Recent Trends and Practices in Malaysian Pharmaceutical Supply Chain – A Qualitative Case Study

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Abstract—The pharmaceutical industry in Malaysia is one of the fastest growing industries that help in increasing the overall country's revenue to a great extent. Medicinal Drugs are supplied to all regions within the country and as well as to other parts of the world. Generic traditional medicines, vitamins and supplements tops the production output but some of the other rare branded medicines are imported from overseas. Handling a very large variety of product families and different type of medicines is a very challenging job nowadays. Sophisticated methodologies and principles are needed to be followed to suffice the requirements of this complex pharma supply chain network both internally and externally. Time consumed at each and every level of the supply chain plays an important role in deciding the on-time delivery of drugs. A qualitative case study was conducted in a top level Malaysian Pharmaceutical firm to learn about the recent practical strategies and methods adopted by them in achieving on-time delivery and tackle product complexity. This study could also help other middle level small scale industries to develop their supply chain and provide better results to their customers in the future. Success of a country's economy not only depends on the top level multi-national industries but also depends on the effective running of small scale manufacturing industries. Many useful insights from this study were derived and applied to develop a conceptual framework on the requirements for the effective functioning of any given Malaysian Pharmaceutical supply chain.

Keywords—Pharmaceuticals; Malaysian Pharmaceutical Industry; Pharmaceutical Supply Chain; Halal Pharmaceuticals; Information Sharing; Supply Chain Resilience; Supply Chain Security; Customer Relationship

1. INTRODUCTION

Manufacturing of medicines should be given a great priority and care rather to other products in order to avoid adverse consequences. National Pharmaceutical Board should take up this responsibility and make sure there is smooth drug production that meets the whole nation's medicinal needs. A quality and resilient supply chain is very much needed to complete the whole production process properly. All other regulatory issues should be solved to ease the supply chain process [1]. Competitive advantage can be created by proper advertisements and market campaigns coupled with easy distribution of products of different variety and different levels of quality [2]. Economic imbalances of a nation may drastically effect a pharma industry since demands may rise and drop anytime. Delivery of drugs at the right time may be lifesaving. Outsourcing some of the semi-finished goods is adopted to tackle this constraint [3]. Sometimes drug pricing fixed by the government and the cost of production may

contradict badly and affect the upstream network. Stack holders should take up the responsibility of maintaining the sustainability of the medicine system. Nominal pricing which satisfies everyone in the value chain should be the key to reformation of pharmaceutical industries [4]. Affordability and availability of medicines are given great priority by improving drug supply chain [5]. Pharmaceutical downstream supply chain faces a lot of hurdles under specific constraints like government regulations, medicinal expiry date and inventory control. Nowadays transportation and storage cost is also considered as a dominant factor which contributes to the firm's overall output [6]. Drug track and trace protocol seems to be difficult because of identity change at every level of the supply chain. Secure databases are now being used to handle this issue and track information needed for drug authentication [7]. Economic performances need to be stable to meet competitions globally. Effective utilization of assets, best customer service, optimal inventory management, better demand forecasts and lenient government norms are few keys to success. Stringent regulations can severely affect products with good turnover [8].

A qualitative case study on the Pharmaceutical firm was really needed to better understand each and every activities that directly or indirectly contributes towards the better functioning of supply chain processes of Malaysian Pharma industry. A top level Pharmaceutical firm was approached to conduct a qualitative case study. This firm is a leading manufacturer, distributer and exporter of pharmaceutical products and medicines in Malaysia. It produces oral antibiotics, creams, dental products, eye drops, sterile injectable solutions, tablets and capsules. Most of the final medicines are generic and follow Halal Standards. The major export destinations are Singapore, Vietnam, Ethiopia, Southeast Asia, Pakistan, Bangladesh, Sri Lanka, Hong Kong and other gulf countries. Business has been established with a huge number of suppliers and customers and the firm is one of the top five leading Pharmaceutical Manufacturing firms in Malaysia.

