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Review Article

Serialized Drug Traceability in the Supply Chain Using Distributed Ledger Technology

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Abstract: Currently, Drug Counterfeiting is the biggest challenge facing the pharmaceutical industry. They are encountering this threat due to high market demand for the drugs and their profit margin. The lack of data transparency and traceability also lured criminals into the counterfeiting of drugs which, is impacting people's health and put their life in danger. Through the drug supply chain, a substantial portion of counterfeit drugs are injected and distributed through the healthcare supply chain network, so the supply chain plays a vital role in drug distribution and impacts patient lives. Through digitalization in the healthcare sector, Distributed Ledger Technology (DLT) provides a platform with ground-breaking results by providing a system for drug traceability with consideration of the critical requirements of transparency, privacy, and authenticity without involving any third party. In DLT, each distribution partner is registered to maintain transparency with the drug information. Real-time transfer of information about the change of ownership with date and time in the form of blocks gives visibility to all the partners in real time about the authenticity of drugs. This article will give information about the benefits of Distributed Ledger Technology to the pharmaceutical industry and the traceability of drugs from end-to-end of the pharmaceutical supply chain.

Keywords: Drug Traceability, Drug Counterfeit, Pharmaceutical Serialization, Distributed Ledger Technology, Supply chain, Blockchain, Track and Trace System

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1. Introduction

The World Health Organization (WHO) defines counterfeit drugs as those that are mislabelled to hide their source or identity by an unregulated organization. These drugs can have the wrong active ingredients or the wrong quantity of ingredients. Counterfeit products can include drugs with no active ingredient, drugs that are super potent, and drugs with dangerous impurities. According to the Centre for Medicine in the Public Interest, sales of counterfeit drugs are increasing globally at about 13 percent annually, nearly twice the pace of legitimate pharmaceuticals. The primary responsibility is to assign the authority to make medicines in accordance with national standards and to regulate the flow of all manufactured items [1]. Regulators and pharmaceutical companies have been compelled to act accordingly to stop the growing trade in fake medicines as a result. Fake medications can be either disguised or falsely represented [2]. Product serialization is still a major factor behind packaging reform in the pharmaceutical industry as it fights against fraud, duplication, deviation, and false returns to manufacturers. In order to decrease the supply of counterfeit drugs, serialization necessitates a sophisticated program to monitor and regulate the flow of prescription medications throughout the whole supply chain. Direct printing of 2D barcodes onto prescription medications, packets, and cartons is a requirement for serialization and labelling. Manufacturers, pharmacies, and hospitals use it to monitor their pharmaceutical products. Automatic

identification allows a customer to check the authenticity of a product by using labels. In addition, vision identification is used for real-time barcode recognition that can be applied to products in accordance with the FDA's specific product recognition requirements. Radiofrequency identification (RFID) is another sophisticated serialization technology used. [3]. The advancement of technology and the growing interconnectedness of the pharmaceutical trade have brought significant advantages to the global healthcare sector. As a result, individuals now enjoy increased access to essential medications from reputable sources. However, this shift has also opened doors for counterfeiters and illicit drug vendors to exploit social media platforms and dark web websites for medicine sales. Various factors drive people towards purchasing medication online, including overcoming geographical barriers, lower expenses, faster market entry, direct customer targeting, and broader customer outreach [4]. A recent trend focuses on patient-led interoperability, wherein patients play a central role in health data exchange [5]. Nevertheless, the healthcare sector is still in the early stages of building the necessary infrastructure, software solutions, and strategic approaches to effectively integrate diverse data types in a reliable, secure, and consistent manner [6]. Risk is especially common among people of Hispanic ethnicity with limited educational opportunities, living in impoverished conditions, lacking citizenship status, lacking health insurance, and facing significant out-of-pocket healthcare costs [7]. Concerns regarding the traceability of the pharmaceutical supply chain within healthcare are mounting due to issues related to effectiveness. The journey of a product from its manufacturer to the end consumer involves multiple stages, including production, wholesaling, retailing, and eventual consumption. Complications can arise at any point along this chain, ranging from minor human errors to the circulation of counterfeit medications. In our traditional system, pinpointing the precise location of these issues can be a challenging endeavour.

