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Reverse Logistics in Pharmaceutical Industry

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Abstract: ***This study looks into detailed aspects of reverse logistics on the issues that pharmaceutical organizations face. Reverse logistics is now following a trend where it is seen as a competitive advantage and a source of potential revenue. The perception is changing from the tradition of returns being a barrier to profits and a cost burden. Also the sustainability issue being addressed by reverse logistics is beneficiary to pharmaceutical organizations with end-of life products. The discussion contributed to the market perspective and to back up the misconception of returns being a cost issue, when it maintains market share by retaining quality. The perception of those industry practices on the environment and sustainability practiced by organizations has shown less enthusiasm than once thought.***

Keywords- *Supply chain management, reverse logistic, pharmaceutical logistics, pharmaceutical reverse logistic*

1. Introduction

In common scenario a product or service is developed to be manufactured or created and go through the supply chain (e.g. manufacturer-wholesaler-retailer) to be sold to a consumer. Supply chain is integrating more activities than those concerned with supply chain alone like including service and product recovery. Here we will focus on especially reverse logistics, i.e. the handling of products back to manufacturer's or producer's end. The objective is to minimize the handling cost while maximizing the value from the goods, or proper disposal. Essentially, reverse logistics is the opposite of logistics management. Goods or materials move in the opposite direction of the supply chain, that is, from the customer back to the supplier. Products are returned to the manufacturer or retailer for any number of reasons. Some of the more common reasons are warranty failures, damaged products, product recalls, incorrect product orders/shipment, exchange of impaired products for functional ones, reusable packaging materials, product upgrading and so on. Whatever the reason, returned goods have to be processed in the best manner possible. Reverse Logistics has become a fairly serious issue in recent times primarily because retailers have been forced, due to increased competition, many forces drive reverse logistics, like, competition and marketing motives, direct economic motives and concerns with the environment. Whatever the reason, returned goods have to be processed in the best manner possible.

Reverse logistics in the pharmaceutical industry is extreme important, not only from the economic point of view, but also from the environment as well as regulatory point of view. The pharmaceutical returns industry is worth US$2.5 billion. There is also an estimated reverse flow of goods worth US$5 billion [10]. Some important considerations for the industry when it comes to reverse logistics are the security of the returned goods, keeping the cost low with the help of automation, traceability of the goods returned from the customer to the final stage of disposition.

2. Literature Review

During the last decade, reverse logistics has obtained focus in research and practice both. In early nineties, the Council of Logistics Management published two studies on reverse logistics. In 1992 Stock [1] first recognize the field of reverse logistics as relevant for business and society generally. Rogers and Tibben-Lembke [2] in 1999 presented a broad collection of reverse logistics business practices, but they had given special attention to the US experience. They found that four in ten logistics managers consider reverse logistics relatively unimportant compared to other company issues. During the last years, many articles dedicated to the optimization and management of reverse logistics appeared, like Guide et al. (2000) [3] on the characteristics of reverse logistics for remanufacturing systems.

In terms of resource recovery, the most often described option was recycling and re-use/redistribution (De Koster et al., 2001) [4]. Products, components, materials, equipment and even complete technical systems may go backwards in the supply chain (for convenience we will use the term products to refer to all of them).

For some time we have been familiar with products being reworked during manufacturing due to unsatisfactory quality, or with good materials or components being returned from the production floor because they were leftover after production (manufacturing returns).

Defective products may be detected after they have entered the supply chain resulting in a pull back of products through the chain (product recalls).

3. Methodology

The methods to be used will be conducting a literature review throughout all the sections, researching websites, books and academic journals.

4. Discussion on Different Reverse Logistics

4.1 Pharmaceutical Industry Scenario

Pharmaceutical producers combine ingredients precisely, under specific conditions, while negotiating a maze of stringent regulations and quality controls. Companies that manufacture, move or store pharmaceutical products must meet similar demands. Many drugs are highly sensitive to temperature; some are extremely valuable; and all are subject to a complex array of government and international regulations. In the pharmaceutical supply chain, every detail counts. Pharmaceutical logistics is such a specialized

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discipline that drug manufacturers have long been reluctant.

