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Securing pharmaceutical supply chain using digital drug serialization

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Abstract

The supply chain process is a very critical process in the pharmaceutical industry, and through digital drug serialization, we can mitigate the risk of counterfeit drug supply and counter the risk of consumers consuming fake drugs. To deliver medicines free of counterfeiting, the pharmaceutical supply chain's integrity must be preserved. In this article, we have focused on how we may employ digital drug serialization in the pharmaceutical supply chain without harming the public's health. Even though pharmaceutical corporations are working hard to combat medication fraud, it is still a persistent and complicated problem in the drug supply chain that costs the pharmaceutical business money and negatively affects patient health. To solve this issue, pharmaceutical companies are implementing a significant digital transformation in the pharmaceutical supply chain by integrating digital traceability and track-and-trace technologies from the initial raw material supplier to the patient.

Keywords: Drug Traceability; Drug Counterfeit; Pharmaceutical Serialization; Supply chain; Track and Trace System; Cold Chain; Blockchain; Enterprise System (ERP)

1. Introduction

The healthcare supply chain entails working across numerous teams, stakeholders, and geographical boundaries to acquire resources, manage supplies, and deliver goods and services to patients. The healthcare supply chain is susceptible to fraud, erroneous data, and a lack of transparency because of its intricate structure. To ensure that patients receive drugs that are free from adulteration (counterfeit, inferior, or unapproved drugs), the pharmaceutical supply chain must be kept honest [1]. Hospitals, dispensing pharmacies, and other providers can receive safe, effective medication from their original source thanks to the pharmaceutical supply chain. This world-wide, complicated system starts with basic resources, which are then processed by manufacturers and correctly dispersed globally. The primary and secondary wholesale distributors, packaging, dispensers, including hospitals and neighbourhood pharmacies, and packaging are all parts of the pharmaceutical supply chain that eventually connect to patients and customers [2]. Although one of the safest in the world, the pharmaceutical supply chain in the US is getting more complicated. The resilience of safety measures is put to the test by external dangers like the importation of shoddy or falsely labelled (SF) medications, Internet commerce, and growing grey markets [3]. Drug dealers now have the perfect opportunity because of social media to sell their unlawful goods online. For the pharmaceutical industry, the sale of fake and illegal pharmaceuticals on social media is a big issue [4, 5]. The US pharmaceutical supply chain is impacted by these concerns because dangerous and ineffective medications are introduced. There are growing examples of supply chain failures resulting in patient harm and death [6]. According to research, millions of Americans purchase medications online, but many rarely or never disclose the source of their medication to their healthcare practitioner. This is why pharmacists are concerned about illegal internet drug vendors. This not only makes pharmacist guidance and handling medications more difficult but also poses a risk of harm to the patient due to the potential dangers of the online-purchased pharmaceuticals. It has been discovered that illegal internet drug vendors provide hazardous or unapproved goods as well as SF pharmaceuticals. Human trafficking and illegal arms sales are all major sectors of the shadow economy, but

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the counterfeit drug market is believed to be worth more than $200 billion (USD) annually [7]. Drug diversion takes many different shapes and manifests itself in a range of contexts, from small-scale thievery to massively scaled and well-coordinated criminal activities. Large quantities of medication are frequently diverted internationally when they are taken from government storage facilities or aid or donation shipments. After that, these drugs are often sold on the black market outside the country where they were originally stolen. Particularly in some regions of Africa and Asia, this is an issue [8].

