Track and Trace in the Pharmaceutical Supply Chain

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Abstract

The complexity of the United States health care system is increasing rapidly. Demographic changes, along with a host of new drugs, are causing greater volumes of raw materials and finished products to move through the pharmaceutical supply chain. Because drugs are expensive, there is always the possibility of counterfeit. Several recent cases of counterfeit medicines have raised American awareness of the problem. Information is an effective tool to combat counterfeit, however, new supply chain structures and relationships will need to emerge to organize and exchange information

INTRODUCTION

The complexity of the United States health care system is increasing rapidly. Demographic changes along with a host of new drugs are causing greater volumes of raw materials and finished products to move through the pharmaceutical supply chain. In many ways, the pharmaceutical supply chain is beginning to resemble the distribution of consumer goods. However, several important differences remain.

The fundamental goal of the medical industry is patient care and safety. To achieve these goals for the public good, the Food and Drug Administration (FDA) and individual States regulate the industry through laws and administrative orders designed to protect the integrity of drugs throughout the pharmaceutical supply chain. These laws and regulations require millions of pages of information to document the flow of drugs from manufacture to consumption.

Implicit in the documentation process is the administrative requirement to do track and trace. **Tracking** involves knowing the physical location of a particular drug within the supply chain at all times. **Tracing** is the ability to know the historical locations, the time spent at each location, record of ownership, packaging configurations and environmental storage conditions for a particular drug.

Track and trace forms the foundation for improved patient safety by giving manufacturers, distributors and pharmacies a systemic method to detect and control counterfeiting, drug diversions and mishandling. These are important aspects of supply chain security. Unfortunately, the current system for the documentation and organization of data is cumbersome because of a reliance on manual procedures and storage of information on paper. As a practical result, track and trace takes place only in an emergency such as a drug recall.

Supply chain wide track and trace provides a difficult problem for APICS practitioners to consider. The next section examines the emerging issue of counterfeit and the legal underpinnings for improved trace and trace capabilities within the pharmaceutical supply chain.

AN INTERNATIONAL PROBLEM OF SIGNIFICANT MAGNITUDE

According to the World Health Organization (WHO) definition, what makes a medicine counterfeit is the deliberate or intentional (criminal) nature of the mislabeling or adulteration of a drug. This type of illegal behavior leads to 1) compromises of patient safety, 2) economic loss to established drug manufacturers, and 3) a threat to the national security of sovereign countries.

The WHO estimates that **between five and eight percent** of the worldwide trade in pharmaceuticals is counterfeit. Many industry experts believe this to be a conservative estimate. For example, the Lancet reports "Approximately 192,000 people died in China in 2001 due to the effects of counterfeit drugs. As much as 40% of drugs in China are counterfeit."

The problem of counterfeit drugs has reached grass roots America. During the past ten years, drugs such as Procrit, Epogen, Serostim, Zyprexa, Diflucan, Combivir, and Retrovir have been counterfeited. Even Lipitor, the widely prescribed drug to control cholesterol levels, was recalled recently because of a counterfeiting incident. In this particular case, the FDA could not determine how many bottles were in each of three counterfeit lots. As well, the current destination of the counterfeit lots could not be determined. While most counterfeit drugs contain harmless ingredients such as water or glucose, the counterfeiting of Lipitor "posed a potentially significant health hazard" according to the FDA.

Even though the overwhelming majority of drugs sold in the United States are safe, the $192 billion per year pharmaceutical market is an attractive target for counterfeiters. With the complete mapping of the Human Genome, there will be a number of new, high priced drugs appearing on the market during the next few years. This will increase the opportunity for counterfeit.

THE CHANGING REGULATORY ENVIRONMENT

With greater awareness of counterfeit drugs, the FDA and States are moving forward with new legislation to combat the problem. On May 7, Florida gained national attention by passing a legislative bill to establish a "pedigree" for each drug sold in the state. The intention of the bill is to verify authenticity and reduce the chance of counterfeit. It introduces a number of important issues for the pharmaceutical industry to consider. Specifically, the bill calls for the

