

EFFECTIVE INFORMATION MANAGEMENT AND DRUG TRACKING IN THE PHARMACEUTICAL INDUSTRY'S SUPPLY CHAINS

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ABSTRACT: The authors do research on pharmaceutical supply chain information management and medication monitoring. In this case, counterfeit pharmaceuticals risk the health and safety of patients. RFID and related technologies such as EPC global's EPCIS and IBM's RFID Information Center are recommended by the authors for tracking individually recognized mass-produced commodities along the supply chain. The current study analyzes the case using Transaction Cost and Collective Action Theory. People in the pharmacy supply chain must obey the rules and work together.

Key Words: Drug Safety, Pharmaceutical Industry, Tracking, Radio Frequency Identification, RFID, Supply Chain Management

1. INTRODUCTION

All businesses benefit from information management. Pharma is no exception in this essay. In this information-heavy business, the PI must be able to manage information in order to ensure that medicines and parts are what they claim to be. When purchasing medications at the shop, consumers frequently ignore their safety. The US pharmaceutical supply chain is getting an alarming volume of counterfeit pharmaceuticals and chemicals. The purpose of this presentation is to explore counterfeit pharmaceuticals in the PI and how RFID and other technology can help. It is also possible to create rules.

RFID technology and PI changes are suggested to prevent the selling of counterfeit medicines. Data from the FDA, WHO, the Wall Street Journal, and the New York Times were used in this analysis. These sources show that identity control and verification can help prevent the sale of counterfeit drugs to patients. They demonstrate how RFID and associated infrastructure can be used to track counterfeit drugs from maker to vendor. To combat counterfeit drugs, this article discusses IM, identity management, pharmaceutical product authenticity, and RFID.

The paper opens with a brief overview of identity management and validity as critical components of information management. Following that, RFID and associated technologies, such as the Electronic Product Code Information Services (EPCIS) infrastructure, are briefly explored in terms of how they might aid in the management of product identity and authenticity, as well as the tracking and tracing of commodities. Following that, we use Transaction Cost Theory and Collective Action Theory to quickly theoretically and conceptually assess our data. The primary concept of the work is then evaluated. Our work is completed with a conclusion.

Information Management: Identity Management and Authentication

ID management is the collection of information about people, locations, and objects. It has both security and technological applications. When cashing a cheque at a bank, identification is normally required. The characteristics that aid in the identification of various commodities are less relevant. Metal origin may not be a concern for nail makers. To determine the source of the illness outbreak, the cattle industry must track each cow's origin. As seen by these examples,

identity management varies per business. confirming genuineness. It can also confirm the name and origin of a product. To establish the legitimacy of anything, compare its characteristics to those of its creator. Picasso is praised by art experts. Real art is influenced by fashion and production time trends. Then we'll go through identity management and verification tools.

2. RFID, EPCIS AND A RFID-BASED INFRASTRUCTURE

RFID should be discussed immediately to reduce PI fraud and IM issues. This RFID technology is old. Radar detected enemy and friendly planes above action during WWII. Walmart only recently started tracking its supply chain with RFID. RFID readers let producers label things. Palette, case, and item processors are designated. This label can help customers verify product authenticity.

Active or passive smart tags. Passive keywords fail. Asking agents employ passive tags. It provides a strong electric field for tag data transmission. RFID reader chipset. Most people choose passive tags since active tags cost more. These tags store license numbers, product IDs, and more. Serial numbers verify a product's authenticity, manufacturing date, etc. Knowing how drugs move through supply systems could save lives. RFID products are being enhanced and standardized, but businesses are adopting them. RFID sales might reach \$2.1 billion by 2016.

EPCglobal covers RFID standards, applications, and acceptance. The biggest RFID standardizer is EPCglobal. We must show how EPC tracks and monitors products, especially pharmaceuticals, worldwide using EPCIS.

EPCglobal hasn't done RFID or bar codes in years. EPCIS became popular due to these efforts. Industry-driven RFID EPC standards in information-heavy commerce networks are EPCglobal's main goal. EPC aims to improve supply chain visibility, efficiency, and information sharing between firms and trading

partners.

