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Securing pharmaceutical industries from problems pertaining to supply of counterfeit drugs by integration of RFID in the supply chain

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ABSTRACT

The following paper is a qualitative research study on the methods that can be used to safeguard and secure the supply chain of the pharmaceutical industry. This is an exceptionally difficult task, taking into consideration, the existence of counterfeit drugs and their growing footprint over the rest of the world. This has also led to an obligatory urgency to authenticate and secure supply chains against counterfeit drugs. This article studies the scope of management information systems, particularly RFID, in facilitating such precautionary measures. The main aim of this paper is to study the applications of the RFID technology in other developed countries which could possibly help the other nations to adopt such strategy and immunize their pharmaceutical industry.

Keywords— Supply chain, Pharmaceutical, Drug pedigree, Counterfeit, RFID, Information system security and safety

1. INTRODUCTION

This industry pertains to the procurement of materials, manufacture of drugs and their supply to the consumers. However, the scope of the industry is not only restricted to the manufacturing and sale of medication but also the research, discovery, and development of new drugs to combat more recently diagnosed diseases. The amplitude of the pharmaceutical industry also extends to ensuring the safety of drugs while in internal and external transit and also to protect misuse of empirical information regarding such drugs due to information theft. Unlike in most other consumer goods industry, the concept of 'seconds' doesn't exist in the pharmaceutical industry. This means that sub-standard medicines cannot be sold in the market unlike other defective goods that are generally sold and subsidized rates.

Hence, it is essential that all medicines fulfill a set of universally accepted parameters. There are 4 such parameters that must be actualized; purity, identity, strength, security, and safety. Fulfillment of each of these characteristics ensures efficacy of the pharmaceutical supply chain.

Because the effects pharmaceutical products are severe, they must always be of superior quality. This can be ascertained by improving the efficiency and effectiveness of the supply chain of such products. According to the 'Seven – Party Trust Model' there are 7 entities involved:

- (a) **Law Enforcement Agency:** the aim of this agency is to control, analyze and record data pertinent to subpoenaed drugs in order to track their movement and store data regarding their manufacture, quality, quantity, etc.
- (b) **Manufacture System:** includes 2 entities;
 - Manufacturing Agent: generally involved in production, labeling and packaging of drugs.
 - Internal Distribution Channel: responsible for timely delivery of semi-finished goods to a different part of the production unit.
- (c) **External Distributors:**
 - CFA: They are generally responsible for maintaining the stock of the drug that is produced and forwarding stock keeping units (SKU's) to the stockists.
 - Stockists: these are distributors that simultaneously handle stocks of more than one company.
- (d) **Retail Pharmacy:** These are the final retail stores to which the manufactured drugs are transported and made accessible to the consumers. Such retailers must be registered. Their aim is to maintain inventory control in real time and identify counterfeit drugs.
- (e) **Recycle Centre:** Because it is important to maintain the quality of the drugs sold, it is a given that a lot of the medicines would be discarded once they cross their shelf life. In order to control such disposal of drugs and ensure the safety of information, the private information must be completely removed.