2. Distributed Ledger Technology Overview

The Distributed Ledger Technology (DLT) stands out as a paramount innovation of our century. It not only offers improvements in operational and regulatory verification but also elevates the traceability and transparency of supply chains across various industries [8]. The concept of Distributed Ledger Technology (DLT), often referred to as 'blockchain,' has ignited the interest and investments of financial services institutions [9]. Blockchain is a decentralized and distributed system where data is recorded, stored, and overseen by a peer-to-peer network of individual computers known as nodes. It comprises a series of unchangeable blocks, each bearing a timestamp and connected using cryptographic hashes. When a new block is appended to the end of the chain, it includes a distinct code or reference (referred to as a hash value) to the information appended in a preceding block. This specific hash value is generated by a one-way encrypted hash function [10]. Wholesalers and distributors are responsible for utilizing the cloud-based database hub to verify the authenticity of medications at various points within the supply chain as an integral part of the supply chain operation [11]. It enables systems and applications to operate autonomously, free from reliance on third parties and trusted authorities [12]. After the blockchain has completed its information processing, all computers within the network simultaneously establish a permanent, unchangeable digital record. Each blockchain system defines the process and permissions for adding new blocks to the chain [13]. The distinctive benefits of blockchain technology lie in its capacity to facilitate data and transaction sharing across an immutable peer-to-peer network, thereby improving transparency and security [14]. Although blockchain has primarily found use in cryptocurrency and financial transactions, other sectors like entertainment, manufacturing, and healthcare are increasingly incorporating blockchain technology to harness its enhanced security and privacy advantages [15].

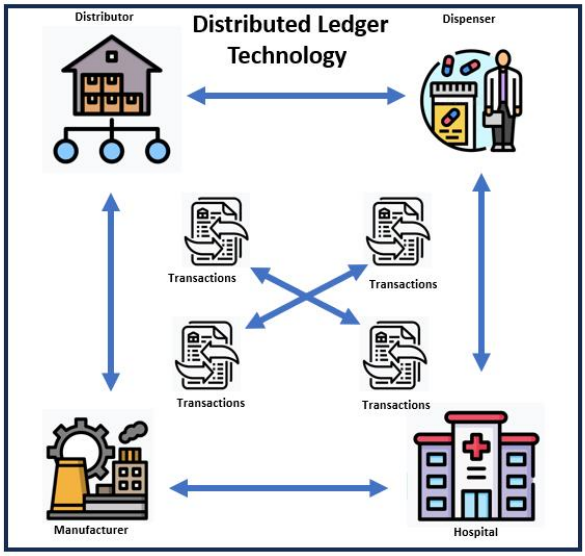

Figure 1. Distributed Ledger Technology in the pharmaceutical supply chain.

3. Core characteristics of Distributed Ledger Technology (DLT)

- Decentralization: A digital public ledger accessible to all network users, with data distributed across multiple systems. Blockchain technology is well-suited for any digital data that requires authentication and consensus on data integrity, and when shared write access is essential. It can effectively safeguard critical medical information [16].
- Traceability: Offers a comprehensive audit trail at every point in the supply chain, including historical records, ensuring the verification of drug authenticity. Enhancing the flow of health data would facilitate remote monitoring and telemedicine consultations by doctors. This, in turn, empowers patients to maintain open communication with their healthcare providers regarding their medical history [17].
- Immutability: Data remains securely preserved and is challenging to alter without full access from a node. As reported by the global cybersecurity insurance company Beazley, healthcare organizations were the focus of 45 percent of ransomware attacks in 2017 [18].
- Autonomy: Each node operates independently within the blockchain network, ensuring reliability and freedom from external interference.
- Transparency: This exceptional feature allows public access to every network node, enabling anyone to verify and track asset information.
- The healthcare sector places great significance on blockchain technology due to its role as a public ledger featuring continually updated and strongly encrypted cryptographic records that are unchangeable [19].

4. Need for Distributed Ledger Technology (DLT) for pharmaceutical drug traceability

Like all major and minor sectors, the pharmaceutical industry is undergoing substantial transformations to align with the evolving times [20]. Utilizing blockchain

technology for tracking and tracing has the capacity to revolutionize the pharmaceutical supply chain. Research has shown that DLT has the capability to significantly enhance transparency, efficiency, and the trustworthiness of transactions within the pharmaceutical sector, which often lacks stringent regulation. Through blockchain, manufacturers and other stakeholders in the supply chain can achieve real-time data access and improved visibility at every stage, commencing from the manufacturing point [21].