But some recent industry trends are making drug manufacturers rethink their strategies. One trend is that some popular drugs are coming off patent. Without popular products to boost their bottom lines, manufacturers try to make up the difference by cutting costs. One way they do this is through cutting cost in logistics operations. In country like India, Bangladesh many drug makers still manage some or all of their supply chains internally. Whichever strategy a company chooses, its supply chain team wrestles with some highly specific challenges.

Pharmaceuticals are not like other common products. When those products are recalled or returned, they can be repaired, resold, or donated. Pharmaceuticals, in contrast, are destroyed. The need for destruction relates to the inability or difficult constraint of regulated facilities of manufacturers to ensure pharmaceuticals were handled properly after leaving their control and to ensure a secure chain of custody.

To put this into perspective, consider temperature. Storing a television or most other products at ambient temperature isn't harmful. But, for nearly half of the new drugs entering the market, maintaining a specific temperature range is imperative. Temperature excursions can reduce potency, reduce shelf life, or alter a drug so it becomes harmful. Live attenuated cholera vaccine is a good example. Stored between 2-8°C, its shelf life is one year. But at room temperature, its shelf life is seven days. "The regulatory aspect of pharmaceuticals is among the most heightened of any product category," explains Jeff Pepperworth, President of Inmar's Supply Chain and Healthcare Networks. Within the pharmaceutical industry, track and trace requirements proving chain of custody are stringent and are only growing more robust. But, from manufacturers' perspectives, chain of custody verification breaks down once the drug reaches its destination. Within the pharmaceutical industry, track and trace requirements proving chain of custody are stringent and are only growing more robust. But, from manufacturers' perspectives, chain of custody verification breaks down once the drug reaches its destination. Pharmaceutical returns also require more vigorous security than most other goods because of the high value of the product. [5]

4.2 Streamlined Returns

Traditionally, when returns arrive at a distributor, the distributor applies the manufacturer's retailer policies and pricing to ensure the pharmacy, hospital, or wholesaler receives credit for the return. Then, the distributor sends the returns to a third party returns processor for destruction. Returns arrive at distributor or manufacturer are validated, policy and pricing policies are applied, accounts are reconciled, reports are filed online for the manufacturer and the shipper, and the pharmaceuticals are destroyed. Documented proof of destruction must have to be kept for regulatory purpose. Here process has to be made to ensure the elimination of errors, duplicate processing and diverted shipment.

Not all returns are credited. But, when manufacturers do credit returns, reverse logistics have the additional challenge of ensuring that returns are authorized, quantities are validated and returns data for lot or batch number and shipper are matched against the original documentation. Returns for credit, primarily, are made by retail pharmacies or wholesalers and typically involve drugs that are three to six months from expiration, explains Larry Hruska, president at GENCO Pharmaceutical Services.

"Consolidated returns tend to arrive from a pharmacy or delivery route in a box with a few hundred bottles of all shapes and sizes," he explains.

4.3 Recalls

Product recalls are similar to returns but require additional identification and have a greater sense of urgency. Recalls and returns differ mainly because of the notification aspects; there should be protocols for notification, including business reply cards. Information regarding what has been returned need to be stored and documented for FDA and other regulated Pharma market compliance purposes. There's also more regulatory oversight. For example, Pharmaceuticals may need to be held for inspection by regulators. Pharmaceutical manufacturers also may need to examine samples. As Richard Smith, managing director of life science specialty services at FedEx Express explains, "Pharmaceutical companies want to tie in returns to a specific batch, so more identification is needed for recalls than for returns. This often is tied to legal actions. It may be only a single batch that contains defects." For example, the October recall of Astellas Pharma's Advagraf 0.5-mg time-release capsules by the European Medicines Agency involved only 12 batches. Ensuring that the correct batch is recalled affects patients but also has significant financial ramifications. Therefore, it's providers are becoming more common as pharmaceutical companies get out of the bricks and mortar business of distribution," Smith says.