EPCglobal describes this effort as follows:

EPCIS enables apps to share EPC data across companies. According to the EPCglobal Network, sharing this information will assist people understand what happens to EPC-bearing devices at work. The idea for an EPC Information Service will standardize EPC data access and enquiry. This will be accomplished by clear service operations, data standards, and user-company-specific security measures. This usually necessitates the use of a single EPC-related persistent database. The Services architecture enables data transmission among apps without the need for persistent databases. EPCIS enables apps to communicate EPC-related data with other apps that require it, regardless of whether the data is stored permanently. There is no mention of database implementation or service functionality. This means that EPCISs should not be taught data acquisition and computation outside of EPCIS protocols. Interoperability and applications aid in the competition of technology and EPC Information Service providers.

EPC Global's EPCIS is excellent for tracking.

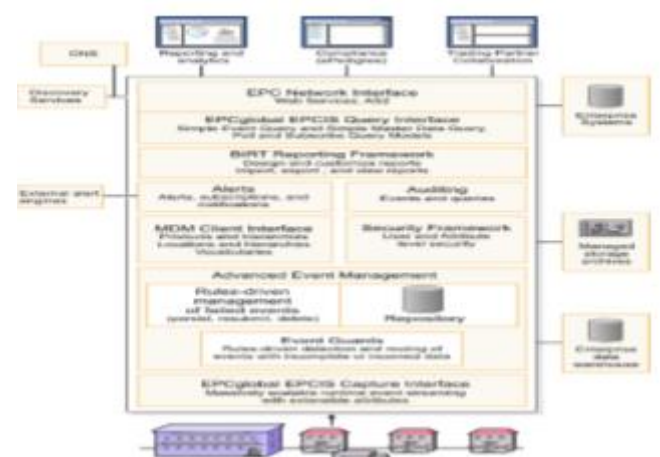


Fig. 1: RFID Information Center System

RFID tags are used by IBM to track, monitor, manage identities, and identify people. IBM's RFID Information Center (RFIDIC) uses EPC EPCIS over the world [6]. This RFIDIC monitors the movement of marked products throughout the supply chain. Regardless of sensor type, the RFID Information Center locates RFID, barcode, and 2D barcode goods. Shipment tracking and receipt verification are

simplified with the IBM RFIDIC Shipment Verification for RFID InfoCenter System. Shipping and receiving automation lowers lost items and employee troubleshooting.

The Shipment Verification [7] technique is divided into various steps (Fig. 2):

Distribution hubs transport containers to retail pharmacies. The RFID Information facility at the shop distribution facility receives shipping events.

Shipping container lists are delivered to retail pharmacies that are looking for subscriptions via retail delivery centers. Panel shipping research is made possible by ASNs. The Verification dashboard displays all received and sent containers, allowing you to view downstream inventory. After-the-fact EPCs can be evaluated and changed.



Fig. 2: RFIDIC Shipment Verification Feature

Source: IBM RFID Information Center. See

Backpacks are sold in drugstores. The RFIDIC in the shop pharmacy receives getting/business step object events.

When a subscription is requested by the retail distribution center, the retail pharmacy offers bags.

IBM RFID Information Center validates freight. See

When evaluating this EPCIC infrastructure, counterfeiters' goals, motivations, and rewards must be taken into account. We've shown that counterfeiting is profitable, especially when the penalties are small. We believe that legal supply networks with manufacturers, pharmacies, and medication sellers are simple to discover and incorporate into the PI. This is especially true when these supply networks do not follow business or customs laws. This occurs even when supply chain players such as the FDA are constrained. This will be covered in a separate section.

Increased visibility and transparency in the supply chain. Many supply chain professionals are relieved that these critical duties are now included in supply chain management software. In industry, just-in-time delivery is frequent. Instead of warehouses, businesses frequently use trucks and containers on trains. Counterfeiters are difficult to catch due to supply networks. Customs and the FDA, for example, must collaborate to establish architectures and processes, conduct daily operations, and manage digital and real-world transactions such as product handling.

To protect supply lines, all of the following processes and policies must be synchronized. Copying would be prohibitively expensive because to the hazards and complexity. The next sections look at process adjustments that increase faking. The section that follows looks at this problem through two theoretical lenses.

3. THEORETICAL PERSPECTIVES OF THE RESEARCH

Transaction Cost and Collective Action Theory are used to investigate the project. Both concepts apply to contemporary events. Many PI activities, particularly sales and distribution, benefit from Transaction Cost Theory. To implement and monitor rules, drug manufacturers, shipping firms, transportation companies, pharmacies, and government agencies such as the FDA and Customs must collaborate. Collective Action works because these groups must collaborate in order to attain their goal. This page provides a quick overview of both theoretical techniques.

