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REVERSE LOGISTIC MANAGEMENT IN PHARMACEUTICAL INDUSTRY – A SUPPLY CHAIN ANALYSIS

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ABSTRACT

The pharmaceutical industry is a sensitive sector where mishandling of expired medicine not only compromises the profitability of the sector but also plays with the health of those who purchase these expired medicine expecting to be treated of their illness. Reverse Logistics refers to the backward movement of unused drugs from consumers to manufacturers due to various reasons. This study mainly concentrates on the backward movement of drugs from retailers to manufacturer. Counterfeit or expired medicines, improper cleaning of channel of expired medicine has implications far beyond the profitability of the sector.Poor implementation of regulations, the temptation of making high profits by producing substandard and/or counterfeit medicines and presence of unscrupulous elements in distribution networks has put the onus on the pharmaceutical industry to safeguard the integrity of their products, and manage the forward and reverse supply chains for effectiveness, efficiency and integrity of their products.Better management and control of returned medicinesare essential to protect company image, as poor control of returned medicines can result in infiltration of expired medicine in new packaging into the market affecting the reputation and profitability of otherwise ethical manufacturers. Research studies were revealed that there is lack of conformity, control and effectiveness in the whole process of reverse logistics. Counterfeiting is a problem and the pharmaceutical companies should have a fairly efficient network in place to counter this menace.

INTRODUCTION

The pharmaceutical industry has faced significant changes in recent years. New regulations have been imposed by governments for tackling the recovery of unwanted/expired medications at different customer zones. Hospitals and pharmacies, as the main consumers of medications, are faced with uncertain andfluctuatingdemand.[1] The pharmaceutical industry is a sensitive sector where mishandling of expensive medicine not only compromises the profitability of the sector but also plays with the health of those who purchase these expensive medicine expecting to be treated of their illness. Counterfeit or expired medicines, improper cleaning of channel of expired medicine has implications far beyond the profitability of the sector. It is a matter of life and death for the consumers.[2] The regulatory bodies have devised all the regulations necessary to protect the industry and the consumers. Poor implementation of

these regulations by the stakeholders, the temptation of making high profits by producing substandard and/or counterfeit medicines and presence of unscrupulous elements in distribution networks has put the onus on the pharmaceutical industry to safeguard the integrity of their products, and manage the forward and reverse chains for effectiveness, efficiency and integrity of their products.[3] The Pharmaceutical supply chain will consists of one or more of the following: Supplier, Pharmaceutical Manufacturer, Distributor, Pharmacy, Consumer/Patient

In the past, the supply chain management concepts were not adopted by the pharmaceutical industry. However, now several factors are pressing each component of the pharmaceutical supply chain to change their traditional manners of conduction business. According to Healthcare & Life Sciences supply Chain Report, controlling cost, globalizing supply chain and improving visibility or tracking are the biggest supply chain priorities, as well as, visibility or tracking issues are the biggest obstacles to globalizing pharmaceutical supply chain.[7]
There are many examples now in the news about the circulation of counterfeit drugs in black market channels and it is the biggest recurring problem in the developing world like Africa and parts of Asia and Latin America where the proportion of counterfeit medicines has been estimated to be as high as 30%.[9]

DISCUSSION: According to a recent World Health Organization report one in ten medicines, mostly in middle- and low-income countries, is substandard**.** Substandard, counterfeit or falsified medicines may be expired, contaminated, have substituted or inappropriate quantities of active ingredients, or bear misleading packaging and labels. The personal and public health tolls are huge, as is the economic burden — up to $200 billion annually. So it is very essential to plug in the loopholes in the supply chain and bring transparency in the distribution of pharmaceutical products. The WHO report suggests that India is a major player in the counterfeit pharmaceutical manufacturing as the country is the largest producer of generic drugs. The Pharma companies have to manage incredibly complex supply chains and manage the operational challenges of working. Also need to interact with huge numbers of suppliers providing ingredients and components to drug production. And now they need to meet track and trace directives and comply with new serialization regulations that require inventory to be auditable as it moves through the supply chain. The pharmaceutical industry has grown over the years, and this has made challenges in shipping and logistics. Finding the best logistics companies have been a major challenge in this industry.[10] A well equipped supply chain management system will provide:

1. Accurate information across the entire chain at any time and at any location
2. Instant access to updates and alerts if cases are detected
3. Supply chain visibility
4. Traceability back to source of all materials
5. Collaboration between stakeholders.