"Particularly as pharmaceutical manufacturers move into the developing world—mainly Latin America and Asia—they are establishing in-country collection strategies and are consolidating shipments," Smith says. Because these compounds are returned for destruction, the requirements for temperature control and express delivery that are present on their outbound transit are non-existent for their return. Consequently, some customers using cheaper ways of carriage, substituting ocean freight for air freight in some instances. Consolidating pharmaceuticals returns has inherent risks, however. Every handoff and each delay in the supply chain increases the chance that criminals will divert the drugs into the black market where expired products will be diluted and labeled as saleable. The risk depends upon the location of the facility and the drug.

Some 3PL logistics [7] company handles recall solutions for medical devices, applying best practices learned in the information technology sector. They had seen several recalls that often were inefficient and poorly organized, so we built a solution for our customers to handle recalls in a more structured way. That solution consists of Recall Alliance and Recall Action, With Recall Alliance; work with customers to build knowledge around their products and the most efficient recall procedures. The most basic level focuses on industry best practices, systems, and management. The premium level also includes readiness, audits, and certifications. Recall Alliance is in the initial stages of launch. It debuted in Europe and launches in Asia and America in 2012. Recall Action is the execution arm, ensuring access to the right logistics.

There's no magic pill for dealing with those issues, but the industry has developed some effective solutions. Here's a look at the state of pharmaceutical reverse logistics today.

4.4 One Batch at a Time

In a typical batch process associated with pharmaceutical reverse distribution, the reverse distributor consolidates and ships returns from pharmacies that have nothing in common other than the wholesaler they purchase products through. These products are then sent back to the pharmaceutical manufacturers in one consolidated shipment that might contain several hundred products from several hundred different pharmacies. It's much more efficient for the wholesalers, manufacturers and reverse distributors to handle the returns this way. The problem is that most reverse distributors take the easy way out when it comes to issuing credits as part of a batch process.

4.5 Managing Regulations

The interesting part of regulation is you have to maintain it all through the value chain. So when products are in their backward journey even it is for destruction it has to be regulated. In highly regulated market in addition to requiring drug makers to ship their products in country and across borders and over long distances, the pharmaceutical industry's nature stymies manufacturers with a complicated array of regulations governing transporting drugs in different countries. "Pharmaceutical industry service providers need to be aware of about 70 different sets of regulations," says Larry Sweeney, chief operating officer at DDN, a Menomonee Falls, Wis., firm that provides supply chain services to companies that make pharmaceuticals, biologicals, and medical devices. [5]. Experts of logistics and distribution understands that challenge from the manufacturer's side, as well. In recent years, members of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) have been trying to bring some unity to the rules.

The industry is also seeking global standards for tracking drug pedigrees. Different countries and U.S. states have established their own requirements for serializing drugs. This typically involves attaching a two-dimensional bar code or other device that uniquely identifies a unit of the product so it can be tracked throughout the supply chain. In some regions, serialization is designed mainly to monitor the chain of custody and keep counterfeit drugs off the market. Outside the United States, governments look to this to prevent reimbursement fraud.
Although the industry has experimented with radio frequency identification (RFID) tags for serialization, that technology has raised concerns, including fear that prolonged exposure to RF signals might harm certain biological products. "Issues also have arisen with some products—such as liquids or packages with metal caps—reflecting energy and blocking the RF tag's reading," Sweeney says.

4.6 Deal with Inventory Security

Keeping inauthentic product out of the supply chain is half the security challenge facing drug manufacturers. Shippers also deal with the opposite issue—keeping genuine product where it belongs. Given the high value of many drugs, loss prevention is a vital concern. There are many examples that might be cited as one pharmaceutical company that lost a noticeable worth of product when thieves arrived at a warehouse after business hours, cut a hole in the roof, and used a gantry to hoist out the product. And those products immediately go to other markets.
To stay one step ahead of the criminals, Sentry continuously adjusts its security strategies. For example, some logistics providers monitor with sensors 24/7 throughout the whole facility. Some 3PL service providers around the globe applies any level of security that an individual customer requests. Among the tactics and technologies it uses are GPS tracking, biometric scanning, video analytics, motion detection, infrared detection, and roving security patrols.

4.7 Controlling the Temperatures

Keeping pharmaceuticals safe means not only keeping them out of the hands of thieves, but also maintaining them at the proper temperature. For many pharmaceuticals, a two-degree Celsius temperature variation is all that's needed to spoil the entire lot. By 2014, seven out of 10 of the leading pharmaceutical products will require temperature-controlled transportation, estimate some industry observers.