Transaction Cost Theory

Economic trade costs are a type of company expense. Search and information expenses vary depending on the transaction type: whether the goods are available, whether company has the best pricing, and so on. Costs for communication, contract drafting, and other services. Monitoring the contract and suing if the other party breaches it are all part of the police and regulation expenses.

Finding the correct service, partner, or consumer, drafting a proper contract, and monitoring and enforcing it are all transaction expenses.

They claim that a company's costs are divided into output and transaction costs. Some people refer to coordination costs as transaction costs. It refers to all the information processing required to coordinate the operations of people and machines to fulfill a transaction.

Costs of production include the physical or other primary processes necessary to create and distribute the goods or services being produced. As Colle recommends, we should look at the pharmaceutical sector and supply chain through his eyes. Cooperation, teamwork, bargaining, and other socially embedded activities are highlighted through this perspective.

The Theory of Collective Action

Collective Action a group pursuing a purpose. Finishing the aim may benefit society (Sandler). Wilfred Pareto and Mancur Olson invented the term in their 1930s economics book *The Logic of Collective Action: Public Goods and the Theory of Groups*. Ronald Coase quantified corporate scale and societal cost with transaction costs in *The Nature of the corporation*. A majority pursuing a public good has higher transaction costs, notably group action coordination costs, than a minuscule minority. This small group gains most from cooperation. One scenario favors many, while the other advantages few. A social contradiction. Another problem is unhelpful group action members. Many call this the free passenger problem. Standards change, diffusion, and acceptability were explored by Markus, Steinfeld, Wigand, and Minton. Transaction Cost Theory and Collective Action Theory provide two-pronged research on PI and supply chain transactional and societal behaviors.

The PI's terrible example shows how worldwide counterfeiting can disrupt consecutive transactions.

Glycerin trafficking through a bogus pharmaceutical middleman for heparin is revealed. This brief case study explains how identity management and verification are crucial, how counterfeit items spread, and how fraud can disfigure and kill over 80 patients worldwide.

Heparin had an unknown substance in 2007. The drug's active ingredient was discovered after several fatal allergic reactions. A forensic investigation determined the cause. The FDA detected a drug-like substance in phony heparin. The FDA has linked this counterfeit medicine to 19 US deaths and hundreds of serious adverse effects. A tiny facility in Hengxiang, China, had tainted heparin after a thorough inspection (Figure 1). Antifreezes needed. Proposed heparin producer: glycerin. For each transaction, the counterfeit product's identification and validity were validated (Fig. 2). Wang Guiping was arrested and sentenced to life in September 2009. Several counterfeit pharmaceuticals have been detected in global and American pharmaceutical supply systems.

4. A POISON'S PATH

1		showing syrup was 99.5% pure glycerin
2	Shipped from port in Shanghai to Barcelona, Spain	Purchased by a new broker, assuming original documentation was authentic, gave additional stamp of authenticity. Resold to broker in Panama
3	Shipped 46 barrels to Colon, Panama	Panamanian government assumed barrels certificates of authenticity were real and purchased for medicinal use
4	Shipped by truck to Panama City, Panama	Government officials used syrup in 260,000 bottles of medicine
5	Medicine dispersed throughout Panama's medical community and pharmacies	At least 100 deaths in Panama are blamed on this counterfeit glycerin, causing numerous severe allergic reactions, with some patients suffering permanent damage, i.e. facial paralysis. In China, at least 81 deaths were blamed on the drug
	After thorough worldwide investigation, contaminated drugs linked to Chinese citizen: Wang Guiping	Receives life sentence in Chinese prison for his crimes

Figure 1: A Poison's Path

Counterfeiting goes beyond drugs. US police seized \$260 million in counterfeit goods in 2009. The problem is pervasive. Chinese criminal organizations sold 80% of counterfeit products arrested last year, according to US data. Shoes deceive the most, followed by technology, luxury, and drugs. At \$26 million, December 2009 saw the largest federal seizure of counterfeit toys, decorations, perfume, and gadgets. In April 2010, U.S. officials reported their largest counterfeit product seizure, worth over \$240 million, as part of an anti-piracy investigation. Federal, state, and local law enforcement, including ICE at DHS, seized \$40 million in counterfeit Rolex watches, Coach purses, Nike shoes, pirated DVDs, and counterfeit medicinal supplies from over 30 U.S. sites in a complete sting operation

Businesses should remember that counterfeit goods take jobs, creativity, entrepreneurship, and innovation. It endangers public safety and aids organized crime.