2. LITERATURE REVIEW

Drug control authority monitors and regulates the outbreak of seasonal diseases. Local firms help in the production of Therapeutic drugs and develop internal Malaysian Pharmaceutical value chain. Costly life-saving medicines are outsourced from overseas locations especially for cardiovascular diseases and diabetes. Pharmaceutical Inspection Co – Operation Scheme (PICS) helps in inspecting all the incoming medicines. Malaysia is considered as the Halal hub for the Southeast Asian countries. Halal standards are now incorporated in producing Halal drugs. Malaysia is one of the twelve key economic areas where other countries wants to establish their businesses. The Good Manufacturing Practice (GMP) is followed to achieve both international and domestic benchmarks. Local manufacturers are producing off-patent generic medicines in a large volume and also export high value biological drugs to gulf and other Asian countries Health National Key Economic Area (NKEA) and Clinical Research Centre (CRC) are now conducting research on sophisticated clinical trials and biological drugs. Some of the nationally assisted firm's drugs are waived from government tax and regulations. High profile treatment facilities have reduced the death rate significantly [9]. Malaysian government's spending on health related affairs have grown significantly very high. Almost ten percentage of annual budget is allocated to healthcare which increases the percentage of importance and efforts that needs to be allocated towards the pharmaceutical supply chain. Better technologies and methods are being adopted to build a strong business in the pharmaceutical scenario [10].

A Pharma retailer's agenda has direct impact on pharma-supplier's profitability. Economic collaborative decision making combined with social collaborative decision-making and can resolve problems related to this issue economically. Waiting time between echelons must be reduced [11]. Governance and integrity also plays a major role in meeting several pharmaceutical supply chain challenges [12]. Anti-counterfeit measures are taken to track medicines across entire supply chain. It shall give information regarding the past position of the goods, present position and the anticipated future location. The true pedigree of information is accessible by all the partners of supply chain [13]. Pharma-supply chain success can only be achieved by collaborative activities and small scale manufacturing companies need to adopt collaborative activities between all the phases of the supply chain that may bring lot of advantages at operational, strategic and political level [14]. Counterfeiting of drugs is the major problem faced by the drug producers that leads to great loss and sales revenue shut down. The brand image of the firm would be at stake if not properly checked. RFID technology can help prevent malicious activities and enhance better drug traceability [15]. Companies must practice better inventory control policies and avoid stock-outs [16]. It is now clearly evident that information and security plays a major role in stabilizing the supply chain and also avoid various risk factors.

Lean tools and techniques should be implemented in pharma industry and not just limit to production facility but also to improve supply chain practices. Just in Time production is very important especially when pharmaceutical industry is involved. Adoption of Kanban can provide strategic benefits and convert a push type into a pull type of production [17]. There is a need to explore pharmaceutical supply chain vulnerabilities and its capacity of resilience [1]. The highest percentage of cost in pharmaceutical production in spent in R&D. Globally outsourcing drugs has become a basic strategic weapon. It helps in developing flexible production, reduce costs, customer satisfaction and also enhancing profit margin. All the risks pertaining to supply chain

outsourcing must be closely checked and avoided [18]. Managerial decisions should not disturb the firm's supply chain. The role of regulatory constraints on product proliferation and pedigree should not affect different service levels towards consumers [19]. The supply chain network is built by an enormous inventory and material flow that tends to change in time. Lean tools shall help in effectively eradicate wastes and waiting time and improve the efficiency of the supply chain.

3. METHODOLOGY

The best method to attain information on all the recent and up to date inventions and implementations in the industrial sector is to study them closely. Complex issues can be explored deeply with respect to real life situations and healthcare tops that list [20]. Case studies help us to understand the current situation in the firm at a very sophisticated phase [21]. Methodology adopted in this research article is the qualitative case study approach which includes semi structured interviews combined physical observation of the process. Interviewees were the firm's supply chain managers, production managers, procurement managers, sales managers and IT managers inside the pharmaceutical firm. Information was collected mainly on the movement of inventory and information inside the firm. Procedures like procuring raw materials, outsourcing, inventory handling technology, demand forecasting techniques, lean principles implemented and various supply chain strategies applied inside the organization to run a smooth and efficient supply chain network were explored.

There are several methods to carry out a case study. Some of the techniques applied are data analysis, experiments, interviews and surveys. The objective and scope differ based on the respective research questions, literature study and individual scholar's perspective. A case study can be exploratory and descriptive sometimes and need not be contemporary all the time. A researcher must be always be ready to avoid traditional criticism [22], [23]. This study is also based on this idea.