Maintaining just the right temperature is a challenge for anyone who ships or stores pharmaceuticals, but it's an even larger obstacle for companies shipping from the warmer climates where many drugs are made today. "When you're moving product out of locations such as Hyderabad and Bangalore or in Bangladesh, a long X-ray screening process at the airport can create complications," says Richard Smith, managing director of FedEx life sciences, specialty services and global trade services in Memphis. For large freight shipments, damages can run into the millions. To prevent these losses, shippers and their service providers have developed some sophisticated techniques for maintaining the cold chain.

Now many global logistics has started with storage environments tailored to the needs of different products. Sentry, for example, recently added a room cooled to -45C to its Minneapolis facility. That building also offers rooms maintained at ambient (15C to 25C), refrigerated (2C to 8C), frozen (-15C to -25C), and ultra-low (-70C to -90C) temperatures. To maintain consistent shipment temperature in transit, companies use equipment such as refrigerated trailers, insulated packaging, thermal blankets, and dry ice.

When a flight delay, Food and Drug Administration (FDA) inspection, or other contingency holds up a pharmaceutical shipment, FedEx Express might add more dry ice to a package, refreeze gel packs, or put items into temperature-controlled facilities. Some companies have introduced active packaging, which comes with a power source to maintain the temperature inside. Active packaging allows shippers to regulate different drugs at different temperatures inside the same trailer or container.

Many companies also use sensor-based systems to document a product's temperature throughout its journey, and sometimes send an alert if the temperature veers too far. Exel, for example, uses a device called TempTale to monitor temperatures inside its customers' packaging. The device maintains a temperature history and validates that the shipment was in compliance from pickup to delivery. Some sensor-based products monitor other environmental exposures as well. Technologies now are able to determine whether a product was exposed to light—which would be bad news for a biologic product—or whether the product was

subject to high vibration. For recalling the product or to return goods for short date or any other reason has to maintain every steps of cool chain validation. As the cool chain is determined during distribution of the products to end customers it must have to be similar for collection for destroying.

4.8 A Journey for five Days with 106 pallets [6]

Temperature control was a major focus when Cadence Pharmaceuticals Inc., San Diego, worked with FedEx to move an unusually large load of its product OFIRMEV from Italy to the United States early in 2012. The drug, an injectable form of acetaminophen, must be maintained at controlled room temperature, between 20C and 25C, plus or minus 10C, says Dave Dezan, Cadence's director of supply chain operations.

Cadence usually transports OFIRMEV in temperature-controlled intermodal containers, which allow the product to stay in the same environment while moving from truck to ocean vessel and back to truck. But in this case, the company needed to move 106 pallets so quickly that marine transport was out of the question. "We considered moving product via single pallets, using temperature-controlled containers on passenger airlines," says Dezan. But in the end, Cadence decided to charter an entire Boeing 777 aircraft. Cadence and FedEx developed processes to keep the shipment in the required temperature range while it was in motion and during mode-to-mode transfers. Two FedEx temperature specialists flew to Italy to oversee the load through the entire trip, from the factory to Cadence's 3PL in Memphis.

The specialists arrived at the factory with the necessary number of trucks, plus one spare. At the airport, they supervised as pallets of product were prepared for air travel and wrapped in thermal blankets. "They set temperature loggers inside the plane, and did spot checks on the loggers we had on our product," Dezan says. "And they were on the flight while the product was being flown from Italy to Memphis."

In Memphis, the specialists supervised as the shipment unloaded, unwrapped, put onto trucks, and sent for and Customs clearance. Cadence worked with FedEx to submit documents to the FDA in advance, to help speed the clearance process.

While waiting for the go-ahead to move the shipment to Cadence's 3PL, FedEx kept the product on temperature-controlled trailers. "They monitored the temperatures, as well as the fuel levels for the diesel-powered generators, to make sure the shipment stayed within the right temperature range Dezan says.