Traditional ERP systems have the disadvantage of lacking visibility. There is a need for collaborative system, equipped with reliable information throughout the supply chain.[11]

The Importance of Supply chain Visibility: The first step toward achieving the directives of track and trace and serialization is to improve visibility throughout the supply chain. A company can see all the activity taking place among its suppliers, shippers, vendors, and partners .A cloud-based supply chain management platform offers visibility to all companies, regardless of size. For a large, multinational pharma business, access to data from all operational regions allows for greater awareness of growth areas, understanding of where hold-ups might exist in the supply chain, and insight into how these might be

navigated in order to avoid impact on distribution, crucially, this can help track and tracing via serialization.[12]

Recent Trends in Pharmaceutical Reverse Logistics Management: Improving the reverse supply chain (RSC) is one way to gain and maintain strategic advantages in thisindustry.[13]Medications recall process is complex in the sense that information about available amounts of left overs, the willingness of customers to return products, and the cost associated with the collection and disposal processes are not always known by the producer. This is due to theresult of the lack of trust and coordination between producers, customers, and 3PL companies.[14] Expired medicine removal is a legal requirement and operational and strategic policies ensure that medicines are removed before expiry from customers such as hospital, pharmacies and other supply chain members.[15] Operational level policies are also geared to inspection at the initial point of return where inspection of damage, confirmation of nearing expiry dates etc is carried out. The problem of counterfeit medicine however requires other controls as either this type of medicines enter the market through non-channel members. The dishonest retailers obviously would not try to return the counterfeit to the pharmaceutical company anyway.[16] The returned products are then handled for disposal. Some companies follow a policy of recovering medicines a month or two before expiry and donate the medicine to charitable hospitals for utilization before expiry and thus serve the community, others claim to destroy the medicines.[17] Legally the medicines cannot be used after their expiry. Moreover, while a typical medicine has a shelf life of two years, the customers (pharmacies) are reluctant to keep the medicine which has a couple of months left in the expiry and cleaning of channel becomes necessary for customer service reasons.[18] The larger pharmaceutical companies have set-up a comprehensive network of medical representatives, sales persons and a system of own distribution or reliable third parties to assure an efficient distribution system.[19] The advent of new technology such as Radio Frequency Identification (RFID) system promises highly coordinated and controlled systems of inventory management in all areas of distribution and retailing and is being recommended for pharmaceutical distribution and return management. Application of information technology in pharmaceutical distribution and return management is an area that requires great investigation.[20] Delayed responses, long processing times for return and poor control of returned medicines create potential problems for the pharmaceutical company. Poor control of returned medicine exposes pilferage and infiltration of the expired medicine into the market with counterfeit packaging.[21] Information about the return, managing returns to improve the efficiency of the reverse logistics process, extracting value where possible and protecting environment from mindless disposal of expired, damaged and end of life products has acquired great importance in the environmentally conscious and highly competitive business environment of today. The majority of companies have their own distribution network and the reverse logistics uses this network. [22] The main focus of reverse logistics is on customer satisfaction and regulatory compliance. The cost associated with reverse logistics cost is considered a marketing and distribution expense and by many claims is considered to be a very small proportion of total costs (1-5%). Managing reverse logistics is therefore of little importance and the medicines retrieved from the market are allowed to accumulate at local collection points for weeks and months until they are disposed of. The medicines are often removed one to two months before expiry due to consumers' reluctance to purchase these nearing expiry medicines. Many pharmaceutical companies are making investments in security measures, data systems and business processes to improve efficiencies in managing recalls. These include, barcoding or RFID tracking on returns packages and increased use of online resources to manage recall data. In an effort to reduce non-value-