This case study on the supply chain practices of a state of the art Malaysian pharmaceutical firm may be helpful to formulate a conceptual framework on PSC that can be adopted by almost all the Pharmaceutical firms in Malaysia to attain better supply chain efficiency. Semi structured interviews were implemented to cover almost all the area of pharmaceutical supply chain. Each interview was about 50 to 60 minutes with a short break. Snowballing of the insights derived from the interview was done to gain better understanding. Many useful insights were also derived from the previous studies done by researchers in PSC at various different locations, scenarios and stages.

4. SUPPLY CHAIN STRUCTURE IN REAL TIME

Various strategies and procedures were followed in this current top level pharmaceutical firm, where this case study was implemented. After each and every step there is an accumulation of finished goods in every level of pharmaceutical production process. Contamination of drugs are avoided by inspecting each and every process. The name, composition and expiration date along with box numbers are labelled after preliminary production. The primary information is placed directly on the medicinal carton boxes. High safety standards are followed during packaging. Primary packaging is done inside the production facility and placed over pallets. Each pallet has a specific quantity of boxes depending on the category of medicine or product family. Unit load principle is followed in some special cases. The manually operated automated fork lift vehicles are used to shift the finished and packed finished good pallets from the production facility to warehouse.

Around 20 to 30 suppliers have established contact with this pharmaceutical organization. The transportation cost is bared by the supplier or sometimes mutually shared in separate cases. Vendor managed inventory is followed for specific set of product inventory which exhibit high volatile demand fluctuations. Suppliers supply a variety of raw materials and primary packaging materials. The raw materials are stored in a separate location inside the warehouse which is very nearer to the production facility. Cold storage drugs are stored and secured at their respective cold storage environments. The raw materials reach the firm which are bar-coded and labelled by the supplier as per the requirement of the firm. The firm produces 6 to 7 types of product families among which ampules and injection vials take more time to synthesis but also provide more revenue or profit during sales at the same time. Product families like solid tabs, capsules, solutions are manufactured in very large quantity. According the ABC analysis of inventory the ampules and injection vials are estimated to be 20 percentage of the whole inventory but contribute more than 60 percentages to the sales.

The pallets containing raw materials are then transferred to the production facility by motorized forklifts. The time for synthesis and manufacturing of the medicines take various levels of duration according to the part families that are manufactured. After

the manufacturing process is over the primary packaging material supplied by the suppliers are taken in the production site to finish primary packaging processes. All the packaging materials are biodegradable and environment friendly to make sure sustainable green production is implemented throughout the supply chain. After Primary packaging process the finished goods are shifted to level two and three of the warehouse for inspection and quality check. The warehouse is run by a SAP powered special warehouse management system. From the warehouse some of the goods are shipped to the customers and some are transported to a secondary storage location by third party logistics service providers. The firm's supply chain structure is shown clearly in Fig. 1.