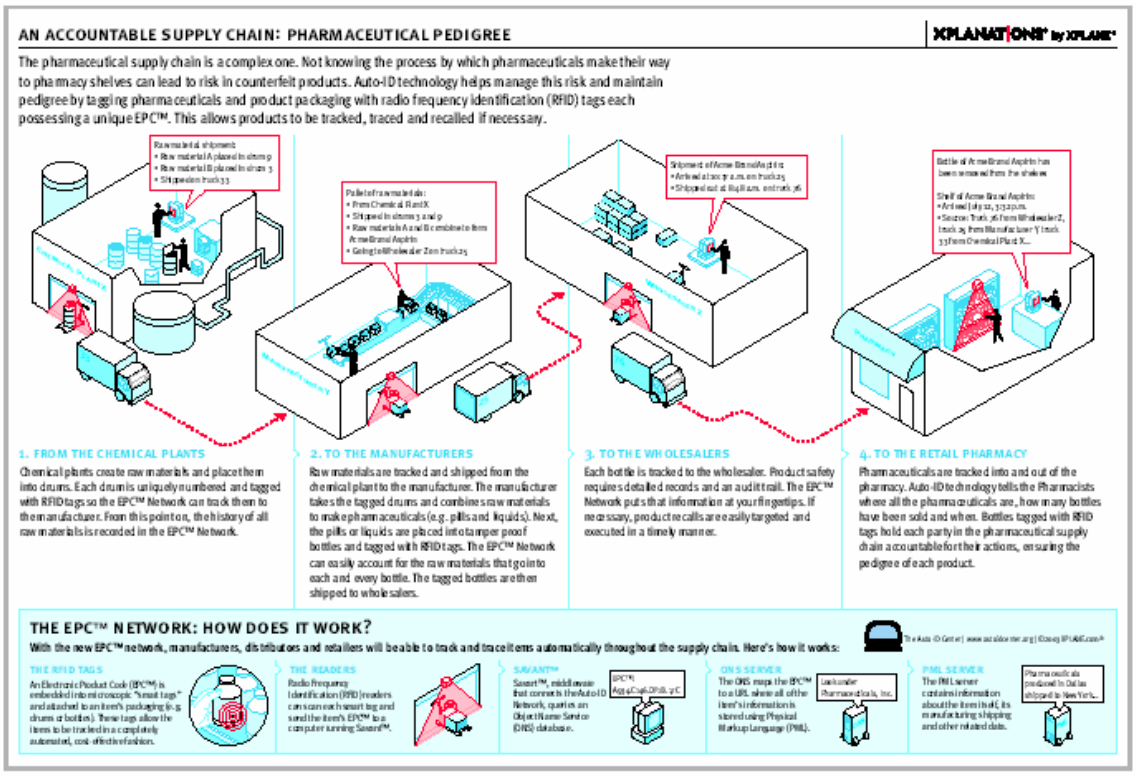
following information to accompany each drug through all steps of the supply chain:

1. Drug Name
2. Dosage
3. Container size
4. Number of containers
5. Drugs Lot or Control numbers
6. Business Name and Address of ALL parties to each prior transaction, starting w/the manufacturer
7. The date of each previous transaction

These requirements add a great deal of complexity for manufacturers and distributors. As an example, the typical drug distributor carries up to 40,000 stock keeping units. Maintaining pedigrees given this volume of drugs is overwhelming with current identification and information technology.

AN EXAMPLE OF PHARMACEUTICAL SUPPLY CHAIN COMPLEXITY

Figure 1 shows a general representation of a pharmaceutical supply chain. The form of the physical goods can change during each step of the pharmaceutical manufacturing and distribution process. Immediately after completion of each step, the product becomes a finished good that continues as an input to the next step in the supply chain. This makes track and trace difficult.



Referring to Figure 1, the finished product for the chemical plant is bulk active ingredient packaged in drums with a specific name, composition, lot number, and expiration date. In contrast, the transport carrier that moves the drums of active ingredient from the chemical plant to the manufacturer sees only a shipment of specific weight and volume. Other attributes are not important to the carrier. There is no direct, continuous link to attributes of the shipment such as lot number or expiration date.

To deal with this situation, pharmaceutical manufacturers have placed select pieces of information directly onto the package by printing bar codes or lot numbers. In this case, the package becomes the vehicle for carrying the information needed for track and trace.

Though the information carrying capacity of this approach is limited, it does guarantee universal access to all parties within the supply chain. Unfortunately, this “self contained” approach of physically attaching information to the secondary package can be, and often is counterfeited. In addition, information contained on the secondary package is hard to access quickly on a meaningful scale and it does not meet pedigree requirements.

The process of identity change continues throughout each step of the supply chain making track and trace, difficult to accomplish even with the self-contained approach for transmitting information. Historically, pharmaceutical manufacturers and distributors have gathered the information needed for track and trace, using detailed forms and secure databases as storage devices. In even the best situations, this information is difficult to retrieve and seldom shared with other parties outside of the firm. In the event of a recall, special teams within firms are charged with the task of accessing data to make important decisions about the extent of the problem. This is usually a labor-intensive process.