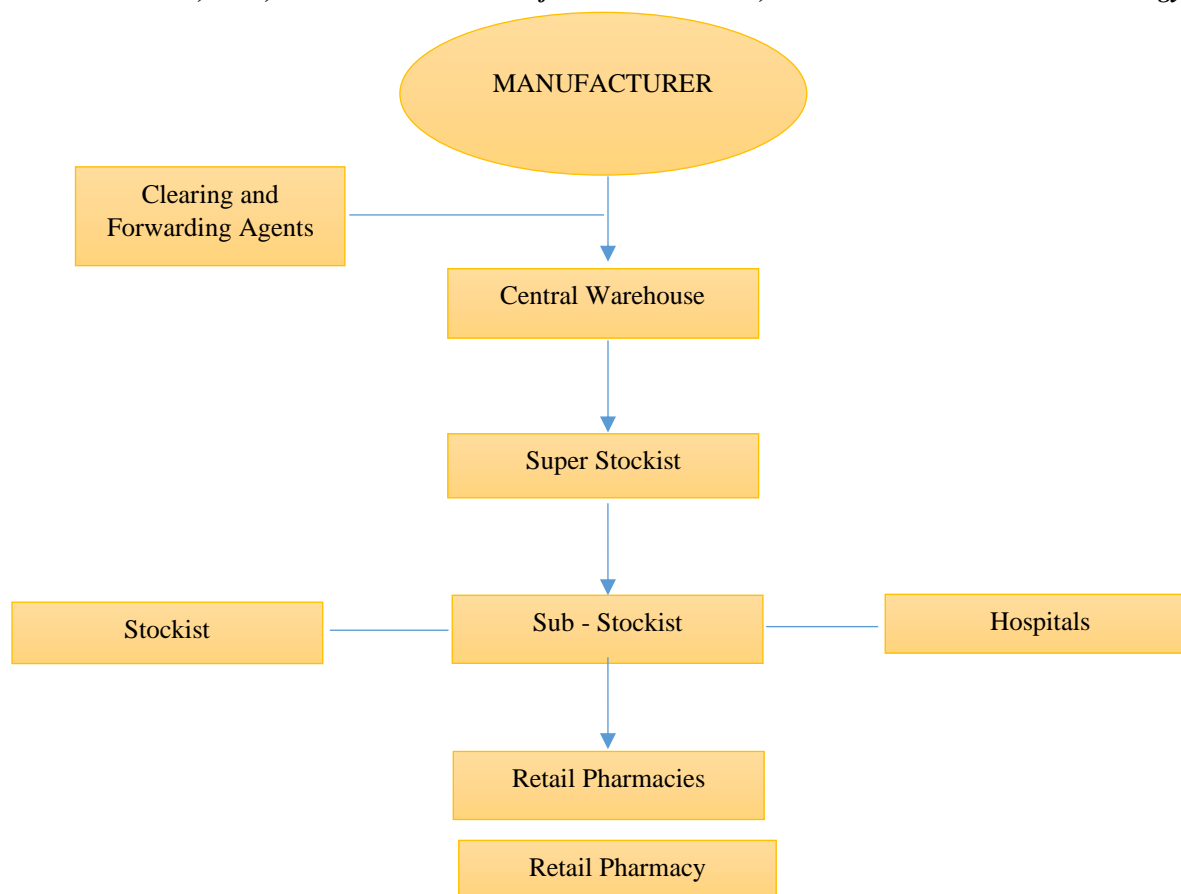


Fig. 1: Seven – Party Trust Model

Despite the increasing importance of ensuring credibility and validity of goods manufactured by the pharmaceutical industry, there are loopholes that exist in its supply chain and manufacturing, a few of which are discussed in the next section.

2. LOOPHOLES IN THE PHARMACEUTICAL SUPPLY CHAIN

Loopholes in the pharmaceutical industry predominantly exist to foster hike in prices for the drugs produced and sold or could even pertain to adulterations made to the quality of drugs, thus increasing risks of mortality. A few such methods are listed below:

2.1 Debranding

This method of altering prices of drugs is most prevalent in the UK and is used in the sale of specific drugs only. It entails re – categorization of drugs to be able to charge a higher price.

2.2 Misuse of ‘Orphan Drug Extension’

Most pharmaceutical companies that are involved in research and development of orphan drugs (that is, drugs manufactured for special diseases) are typically offered an additional 7 years of exclusive patent rights to protect their interests as producers of new drugs. However, many companies now misuse this provision made by the government by devising new methods of producing already existing essential drugs by seeking an extension for the same.

2.3 Sterilization Enforcement by the USA

In order to ensure the safety of drugs while in transit, in the supply chain, countries aim to improve sterilization techniques. This could be done by employing companies of the sterile medical packaging industry which is forecasted to experience an 8.8% CAGR and grow to \$6.3 Billion by 2021. This requires companies to install heavy equipment and technologies to support transport of drugs which is particularly difficult for small and medium scale industries.