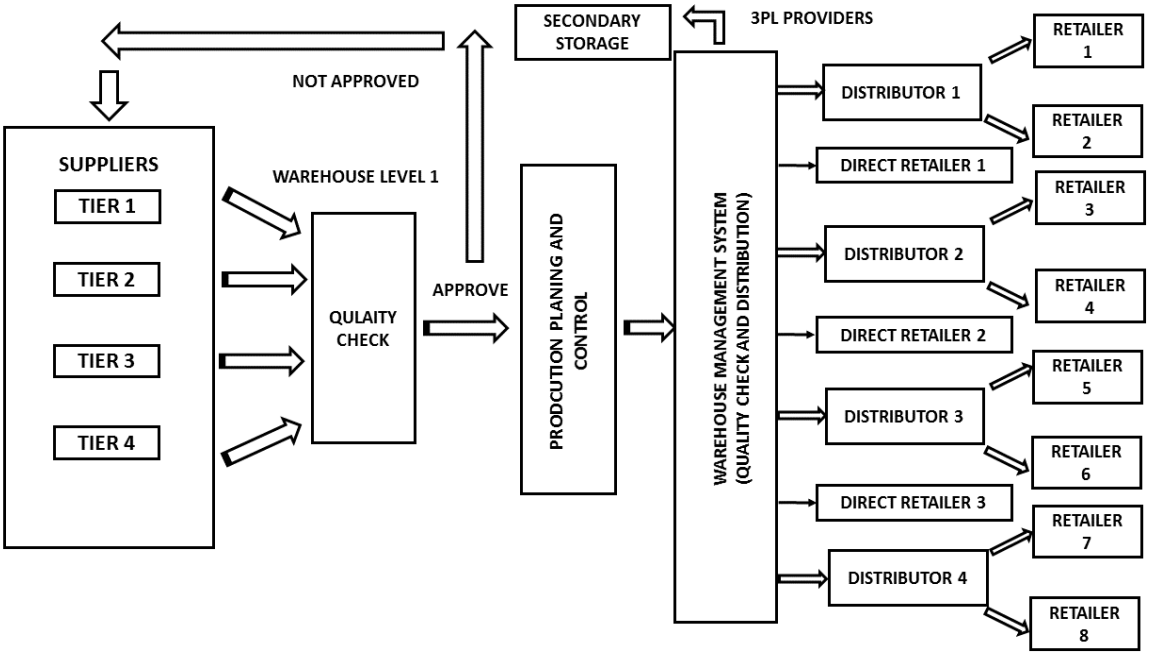

Figure 1: Pharmaceutical Supply Chain Network of the firm.

Warehouse Design

The firm's warehouse has three levels to carry out the warehouse operations. The ground level is divided into three section. The first section is used to store finished goods which are ready for cross docking and shipment to the customers. The second section accommodates a huge variety of raw materials received from multiple suppliers. The third section is a supermarket of finished goods safety stock which will be later shipped based on the demand. Level two consists of two sections in which one section is especially dedicated to store medicines that demand cold storage between 2-8 degree Celsius. The rest of the level two is used for secondary packaging and labelling. The Third level consists of highly hazardous drugs which can be accessed only by authorized professionals. The goods are transferred in pallets using manually operated fork lifts and heavy duty lift conveyers are used to shift inventory between different levels. The Warehouse professionals, finance, inventory division and accounts division are all situated in one of the corners of the third level. The production facility is situated near to the warehouse. Supply chain information and security is managed properly without any hindrance by adopting state of the art technologies. Supply chain resilience is always monitored and avoided for both major and minor risks in the near present and the future. The firm adopts effective information sharing by the help of Electronic Data Interchange (EDI) technology.

Information Flow

The organization deals with thousands of customers constituting both private sectors and government sectors. Sometimes drugs directly reach to individual pharmacies that place bulk orders to the sales and marketing division. The government sector includes government hospitals and clinical pharmacies and private sector includes private hospitals and private clinics. Export of drugs to countries like Saudi Arabia, Iran, Oman, Indonesia, Hong Kong, Macau and Brunei bring huge revenue to the firm. Six Sigma and Halal standards are implemented in manufacturing the medicines inside the production facility. The sales, marketing and IT departments inside the firm are the major players in forecasting the demand by looking into historical data and also by using special forecasting techniques. This valuable information is later passed on to production planning and control department. Effective information sharing is followed by all the players inside the supply chain using Electronic Data Interchange (EDI). Usually the safety stocks are stored between the range of three to six months and sometimes it exceeds this range when there is

a shortage in demand. The secondary storage of finished goods using 3PL logistic providers was the main concern for the supply chain department. Lack of enough space to store the finished goods in the warehouse was also another major problem. This was mainly due to the increase in the percentage of production due to very high demand. Efforts are undertaken to build a new warehouse in order to completely avoid secondary storage of finished goods. The most important decision making is done by the sales and marketing team on forecasting the correct demand for the future. Suppliers contact the firm's warehouse and retailers to make the stock ready to ship to the firm. The vendor managed inventory is followed in this case. The Electronic data interchange and effective information sharing is effectively carried out between procurement, sales and marketing, production and warehouse departments to make correct decisions regarding capacity planning.