added activities, redundant handling and associated costs in reverse logistics, many major 3PL service providers have developed so-called "one-step" or "one-touch" programs, by which they function as the single intermediary between manufacturer and downstream trading partners. In the traditional scenario, upstream manufacturer and the downstream trading partners would each engage their own 3PL partners to handle routine returns. Using the newer approach, a single intermediary handles the entire return from initiation to final product destruction, acting as a partner to the drug maker, pharmacies or other retail partners. Proponents say one-step programs offer many benefits, a number of which are linked to fewer touch points, sustainability, cost improvements and collaboration. For instance, by reducing the number of times product is picked up and handled, it helps decrease redundancies in processing and minimizes opportunities for theft or diversion. Choosing a 'one-touch' provider gives the data quickly, allowing to make confident business decisions rapidly. It also minimizes the processing cost for the manufacturer by "touching" the product only once. One-step programs are implemented by some 3PLs in an effort to curb redundant handling and the costs that come along with such a platform. Over the next five to 10 years, it is anticipated that most, if not all, drugs will be serialized to the individual bottle or package. By reporting back the serial number, a manufacturer has the ability to review the actual purchase order where the drug was originally procured. Implementation of 2DDatamatrix serialization and EPCIS product tracking and history, will provide full visibility to chain of custody. Some reverse logistic providers offer technology tools that provide online access to returns status down to NDC/UPC level, authorization tracking, issuance of RAs online, easy discrepancy reconciliation, shipping information and proof of destructions. Reverse logistics planning and execution is also improving through wider adoption of standard electronic communications. Technology advances for product tracking, data management and improved communications between industry trading partners is helping drive reverse logistics to the next level. A case in point is the use of electronic data interchange (EDI) standards, EDI 180 and EDI 812, which has reportedly expanded from forward to reverse logistics in recent years. EDI 180 provides a standardized, multidirectional electronic format for the transaction set used when trading partners issue a request, or notification of, a return, and pharma companies need to respond and issue the return authorization. EDI 812 is a bi-directional transaction set that aims to automate and standardize financial elements of a return, requesting and authorizing debits and credits between trading partners. HDMA and others have been supportive of efforts to develop standard practices for serializing pharma packages with barcodes or other unique identifiers; many studies of the subject point to substantial savings in managing returns, recalls, and credit reconciliation when individual products can be tracked up and down the supply chain. Utilization of electronic methods allows for the reduction/elimination of human input error and also speeds up the reconciliation and crediting process.The ability to fully automate and standardize electronic communications related to returns can lead to improvements in time efficiency, accuracy, and flexibility. Communicating with standardized electronic communications, such as EDI 180 and 812, is expected to help streamline the reverse logistics process, and lower the cycle time from notification and authorization to shipment and credit reconciliation of a return. The extent of information technology use in reverse logistics is limited to computerized tracking and recording of retrieved products. The emerging technologies such as RFID will add a whole new dimension to managing distribution and return of pharmaceuticals. The implementation of RFID is still in early stages in countries where the hardware required to implement the technology is already in place.[23]

CONCLUSION

Better management and control of returned Pharmaceutical products is essential to protect company image as poor control of returned medicine can result in infiltration of expired medicine in new packaging into the market affecting the reputation and profitability of otherwise ethical manufacturers. Research studies were revealed that there is lack of conformity, control and effectiveness in the whole process of reverse logistics. Counterfeiting is a problem and the pharmaceutical companies have a fairly efficient network in place to counter this menace. The increasing availability of information technology is bound to bring developments such as 2D bar codes and RFID technology to the pharmaceutical sector. This will help in better management of pharmaceutical medicines and also help in managing returns. Governments' regulation on the pharmaceutical industry and customers attention to sustainable practices, all play a crucial role in changing the Reverse Supply Chain practices in thisindustry. Hence, pharmaceutical companies have to be enthusiastic in addressingthegrowingneedsforimprovingtheirReverse Supply Chainperformance. Since the profitability of the return medication is almost negligible, there cover processs is challenging for this industry.

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