2.4 Parallel Trade:

The expression "parallel trade" means acquiring merchandise from a lower-valued nation and exchanging them in a higher estimated nation without the approval of the authentic producer which holds the licensed innovation privileges of that item. It is an exchange of products outside a producer's appropriation channels. Parallel dealers try to pick up from the distinction in costs of an item across various markets. As the interest for less expensive items has developed, parallel exchange organizations have prospered. Be that as it may, it is still difficult for pharmaceutical organizations to follow items through every one of their channel accomplices over the store network. Besides, it is additionally hard for these organizations to comprehend what has been sold where and whether it was utilized in the nation for procurement or re-traded. Sale of drugs through Online Pharmacies and Parallel Trade also increases risks of sale of counterfeit drugs.

3. COUNTERFEIT DRUGS

Counterfeit drugs are essentially contaminated or fake drugs that contain unhealthy amounts of active ingredients that are harmful for consumption and could lead to additional health issues. They may also contain the wrong ingredient thus endangering a patients’

life. The Food and Drug Administration is responsible for the administration of the sale of drugs and to ensure that it's kept to its minimal keeping in mind the interest of the consumers.

3.1 Counterfeit Drugs Supply chain

The counterfeit drugs have a different supply chain. It is when an aspect of the drug is not proper and will have more than one side effect on the patients. The entire process is given below:

3.1.1 Manufacturers: The entire concept of counterfeit drugs come from the lack of responsibility from the side of the manufacturer. They either forget to put some crucial aspect of the drug, the wrong dosage, expired chemicals, etc. They operate out of a small lab and may or may not intentionally alter the components of a drug in order to make higher profits.

3.1.2 Distributors: The Company that makes these counterfeit drugs cannot sell their medicines to the distribution companies due to the possibilities of being tracked, and hence set up their own channels so that such medicines can be sold in the market. The company then sells the product to the pharmacies so that it can finally reach the consumers.

3.1.3 Pharmacies: The main issue lies in the Pharmacies. Due to ignorance on the part of consumers or the lack of knowledge on the possibilities of being sold counterfeit drugs, they only mention the brand of the product they want to purchase. The prices being lower is enough incentive for the consumers to purchase the medication. These are drugs that are got from different countries and then are sold in more profitable countries to improve profit margins. Also, the cost of original drugs are increasing by the day and people aren't able to buy such costly medicines and hence resort to buying counterfeit drugs as they believe it to provide the same results. The online pharmacies have more of an incentive to sell counterfeit drugs as they provide large discounts and lure the customer to those drugs, still earning huge profits.

4. SOLUTION TO SUPPLY OF COUNTERFEIT DRUGS

The healthcare sector today has so many products, services, and data that is related to its patients and is transferred across the different healthcare sector participants. The current IT infrastructure is extremely fragmented which leads to a lot of errors and hence decrease in the responsiveness.

This issue is seen more frequently in the pharmaceutical supply chain. The supply chain process has an influence on the quality of medicines and the well-being of patients after taking that medicine. As mentioned and discussed previously, there still exist numerous loopholes in the supply chain of such products, more so in developing countries such as India, Russia, etc. One such substantial problem is the existence of Counterfeit Drugs. Such problems exist due to the inability and to some extent, the resistance of such countries to adopt data capturing systems to aid tracking, tracing and warehouse management.

One such information system that could help in database management would be Radio Frequency Identification (RFID). One of the main features of RFID is that it can help in shrinkage of Inventory (which could occur because of theft, damage or misplacement). It will increase the accuracy of the records of inventory present in the company so that every unit of a product is kept track of. In terms of the technological aspect, the functioning of RFID is exceptional but it cannot be effective in an organization without the improvement of the rest of the infrastructure. This will provide holistic development to the firm. It will help the firm in more than one way.