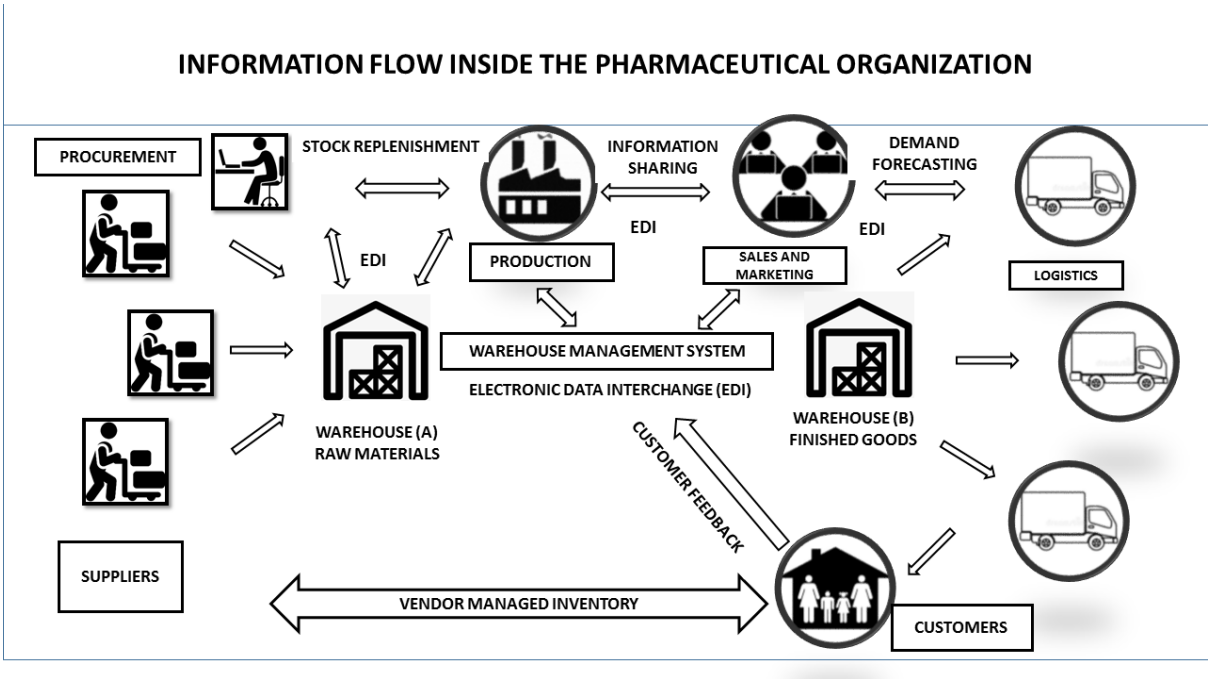

Figure 2: Information Flow Inside the Firm.

Customer Relationship Management

As mentioned earlier the marketing and sales department forecasts the demand and passes on the information to the procurement division. Healthy information sharing between the two departments were seen. The customer orders are received and the production unit is intimated about this aspect every single day. The production department processes the orders and shifts to the warehouse after primary packaging of the drugs using manually operated motorized fork lift vehicles. After the secondary packaging and quality check at the warehouse the orders are shipped to the respective customers based on the demand priority. Some of the medicines which are not being sold by the customers to their users due to sudden demand variations or other unavoidable reasons are sent back to the firm itself. The firm pays back the cash to the customers and then tries to sell it to other customers at a subsidized rate and makes sure all the necessary quality standards are still completely met. Based on the interview with the supply chain manager and sales manager it has been found out that this kind of customer relationship management strategy cannot be seen in all type of manufacturing sectors since most of the sectors do not replace sold goods or accept returns. This builds healthy relationship between the firm and the customer. More and more customers tend to buy products from them since they follow an efficient customer friendly management strategy. In this case, if a customer is not satisfied with the quality of the drugs a direct return of goods can be initiated towards the firm. The firm will also get back the medicines and drugs if the customer was not able to sell it to their users within a specific period of time. This return policy adopted by the firm is very customer friendly and tend to increase the loyalty among many customers. Since the drugs and medicines have expiry dates the sooner the decisions are made the greater is the benefits acquired. The major customers are the hospitals and clinics. Periodic information related to the total number of sales at the customers end are acquired by the firm to make precise decisions which can be seen clearly in Fig. 3.