AGGREGATION AND INHERITANCE

Although the physical form of goods changes throughout manufacturing and distribution, a link still exists for all raw materials and work in process used to produce finished goods. This type of link demonstrates inheritance of specific attributes. Each medicine used by the patient has a specific lot number and expiration date printed on the container. The drug is shipped on a specific truck,

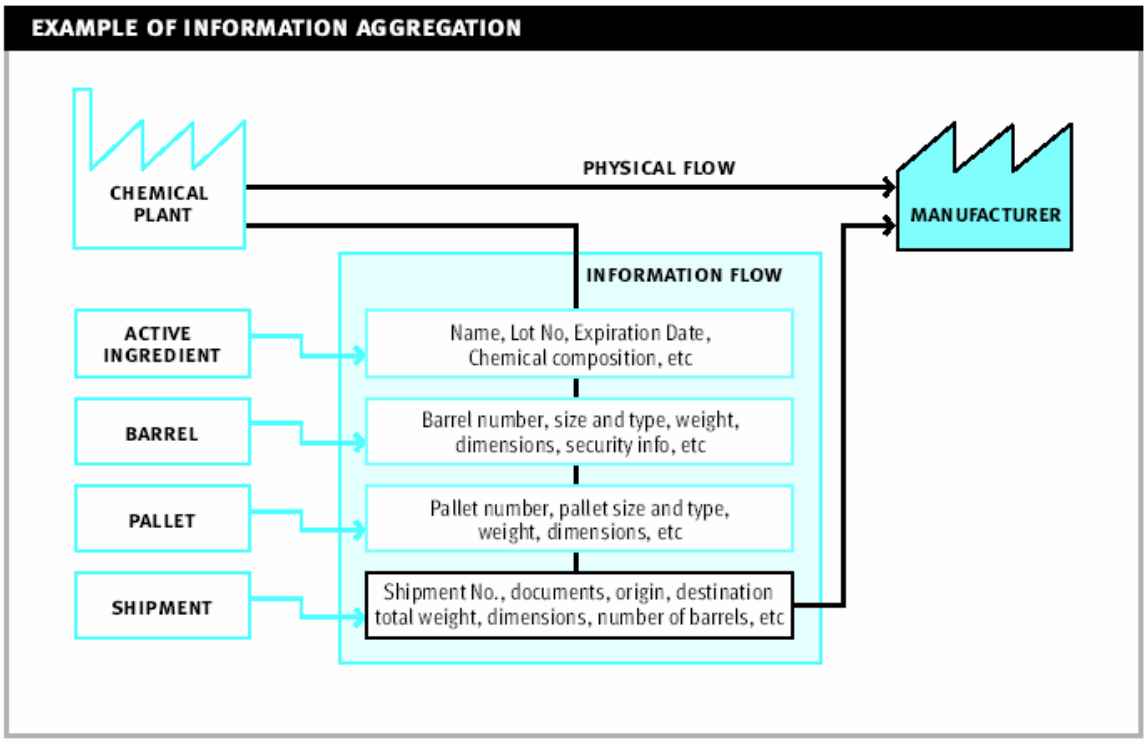
at a specific temperature for a specific duration. The effectiveness of the medicine ultimately depends on the quality of the manufacturing process and the environmental conditions of transport and storage. These are all inherited attributes.

Organizing the large number of informational links for drugs in the supply chain requires adherence to two concepts:

Data Aggregation is the logical equivalent of item aggregation or assembly. By viewing data within a supply chain as a series of parent – child relationships, track and trace becomes possible.

Data Inheritance is the history of the parent data. To reconstruct the history of an item, each change in form must transfer from parent to child.

Data aggregation reduces the number readings at critical points within the supply chain, making capture of informational links needed for large-scale track and trace feasible. Figure 2 shows a visualization of data aggregation for the flow of information between a chemical plant and the manufacturer represented in Figure 1. In this case, information flow is in parallel to physical product flow.



AN ANTI-COUNTERFEIT SYSTEM BASED ON INFORMATION

It is only through data aggregation and inheritance that robust track and trace across the entire pharmaceutical supply chain will be possible. As an anti-counterfeit measure, location information is extremely important because it provides 1) the past position of the goods, 2) present position of the goods, and 3) the anticipated future position of the goods (assuming a scheduled shipment exists). Time stamps at each location allow the calculation of residence time.

. This capability provides true pedigree information about drugs, accessible by supply chain partners. Effective track and trace will be required for accurate drug pedigrees. Supply chain wide information presents a difficult barrier for potential counterfeiters to overcome. However, with improved information and

identification technologies, track and trace will become a new weapon in dealing with counterfeit drugs.

Conclusion

Track and trace also serves as the foundation for future applications of importance to the health care industry. For example, the Human Genome Project creates greater opportunities for engineering drugs to treat small groups of individuals that suffer from specific illnesses. These “designer drugs” will be manufactured in small lot sizes on a make to order basis. In this environment, logistics and coordination takes a new form as thousands of biotechnology drugs flood the pharmaceutical supply chain. Delivery of these new drugs to the right group of people presents a challenge that the current logistical system cannot handle effectively. Advanced track and trace systems, currently being researched at the MIT Auto-ID Lab will lay the foundation for the management of this not-to-distant complexity and provides the framework for a safer and securer Supply Chain.