There are studies that show a significant growth in the Industry but that growth has also seen many drawbacks and increased costs of manufacturing and distribution.

(FDA, 2016) Counterfeit drugs mostly emerge in places where there is very less supervision on the regulation of the drugs. Counterfeit drugs are illegal drugs or the prescribed drug only but with the wrong dosage which could harm the consumer/patient. According to (WHO, 2010) "There is a flow of products coming from everywhere and going to everywhere, there are so many hubs" says the Interpol Officer of Aline Plançon, and so there is a high possibility of circulation of the counterfeited drugs. Asia accounts for the biggest share of the trade in counterfeit medicines, according to the industry funded organization, the Pharmaceutical Security Institute.

(GAIA TRADE, n.d.) Identifying the mode of transportation for the supply of drugs is also a task in this industry as the drugs need excessive care and is a temperature controlled supply chain. Cold chain logistics is the most frequently used mode of transportation as temperature should be given importance in the storage of the drugs till it reaches the end user. Coldchain equipment increases the lifetime of the drug by providing the right temperature required for the drug. Pharmaceutical coldchain management is the process of storing the drugs at the right temperature so that the quality and the lifetime of the drug is taken care of until they are ready for dispatch to the pharmacists and end users.

Temperature control is another major issue faced by the pharmaceutical supply chain as India's environmental conditions and temperatures vary indefinitely at different places. (Kapoor D, Lupin Publishers, 2018) Keeping up with the requisite temperature is a big challenge for the drug manufacturers throughout the storage and distribution lifecycle. The drugs that usually require more efforts to maintain the efficacy of the drug through proper temperature are often expensive and targeted by the drug counterfeiters as they hold more value. Lack of supervision on the temperature check of the drugs can lead to the decomposition of the drug which can lead to toxicity and even death.

The main reason why cold chain equipment is used in the entire supply chain process is because most of the drugs require excessive care especially in a country like India where the temperature of the weather is highly humid and unpredictable.

Expiration of the drugs is another threat to the pharmaceutical industry. (Unfried, n.d.) Purchase of excess drugs and stocking up the inventory will lead to expiration and waste of unused medications. The pharmacy has to keep a balance of right amount of inventory for use. This can be done by having a computerized inventory system as the barcode system helps in keeping track of the flow of products and information. Computerized inventory control is the most efficient way of work flow system in pharmaceutical industries as there about a million drugs and for them to be available at the right time, keeping track of the prescriptions is necessary. The supply chain in pharmaceutical industries need to be quick and highly efficient, if not it may lead to unnecessary credit returns and disturbs the whole supply chain.

(Mach1GlobalServices.Inc, 2017) explains that lack of coordination is the main issue faced by pharmaceutical supply chain as there are a million types of drugs and people are always in need of them. If there is no coordination and flexibility in supply chain, it can affect the people directly and this can make them choose other counterfeited alternatives. According to (Mukhoti, 2012), "there are two parts in supply chain planning and coordination which is called as the Master Planning of Resources and the second is called as the Scheduling." Master planning of resources is done 2-3 months before the manufacturing of the product. The historical data as in how much of the inventory is left, raw material requirements, expected delivery time etc. is determined using software such as ERP to come up with the plan. The plan that should be executed is forwarded to the procurement team. (Mukhoti, 2012) The next step is scheduling which is the immediate future and at a more micro level; for example, it is more granular, stage wise breaking of tablet production into granulation, compression, coating and packing. These levels of automation helps in better coordination.

(Shang, 2008) "has observed that determining optimal inventory levels in the pharmaceutical supply chain is a complex problem because of the involvement of various stochastic variables". Pharmaceutical supply chains require efficient inventory management and coordination between the manufacturers, distributors and pharmacists. Improper

inventory management and warehouse management can lead to many problems in the supply chain. Lack of proper inventory management can lead to the decomposition of the drug and it is highly dangerous as these drugs have a direct impact on the consumers.

Pharmaceutical industries will face a lot of supply chain problems as there is a lot to deliver to the people in a short span of time and it requires excessive care throughout the process of this supply chain. (Barraclough, n.d.) Even though most medicines are packaged in sealed containers, moisture can still be more damaging to medicines than high temperatures.

(Mir Javid Iqbal, 2017) Drug quantification is a process used to determine how much of a product is required for the purpose of procurement. (MSH.Org, 2012) Essential Medicines List (EML), average consumption, epidemiological information, prescription patterns, minimum and maximum stock levels, frequency of stock-outs and length of the procurement cycle etc. is required to determine the accurate drug quantification. Pharmaceutical supply chains in India have trouble in determining the quantity to be manufactured and supplied due to lack of information and coordination in the process.

6. NEW TRENDS

6.1 Big Data and Cloud Computing

(Hughes, 2018) in the article tells us how the new ways of collecting data from a variety of sources to predict and analyze the patterns and past to prepare for future. Getting full real time data and sources can be challenging but after this process the organization reaps a lot of benefits. By having a proper flow of medicines made, sold and in inventory, they can reduce the greatest problem of all times, counterfeiting of drugs. The organization needs to bring together all its operational data, new technologies, ERP, warehouse, etc., to integrate the data computing systems to get more accurate results.

6.2 Internet of things (IoT)

A group of interconnected devices and network leads to Internet of things which is a new way of managing inventory with new devices and supply and demand. From production till the very end of distribution, all the processes can have a real time visibility and this leads to manufacturers control cost. With new devices to pinpoint temperature for pharma goods, this technology is very promising. (Hughes, 2018)

6.3 Data flow between every link in the supply chain through AI and data connections

(Systems, 2019) talks as to how the connection between each link will be bridged with efficient flow of data using new AI technologies. Now any data from clinical trials and hospital requirements will directly go the R&D department which coordinates to get raw materials from supply chain department which is already aware of the material quantity and quality due to efficient working of AI connecting systems.

7. CONCLUSION

From this paper and the literature we found out how the essential drugs are being made and moved with ever increasing demand for them. The regulatory bodies are becoming more and more strict about these drugs due to counterfeiting and pricing issues. Even though the manufacturers are trying to cover majority of areas, they still do not have a proper system of distribution and collection due vast area of the country. The daily issues like transportation and temperature control are the major challenges faced by the companies. Some medicines have to be kept under certain degree of temperature to keep them safe for use which is a major issue for the companies due to high cost and poor infrastructure of India. The new trends to change these issues are coming up slowly which is likely solve the issues but will take time to be accepted by the companies. The reach of the essential drugs to every part of country will solely depend on the improvement of infrastructure and transport facilities of the country. Lastly it is very clear that supply chain plays a major role in pharma industry and the role they play keeps the company on the surface.

8. RECOMMENDATIONS FOR FUTURE RESEARCH

Following researches should be made based on literature reviewed-

- Further research on challenges of supply chain for essential drugs in rural areas of India and how to solve them keeping in mind the current scenario of India
- Research on new technologies for supply chain and inventory management in upcoming future for pharmaceutical products.

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