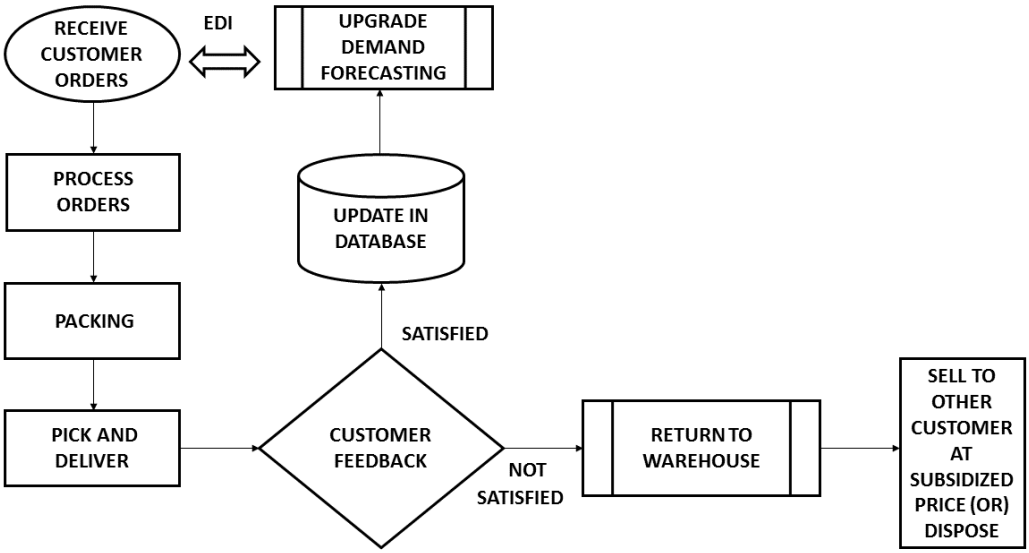

Figure 3: Customer Relationship Management.

Import and Export Strategies Towards Overseas Customers

Cost, Insurance and Freight (CIF) and Free on Board (FOB) are the two main import and export strategies used by the firm especially when it deals with international customers. This is applied to both goods acquired from the suppliers and goods shipped to customers. Cost, Insurance and Freight (CIF) is the strategy adopted by the firm to export the medicines and drugs to international countries from Malaysia. This denotes that the cost of insurance and final quality check and maintenance are incurred by the customer itself. The organization just needs to take care of the logistics services. One more strategy called as Free on Board (FOB) is the strategy used during the export process. The firm handles all the logistics and transport cost till it reaches the port of destination. It is the responsibility of the buyer to handle all the supply chain risks till it reaches there warehouse. There are also cases were already manufactured goods are purchased at a subsidized rate from another pharmaceutical organization and shipped to different locations after specialized secondary packaging.

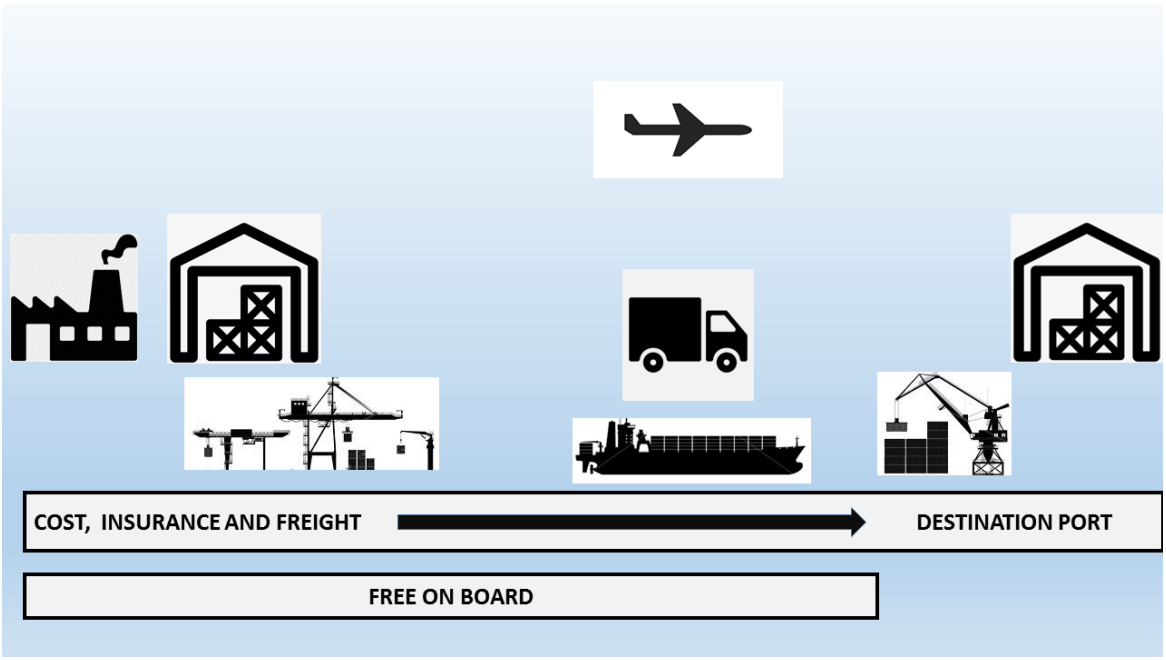

Figure 4: Shipping Strategies.