2. Pharmaceutical Drug Serialization

Pharmaceutical items that are manufactured and sold as counterfeit drugs have the goal to misrepresent the validity, provenance, and efficacy of the original medication [9]. The term "counterfeiting" refers to both branded and generic products. The ingredients of a counterfeit product may be present in the right proportions or the wrong quantities, with the right ingredients or the wrong ingredients, and with fraudulent packaging. Even if the counterfeit product includes the right ingredients in the right amounts, its manufacture and distribution are not under the control of the relevant country's regulatory authority. In the United States, the majority of the population may be exposed to drugs that are fake or stolen. Fundamentally, on November 2018, the United States of America entered the serialization compliance. Although the serialization requirement was supposed to go into effect in November 2017, compliance was delayed for a year due to the manufacturers', supply chain partners', and wholesalers' lack of preparation [10]. All pharmaceutical prescription drugs must comply with this serialization requirement and have a distinctive product identifier for Pharmaceutical items that are manufactured and sold as counterfeit drugs have the goal of misrepresenting the validity, provenance, and efficacy of the original medication [9]. The term "counterfeiting" refers to both branded and generic products. The ingredients of a counterfeit product may be present in the right proportions or the wrong quantities, with the right ingredients or the wrong ingredients, and with fraudulent packaging. Even if the counterfeit product includes the right ingredients in the right amounts, its manufacture and distribution are not under the control of the relevant country's regulatory authority. In the United States, the majority of the population may be exposed to drugs that are fake or stolen. Fundamentally, on November 18, 2018, the United States of America entered serialization compliance. Although the serialization requirement was supposed to go into effect in November 2017, compliance was delayed for a year due to the manufacturers', supply chain partners', and wholesalers' lack of preparation [10]. All pharmaceutical prescription drugs must comply with this serialization requirement and have a distinctive product identifier for traceability. The Drug Supply Chain Security Act (DSCSA) has developed a step-by-step implementation plan that will take eight years, from 2015 to 2023 [11]. As part of this approach, it has been mandated that each individual medicine packet contain a unique product code and a 2D data matrix for electronic traceability [12]. The GS1 Data Matrix is a two-dimensional (2D) bar code that effectively allows the encoding and marking of more data in a smaller area and that offers error detection and correction capabilities to improve bar code readability despite irregular packaging or physical damage to a label [13, 14]. Additionally, for unit-level traceability, all supply chain partners, including manufacturers, re-packagers, wholesalers, and dispensers, must send data electronically. Additionally, it mandates that thet packaging hierarchy of aggregated data be included in then EPCIS file and electronically transferred to the supply chain partner for electronic traceability. Additionally, for unit-level traceability, all supply chain partners, including manufacturers, repackagers, wholesalers, and dispensers, must send data electronically. Additionally, it mandates that the packaging hierarchy of aggregated data be included in then EPCIS file and electronically transferred to the supply chain partner for electronic traceability. The DSCSA 2023 Act would ultimately replace the requirement for lot-level traceability with unit-level traceability, and all supply chain participants would be required to electronically share serialized data using an interoperable technological manner. Additionally, this clause will make it easier for the pharmaceutical industry to adopt and use a robust system. For product traceability, the electronic traceability system should be able to store and handle large volumes of data [15]. The European Medicines Agency (EMA) and the European Commission are connected to more than 50 regulatory organizations from 31 different countries through a broad global network. The safety of every drug sold on the EU market is regularly evaluated by the European system of drug regulation. According to EU Directive 2011/62, all medications—aside from those on the whitelist—must be validated and identified [16, 17]. Generic and prescription medications are frequently imported into the United States. In 2018, the DSCSA required that pharmaceutical makers serialize all prescribed medications sold in the US market. Despite their best efforts, regulatory authorities in the US market continue to face difficulties with drug counterfeiting [18]. The FDA and DSCSA have worked hard to firmly manage the supply chain by enacting stronger regulations and sanctions in order to address this problem [19].

3. Pharmaceutical Supply Chain

The procedure of obtaining a product from its maker and delivering it to the end-user (consumer) is referred to as a supply chain. Any product can have a supply chain, including those for apparel, cars, and even medical supplies. The

healthcare supply chain, like other supply chains, comprises a large number of participants, starting with the provider of the raw materials and moving on to the manufacturer, wholesaler, and distributor, and eventually the pharmacist and the client [20]. The digital supply chain has been referred to as an intelligent, customer-centric, system-integrated, globally connected, and data-driven mechanism that leverages new technologies to deliver valuable products and more accessible and affordable services [21, 22]. The pharmaceutical supply chain is complex and regulated. Drug costs are greatly affected by the efficiency of the supply chain. In a competitive global environment, supply chain agility and reliability are the most critical elements to the success of an organization, but the current situation needs to be more assured [23]. The digital supply chain is part of the fourth industrial revolution, also known as Industry 4.0, that helps organizations connect ecosystems within their functional areas. The digital supply chain is called the smart supply chain, a new interconnected business system extending from isolated, local, and single-company applications to systematic smart implementations of the supply chain [24]. For supply chain management to accomplish the aforementioned goals, supply chain risk management (SCRM) is a critical and integral component [25]. Therefore, to lower and limit the likelihood of unfavorable events and their effects, it is crucial to identify, evaluate, and prioritize all risks [26]. Its goal is to manage the risks of intricate and changing supply and demand networks [27]. Supply chain integration has become an important trend in the pharmaceutical industry. A supply chain that is genuinely integrated does more than merely decrease expenses. Additionally, it generates advantages for the company's customers, shareholders, and collaborators in the supply chain [28, 29, 30]. The goals of supply chain management (SCM): accessibility, quality, and affordability will be met by health systems through managing hazards in the pharmaceutical supply chain, which can also result in process optimization, productivity growth, and the reduction of business risk [31].