5. FUNCTIONING OF RFID

RFID can be a part of any system that requires data transferring and transmission over any kind of wireless media. Such data capturing techniques use radiofrequency waves to transmit data. These waves are emitted by the radio frequency tag, also known as the RFID Tag, and are unique in nature and hence are easily identifiable. The RFID Reader interprets the data transmitted by the Tag and the information thus obtained is further studied to draw useful conclusions. The specific hardware components of both parts of the RFID system are as follows:

5.1 RFID Tag

The RFID Tags generally comprise of:

- A microchip transponder or a processor which is responsible for executing the instructions transmitted by the reader.
- A memory card which is used to store the data pertaining to the product on which the tag is attached. The information on this memory card is emitted to the reader upon instructions, as and when required.
- RFID tags can be of 2 types, Active or Passive. The difference between the two lies in their ability to power their own batteries which are required to transmit data. Active tags are self-powered and cover a wider range of area because they aren't dependent on the readers to obtain operating power, unlike Passive tags. This is also the reason why most active tags are comparatively more expensive; due to the presence of an internal battery in them. Hence, active tags could be read and write only tags or write only tags, however, Passive tags are mostly read-only, i.e., they can't alter information stored in them.

5.2 RFID Reader

This hardware component performs the function of reading the frequency waves emitted by the RFID tag and communicating said data to the middleware. The Reader comprises an antenna which is the part that emits the radio waves. It is a conduit between the tag and the transceiver.

Generally, when a drug is manufactured and dispatched to reach the end consumer, a 'Drug Pedigree' is maintained. A pedigree is a document which entails details regarding the drugs manufactured, its contents, date of manufacture, and other information

regarding its sale and acquisition. Such information is stored in the barcode on the RFID tag. As mentioned above, the antenna, when packaged with the transceiver and decoder, becomes a reader or an interrogator which can be used as a fixed or a handheld device. This reader emits waves depending on the power output. When an RFID tag passes through this radio frequency zone, it detects the reader, which decodes the data which is originally encoded in the tag's circuit and the data is passed to the host computer for processing.

Many objects today require identification and any such object requires RFID. The tag is then read by an RFID tag reader with the help of Radio Waves. The present code is read and presented to the back-end systems, using which they make business decisions. The RFID technology can interact only if it has good IT Infrastructure. The IT Infrastructure includes Hardware, application and the interface to be used. The data that is generated after the RFID reader is done reading is called the event data.

The event data is then made ready for processing in the enterprise systems. One of the systems of IT Infrastructure is ERP. The layer of Business Process Analytics is the part where the data is used to meet that objective for which an RFID system had been deployed. An enterprise would always like its RFID technology to connect with the ERP, supply chain, customer relationship management, etc. It provides a window of opportunities for its uses and provides as a base for the company if they would want to add more technologies.

RFID bridges the gap between the physical flow of goods and the flow of information in the IT Systems of the organization. This is made available due to the software that the company uses. It provides opportunities for the company and then allows them to make crucial decisions using Business Analytics.

RFID may be costly to implement but is extremely beneficial to the company in the long run, both in terms of cost efficiency and time efficacy.

6. IMPLEMENTATION OF RFID IN ASIAN AND EUROPEAN PHARMACEUTICAL SUPPLY CHAINS

For this purpose, we have essentially taken into consideration the Indian and the Chinese pharmaceutical industry as an indicator of common trends in the continent. While the Chinese pharmaceutical industry specializes in manufacturing of Active Pharmaceutical Ingredients (API), the Indian industry excels in the utilization of the API in the production of generic drugs. These drugs are in turn sold in the North American and European markets. However, disturbances in the supply chain of such products due to entry of counterfeit drugs and loopholes as discussed earlier contaminate the industry. Even though every year, thousands of cases relating to counterfeit drugs are reported in India and China, most Western countries such as America still wish to collaborate with them. This is mainly because the pharmaceutical industries in these countries are still in their infancy stage.