In the Free On Board strategy the seller takes up all the responsibility of exporting the medicines to the customer destination. This term is used during transportation through water medium. The charges incurred in the dispatch terminal and other miscellaneous costs associated to shift the drugs on board are fulfilled by the firm. In Cost Insurance and Freight Strategy the organization takes up the responsibility to pay all the freight costs associated till the item reaches the destination port. The in-house information sharing strategies, supplier selection strategies, production scheduling and demand forecasting, customer relationship principles and import and export strategies followed in the pharmaceutical firm are designed to a higher level of flexibility. Customer satisfaction and feedback is the main driving force in decision making regarding procurement and manufacturing of the drugs.

Halal Pharmaceutical Production

Malaysia is considered as one of the major Halal hub where all the Halal standards are incorporated inside the value chain of food, medicine and other products. The firm is already a leading exporter and consumer in the halal industry. The firm adheres to the requirements stipulated by the Halal standards of Islamic Sharia Law to satisfy both domestic as well as global Muslim Pharmaceutical market. The infrastructure and resources to develop Halal ingredients are effectively designed and built. A better care is taken to avoid sudden shortage of Halal ingredients. Efforts are taken to develop mutually recognized and harmonized global Halal standards and also to improve coordination between government agencies and firm's management. The procurement division confirms that there are no contamination of Non-Halal items that are being shipped by the suppliers. The production facility makes sure that there are no counterfeiting and adulteration of medicines during any of the production process. Warehouse officials store the goods in Halal storage facilities. All the Halal standards and practices for pharmaceutical production are adopted to meet all the Halal requirements to manage customer expectations effectively.

5. CONCEPTUAL FRAMEWORK FOR THE MALAYSIAN BASED PHARMACEUTICAL INDUSTRY

There are certain requirements to be met while manufacturing medicines and drugs especially in Malaysia. All the phases of production needs to be approached in a Halal way unlike other normal countries. Import and Export strategies should satisfy supplier and customer constraints. There is a need to develop unconventional demand forecasting techniques. Electronic Data Interchange (EDI) between departments should shift to cloud computing atmosphere. Logistics and shipping strategies should be designed to strengthen customer ties. A conceptual framework is proposed based on the results derived from the interviews in the firm for overall pharmaceutical production supply chain requirements according to Malaysian context which is depicted in Fig. 5. This framework was validated by the supply chain department.