4. Ongoing Problems with Digital Drug Traceability in the Supply Chain

In practice, supply chain risk and uncertainty are frequently used interchangeably [32, 33]. Uncertainty and risk in the supply chain can take many different shapes and have a variety of sources, effects, and drivers. Internal operations uncertainty and risk can refer to an unanticipated occurrence, result, and/or accident that occurs during internal processes. Furthermore, it gives drug traffickers and counterfeiters a chance to sell drugs on dark web sites and social media. People are drawn to buying medicines online for a variety of reasons, including geographic restrictions, lower prices, quick time to market, direct client targeting, and more customer reach [34]. The requirement for manufacturers or supply chain actors to produce, record, and share serialized event data with clients and regulatory agencies is another significant barrier to the deployment of pharmaceutical serialization [35, 36]. Data must ultimately be shared on a constrained and secure network. Data must ultimately be shared on a constrained and secure network [37]. These events typically happen in pharmaceutical companies and include decision-making errors, quality problems, machine failures, mistakes, unexpected costs, etc. The pharmaceutical industry's engagement in medication development has made it clear that there is quality-related uncertainty and risk. Supply uncertainty and risk, demand uncertainty and risk, and environmental uncertainty and risk are the three basic components of external uncertainty and risk [38, 39]. There are two risk management approaches that can be used to control the inherent risk in a system: lowering the uncertainty at the source or managing it without attempting to influence, change, or even identify the source. Instead, the second strategy looks for ways to adapt that would minimize the risk's impact [40]. Recently, COVID-19 also significantly contributed to the collapse of their entire healthcare system. Global supply chain limits and resource scarcity have an influence on developing nations, causing inflation and unemployment [41]. At the same time, strategies for reducing supply chain risk and uncertainty, both internally and externally, are taken into consideration. In a real-world setting, occasionally, even a minor error or malfunction might cause an interruption. Additionally, risk and uncertainty frequently coexist, and both have an impact on decision-making. Like other industries, the supply chain in the pharmaceutical industry begins with the sourcing of material for production. Active pharmaceutical ingredients (API) along with other inactive materials are planned to be formulated into standard dosage forms and filled into primary and secondary packages with different configurations. From the warehouses of manufacturers, finished goods are moved to distributors, retail and hospital pharmacies, and then consumers. In contrast, the flow of information and money begins with end users and travels through many channels to producers [42].

5. Pharmaceutical Supply Chain improvement with Digital Drug Traceability

The application of new technology to improve product quality and R&D processes, streamline current manufacturing procedures, and cut down on wasteful rework is the other improvement strategy. Pharmaceutical businesses can boost flexibility, product quality, and customer pleasure by investing in cutting-edge technology [43]. Additionally, responsiveness can be increased by cutting down on production lead times. All of these actions enhance both actual sales and market share. According to studies, environmental uncertainties are related to the requirement for new technology to be adopted more quickly in order to be more adaptable and responsive. By investing in cutting-edge technology, pharmaceutical companies may increase flexibility, product quality, and customer satisfaction. Additionally,

reducing production lead times might improve responsiveness. All of these activities increase market share and actual sales. Studies show that the need for new technology to be adopted more quickly in order to be more flexible and responsive is related to environmental uncertainty [44]. Lack of medical information exchange not only compromises the healthcare supply chain's effectiveness or prevents organizations from tracking and tracing medicinal supplies, but it also puts patients' safety at risk. In the healthcare sector, a lot of data is produced every day. The information covers patient care, record keeping, and compliance and regulatory needs. The cost of healthcare can be decreased, and the quality and efficacy of the healthcare system can be enhanced if the data can be evaluated, transformed into information, and shared throughout the supply chain participants. Additionally, it has been shown that clinical therapy, rather than customer or patient demands, is what drives medicine dispensing. The clinical preferences of the physician play a major role in drug selection. Patients or end users who lack medical training cannot completely understand medical procedures and make informed product choices for themselves [45].

6. Blockchain Technology for Preventing Drug Counterfeiting in the Supply chain

Blockchain is a distributed ledger technology architecture that is decentralized. It is made up of a series of blocks that each carry transaction data [46]. If the link is broken, the chain is no longer valid. A blockchain system is a type of distributed immutable database; once data is stored, it cannot be changed [47]. A block often includes a timestamp, a unique identification number (UUID), and other pertinent data, such as a list of transactions [48]. For monitoring reasons, this level of transparency offers a large amount of detail. The network is strongly reliant on the nodes' ability to maintain records. Each node maintains an exact copy of the blockchain and comes to an agreement as a whole every time a block is added to the chain using a consensus mechanism, as there is no central server or authority to assure the integrity of the data [49]. The metadata of the blockchain is found in every block: A nonce is sometimes referred to as a proof-of-work, a timestamp, or the Merkle tree root for transactions in a block. It serves as a reference to the preceding block. To address the issue of trustworthiness, the concerned parties develop a consensus as a common basis for truth. It assures that all network nodes share the same data, eliminating data tampering by malicious parties. Security is the primary justification for using blockchain in the pharmaceutical supply chain. Blockchain transactions and data cannot be altered by a network participant thanks to its consensus method. A new transaction is published into the blockchain each time the ownership of a medicine changes, allowing it to track the movement of products across the network. Smart contracts are among the key justifications for using blockchain in supply chain management. A smart contract is a computer program that specifies the terms and conditions for providing services, sending items, and receiving payments from parties to an agreement. They operate automatically, enhancing the blockchain's intelligence and strength.

7. Conclusion

Management of the supply chain and logistics has grown in significance over the past few years. It has been taken into account that integrated supply chains and stakeholder participation not only increase supply chain performance but also help the healthcare sector deliver better patient care. As a result, it promotes process efficiency and improves patient safety. An in-depth analysis of healthcare supply chain and logistics management paints a clear picture of the best practices in five different countries. Modern risks to the US pharmaceutical supply chain will be addressed in a coordinated and planned manner. Leaders in pharmacy and healthcare are well-positioned to take the initiative on these initiatives. Technology will be essential in assisting with the security of the global pharmaceutical supply chain, even though numerous solutions will be required.

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