The delivery went just as fast as Cadence had hoped. "Pickup started on Friday, and product arrived at our 3PL on Wednesday," Dezan says. "For that type of shipment, and requiring FDA clearance, it doesn't get better than that." In some sectors of the pharmaceutical industry, getting product to market as fast as possible is essential. This is especially true for generic drugs. "Generics have a very short window of profitability," explains Saponaro. "Once the drug goes off patent, the first one to market wins. Manufacturers have a 30- to 60-day window to make huge profits, and then it starts to level out."

In some cases, the FDA gives one company the exclusive right to sell a generic for 180 days before other manufacturers can jump in. That makes it even more urgent to get the product to market. "Every day a company loses sales is total lost value," says Wiesman. "When the market is opened to other generic manufacturers, prices drop dramatically." Competition will very quickly push the price down by as much as 80 percent. While speed is of the essence, a manufacturer introducing a generic drug faces multiple hurdles that can slow the race to market. For one thing, the drug has to meet FDA requirements for release into the U.S. market. The FDA might also require some changes to the labeling right before the launch. "Changing labeling rapidly would require great logistical efforts," Wiesman says.

4.9 No Error Focused Trials

One logistics function unique to the pharmaceutical industry is the work that supports clinical trials. Rather than distribute large quantities of a drug for use in the market at large, manufacturers conducting trials move product to labs and hospitals and, often, directly to patients' homes. The demand for shipments to clinical trial sites tends to ebb and flow, and each project is unique. "Various studies go on at the same time, and all have different requirements," Saponaro says. "It's a new learning process each time."

Depot services for clinical trials make up one of the fastest-growing business areas for Sentry BioPharma. The company helps clients move product from manufacturing facilities around the world to locations in a variety of c ountries. Some destinations are growing increasingly important. "Our U.S. and Canadian clients need to get product to test sites in Central Europe, where it seems to be easier to find test subjects for these programs," says Mitchell.

The drive for cost containment is causing pharmaceutical manufacturers to combine their clinical and commercial logistics operations under one logistics contract. In established lanes, that strategy is effective. In developing regions of the world, however, Fisher Clinical Services advises its clinical trials customers to use specialized service providers to ensure that therapeutics, diagnostics, and patient samples can travel among sites easily [8].

Every pathway for the retirement of the products has to be tracked and documented for regulatory purpose and compliance issues. The logistics has maintained, for sending the products to the market has to be strictly followed for recalling and return. Taking back the pharmaceuticals has equal importance and must have to be the same way they were sent.

4.10 The future—parallel logistics

The development of personalized medicine means that fewer, but more expensive, drugs will be developed. With average costs of $1 billion and 15 years to bring a drug to market, the pharmaceutical industry is looking at ways to reduce those costs. Some involve clinical trial logistics. Today, when patients drop out of trials or trial enrollment is insufficient, the drugs shipped to a trial site are destroyed. There is discussion, however, about developing regulatory requirements for drug storage at clinical trial sites like those for manufacturing and distribution, according to Fisher’s Smith. If that occurs, it may be possible to shift drugs between trial sites and thus reduce overage, transport less material, create fewer returns, and reduce the need for disposal.

That future remains years distant, however. For the foreseeable future, the best strategies for reducing the costs of pharmaceutical returns involve process improvements and integrated logistics [9].

5. Conclusion

Reverse logistics in the pharmaceuticals industry works differently from many other industries. Drugs or products returned in a pharmaceutical industry are seldom repaired or resold. Instead, they need to be destroyed and disposed properly. There are various considerations to be taken into account such as

- Need for accurate tracking and visibility
- Batches and Expiry control
- Cold Chain requirements
- Proper storage and disposal
- Pedigree reporting
- Anti-counterfeiting and so on.

Reverse logistics is considered a bullet in company's profits and an expensive process most times. Yet, it is an imperative process in modern times due to various reasons such as government regulations, growing environmental concerns, growing consumerism, and competitive advantage. An important consideration for companies is to perform the operations in reverse logistics effectively so that it reduces the cost involved.

When it comes to legal complexities, especially in the global context, the regulation states that, goods once sold by the manufacturer can be brought back only through declaration to excise authorities and proper documentation. This process is cumbersome and takes time. Non-compliance also leads to legal actions.

What else will the future hold for the pharmaceutical supply chain? New security systems? Even better methods for maintaining and documenting temperatures?

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