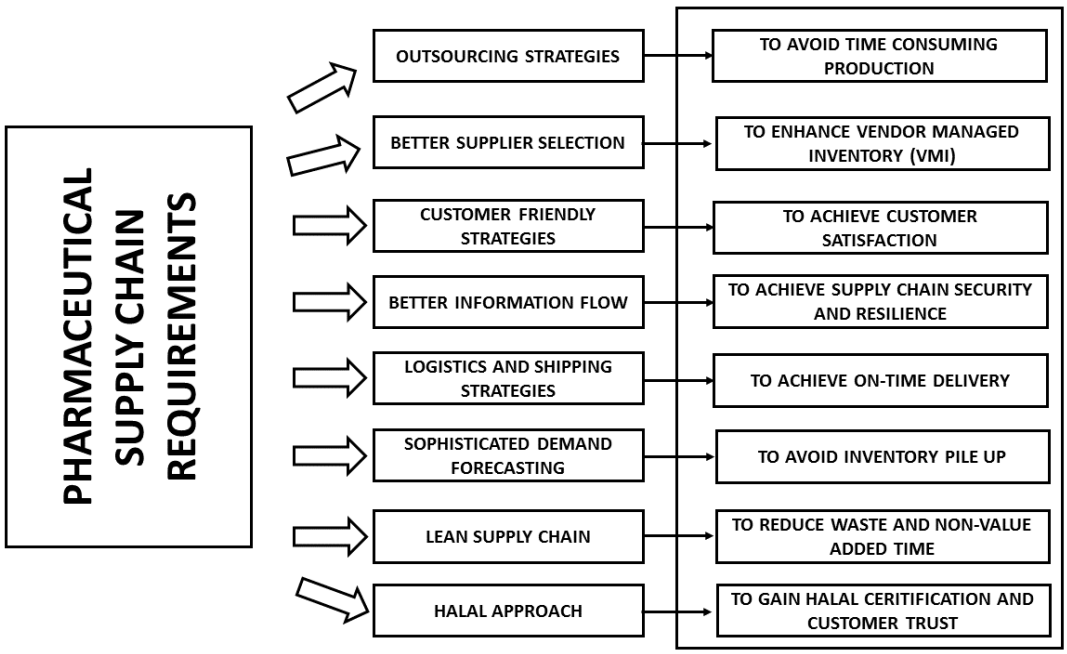

Figure 5: Conceptual Framework On Pharmaceutical Requirements.

6. DISCUSSION AND CONCLUSION

Significantly a large amount of revenue in the healthcare is generated by Pharmaceutical production [24]. Healthcare system is affected drastically by shortage of drugs compromising the patient's safety largely. PSC should be designed in such a way to improve the patient service level [25]. Supply chain intermediaries play a major role in delivering medicines to end customer [19], [26]. Efforts are taken to integrate production and distribution with other health services [27]. Disruption and Risk assessment need more limelight to asses any PSC. Improper control of these attributes may reduce the efficiency of healthcare system [28]. Modelling and simulation can ease the process of supply chain design by visualizing the supply chain disruption risk in Pharmaceutical Supply chain [29]. The production-centric nature should be reduced and more importance should be given to analyse the healthcare outcomes and customer satisfaction [30].

The framework was formulated based on the interview conducted at the supply chain and operations division of the firm. The first important criteria that helps to build a better PSC is the outsourcing strategies adopted by the firm. A huge amount of unnecessary time is being avoided by effectively outsourcing various products that need for the production process. This is further coupled with better supplier selection strategies to enable Vendor Managed Inventory (VMI). Here the Supplier himself will take up some of the responsibilities to help the firm achieve better customer satisfaction and also fulfil volatile demands. Better information flow using Electronic Data Interchange (EDI) promotes healthy logistics and reduces supply chain risks. Halal ingredients are outsourced and also produced at the firm to satisfy Halal market demands. There are still a lot of scope towards the implementation of lean tools and techniques inside the Pharmaceutical warehouse and other logistic divisions of the chain where there are great volumes of material movement and inventory pile-up.

The current Malaysian Drug regulation norms and government bodies sometimes pose a threat by increasing the time taken for procurement, manufacturing and on time delivery of goods due to various regulations and constraints. In that case, internal inventory movements can be quickened up by implementing lean and agile procedures. Demand fluctuation and production control and planning do not favour the firm supply chain all the time. This can be eradicated by studying the behavioural characteristics of each process inside the firm with respect to time with the help of best suitable mapping and simulation techniques. The greatest problem faced by any pharmaceutical firm is the problem of demand fluctuation. International supply chain network must be designed strategically every day to grow globally. Sales and marketing division should set the pricing more flexible and competitive and allow product variety, volume updated according to the demands. Historic data should be tapped precisely and better forecasting techniques must be developed every year. More efforts should also be done to regulate the work in process to help meet the demand fluctuation. This will help the top management to execute better management trade-offs. Correct work in process inventory level should be monitored effectively to meet any sort of demand variation. Enterprise resource planning should be properly carried out with the help of state of the art electronic data interchange system interface inside the firm. Pharmaceutical organizations should go a step ahead by sensing and analysing the weather forecasts and disease outbreaks to predict a better future demand forecast plan and maintain required medicinal safety stocks ready inside the warehouse supermarket. Furthermore efforts must be taken to develop techniques to solve medicinal tracking and traceability issues and swift product delivery. Better end-to-end supply chain visibility must be established between all partners of the supply chain and share information between them. Due to a complex material movement in the PSC especially in the warehouse there is a need to apply lean tools and graphically simulate the time lags in each and every warehouse activity to a maximum possible extent to increase the supply efficiency by reducing the cycle time of each and every process that limit to only production and manufacturing.

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