Fig. 2: False certificates of authentication were issued for each step the fake product was sold. Pirated movie, music, and pharmaceutical websites are referred to by ICE as the next great frontier. Clearly, the United States must combat counterfeiting on a global scale. When patients' lives, health, and safety are jeopardized, drug fraud is exceedingly dangerous. PI and its supply chain partners are combating the development and distribution of counterfeit drugs. To achieve these objectives, governments, regulators, pharmaceutical manufacturers, distributors, importers, pharmacies, and patients must all collaborate. A call to action is then issued.

5. REGULATORY EFFORTS: A CALL FOR COLLECTIVE ACTION

First, European experts discuss supply chain stakeholders' counterfeit medication concerns. From 2006-2010, the EU funded this research. Initiative: ITAIDE. Study: Europe must balance multinational trade security with corporate and government regulations. Recent corporate agreements matter. Information gathering costs businesses and governments. European enterprises must balance information collection costs and control to compete locally, nationally, and worldwide. ITAIDE tracks European beer, paper, food, and PI drug circulation. The ITAIDE project combats fake medications. Experts are researching supply chain security and management to increase patient safety. This study investigates legislative and organizational

coordination, orchestration, and tracking technology.

Drug supply chain stakeholders include governments, agencies, regulators, producers, distributors, importers, pharmacies, and patients. Numerous federal authorities protect prescription drug users. Global organizations exist. WHO, ICHR, UMC. Government agencies like as CMS, FDA, DEA, CDER, and FDA have assisted in enforcing laws and criminal investigations. PDMA 1987 supported these efforts. US PDMA controls drug distribution for safety and efficacy. This law prohibits selling expired, ineffective, adulterated, misbranded, or counterfeit prescriptions. Wholesale prescription drug diversion market. The 1992 Amendments altered PDMA. PDMA recommendations were released in 1990 and 1999 by FDA. FDA utilizes RFID.

RFID is the fastest and most accurate data tracking method, according to FDA. FDA approved RFID technology in 2004 and anticipates track and trace technology that provides a drug's pedigree or life history to be widely used by 2007. Pharmaceutical supply chains will be protected by this technology. Drugmakers, wholesalers, and retailers track supply chains via RFID. Pharmaceutical wholesalers and unlicensed distributors had to register and provide transaction histories. Many stakeholders worry about pedigree distributors' finances.

RFID and other trackers cannot combat drug counterfeiting. Complex coatings, color-shifting dyes, and holograms protect packaging. Tech alone won't help. Combating counterfeit goods requires education, inspection, sanctions, and government involvement.

6. CONCLUSIONS AND OUTLOOK

This article covers medication monitoring and pharmaceutical supply chain information management. Identity and authentication are needed for information management. A study found that fake medications jeopardize public health and patient safety. RFID and related

technologies like IBM's RFID Information Center and EPC Global's EPCIS are recommended for serialized, individually identifiable product supply chain tracking. Current research is explained in two parts: Theory of Transaction Cost and Collective Action. Regulations require pharmaceutical supply chain participants to communicate.

Pharmaceutical corporations, rules, regulations, compliance procedures, manufacturers, distributors, pharmacies, importers, and quickly developing technology and applications form a complex web. Fake medications endanger doctors, patients, and the public. Drug counterfeiting is global because international pharmaceutical vendors offer fundamental and intermediate chemicals. Transparent, manageable supply networks are emerging. Supply chain stakeholders like counterfeit-resistant supply chain management software.

Dr. Marv Shepherd's Wall Street Journal China Never Investigated Contaminated Heparin, Says Probe comments complicate matters.

Not surprised. I battled counterfeit medications with Chinese in 2008 and 2009. Our drug exports are not our problem; they are your (US) problem, claimed a Chinese FDA. This properly characterized the incident.

Forgeries in supply networks are hard to spot. Most supply chain participants, including Customs and the FDA, must work together to build architectures and processes and conduct daily transactions (physical (product handling) and digital (documents, payments, etc.)). Supply chain security needs active participation and cooperation in all procedures and policies. Due to these risks and complexity, counterfeiting is costly. Knowledge, monitoring, punishment, and government engagement are needed for counterfeit threats. There are other cutting-edge tracking and tracing alternatives besides EPedigree, RFID, EPCIS, and the RFID Information Center. Medication fraud affects businesses and individuals. Many supply chain players must cooperate. Businesses, governments, foreigners, and supranational organizations must collaborate to tackle this

issue.

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