A major reason for this is the lack of implementation of new technology and information systems. This creates ginormous opportunity for more production of pharmaceutical drugs thus increasing threats due to mass production. The economies of scale will make it more difficult than ever to keep track of each unit produced. Developed countries such as USA and France re much ahead in these terms. Many European countries have already performed a pilot study by implementing RFID in their distribution systems. This pilot study was first conducted by a U.K based pharmaceutical company called 'Agate' in collaboration with about 6 other companies. The threat of adulterations in the UK industries is also at a rise due to most E.U companies having joint ventures with companies in India and China. The wider the supply chain is spread, the more scope there is for contamination of the distribution channel. With the growing import of drugs from the Asian market elsewhere, there is no guarantee to the fact that supply chain channels will be free of counterfeit drugs. Adoption of information systems such as RFID help to at least trace and track down the route through which such drugs might enter the supply chain and help take precautionary measures.

7. USE OF RFID IN INFORMATION HIDING TECHNIQUES

The techniques mentioned below, help to ensure the safe and lawful sale of drugs by hiding specific information in the RFID tag, which would otherwise be mentioned on the product package and could be used to deceive consumers. The discipline of concealing information is termed as Information hiding. Few examples of the same include: concealing copyright information in digital videos or images or concealing secret letters in the photo. This technique to conceal data in digital media is named as Steganography. It can be utilized for concealing some pivotal information on 'RFID tags'. This section examines some applications of information hiding:

7.1 Expiry Date Hiding Stenographic techniques

This technique can be used to conceal the best-before date of any pharmaceutical drug on the 'RFID tags' hence stop the sale of expired drugs. For instance, if the RFID reader scans a particular drug which is already expired, it would streak a sign saying this medicine shouldn't be sold as it is expired. This can be implemented effectively on an RFID tag. RFID tag provides sufficient space to conceal the month and the time of expiry of the medications. Serial Number Tag can hide the expiry date which provides 36 bits of room, And for representing the month and year, we just need a limit of 11 bits. The remaining 25 bits can be used for generating the serial number. Unique items that belong to one product can be represented through these serial numbers. Hence, this fills both the needs which are concealing the expiry date and offering a unique identification.

7.2 Fraud Detection and Prevention

Detection and Prevention of frauds can be done through RFID and Information hiding put together. A basic case of RFID fraud is exchanging a tag from a less expensive pharmaceutical item to a costly pharmaceutical item, trying to save expense. For instance, exchanging the RFID tag from costly medications (like those utilized for relieving heart diseases), with basic pain killers. The fundamental thought is to conceal the weight of the item in the respective RFID tag. This weight would be inspected at the time the

RFID user scans the RFID labeled item at the 'Point of Sale' (POS). In the event, if a mismatch is identified, it would show attempted fraud. This arrangement could then be utilized to anticipate any further attempts of fraud.

7.3 Tamper Detection

Tamper detection of RFID tags is one of the applications of information hiding in the pharma world. There could be a possibility of tampering or overwriting the RFID tags by another RFID reader. Such tampered tags when scanned can show a wrong drug. This case could turn out to be more terrible when RFID technology is coupled with smart shelves. In this situation, there might be chances of picking and delivering wrong drugs because the tampered tag could point towards another drug leading to an incorrect diagnosis

8. CONCLUSION

What we have discussed in the sections above is probably just the tip of a bigger iceberg. Although our study clearly shows that the need to integrate highly responsive data capturing systems into the supply chains of pharmaceutical industries is indispensable, we must also take into consideration the detrimental impact of the same on small and medium companies. There are multifarious factors that could hinder the implementation of RFID technology. Any obstacles in the way of the wave transmission such as the presence of specific metals weaken the ability of the antennae to capture radio frequencies. Another drawback of RFID tags would be the inflexibility in selecting information. Unlike with barcodes, RFID readers do not permit to read one tag at a time, instead, all tags within the frequency range are picked up and read together.

Noting the features, functioning and the advantages of the system, we can conclude that help a business in sustaining its competitive advantage in the industry. Furthermore, it is of utmost importance that a company chooses the right design, plan and implementation technique while incorporating the RFID system into its supply chain.

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