Major Highlights of DLT are:

- Enhance the transparency of drug or medication movement across all stages and stakeholders in the value chain. This heightened traceability supports the optimization of drug distribution and a more efficient inventory management system, resulting in significant enhancements in stock planning.
- The drug in transit can be monitored along the entire supply chain, ensuring visibility at every ownership juncture. Moreover, the transparent ledger simplifies the process of tracing the participants or entities engaged in the shipping process. Blockchain possesses the ability to pinpoint the origins of issues that might surface during the drug or medicine supply process.
- Entries are appended to the distributed ledger in an incremental fashion. This ledger is hosted within a peer-to-peer network, ensuring that all participants maintain identical copies of the ledger continuously.
- Blocks are generated exclusively after all network peers have validated and verified the transactions. This consensus mechanism ensures the accuracy of the information stored in the ledger.
- Pharmaceutical drug origins can be readily traced with the help of blockchain, as ownership transfers are permanently recorded in real-time on the immutable ledger.

Blockchain, an electronic cryptographic DLT, operates on a decentralized network model where data is shared and synchronized across all network nodes [22]. The system employs a consensus mechanism to prevent duplicate transactions, allowing nodes to validate data accuracy before it is promptly added to the ledger [23]. Blockchain is a decentralized architecture for distributed ledger technology, consisting of a sequence of blocks, with each block containing transaction data [24]. A thoughtfully constructed blockchain-based system can significantly simplify the management of pharmaceutical turnover for authorized government agencies. In contrast to centralized alternatives, a decentralized approach offers numerous advantages that enhance the security of information in these systems. A blockchain network comprises multiple computers collaborating under a shared protocol to process transactions and append new blocks to the chain. Every user within the public blockchain ecosystem has the capability to observe and scrutinize every transaction transpiring on the network, as well as participate in the consensus-building process [25].

5. Impact of Distributed Ledger Technology (DLT) in the pharmaceutical drug traceability

Pharmaceutical medication traceability systems refer to the systems designed to monitor the movement of products or product characteristics throughout the production process or supply chain. In this context, digital technologies are bringing about a

transformation in supply chains by enabling adaptable production, automation, and the implementation of sensors to monitor the whereabouts, quality, and authenticity of products [26]. Traceability requirements typically evolve according to specific circumstances. The information to be collected is determined based on the core needs and objectives of each organization. The most effective approach to combat illicit trade and address smuggling, in general, involves implementing robust traceability measures [27]. Implementing traceability systems in the pharmaceutical sector is a complex and often costly endeavour. Government regulations have enhanced the safety of pharmaceutical product distribution, with many countries, including the United States, adopting regulatory frameworks and mandatory requirements. This has led to heightened operational challenges for multinational manufacturers and distributors, necessitating the development of flexible systems to serialize products for different markets in alignment with regional regulatory norms [28]. Within a traceability system, managerial decisions encompass more than just preventing product substitution and falsification during crises. Different stakeholders within the supply chain often place varying degrees of importance on traceability, whether for enhancing risk management or streamlining operational processes. This, in turn, offers consumers an additional layer of value primarily associated with product quality and safety. Beyond ensuring regulatory compliance, traceability serves as a tool producers can leverage to avert disruptions in market supply that might harm their brand reputation [29]. Fundamentally, traceability is an integral element of quality management. Striving to improve and enhance data collection, plant control, and quality assurance can also act as a driving force for the creation of a state-of-the-art internal traceability system. Furthermore, as outlined by Moe (1998), the development of a data model is imperative for monitoring fluctuations in the quantity of unit-traceable resources over time or the historical record of process activity [30]. Currently, there are no globally accepted standards in place. The implementation, coordination, and control of serialization require a significant financial commitment and a thorough understanding of the relevant regulations [31]. The primary objective of instituting a traceability system is to reassess the responsibilities and objectives within the entire realm of supply chain management. Within a traceability system, managerial decisions encompass more than just crisis-related actions like preventing product substitution and falsification. Traceability often holds varying degrees of importance among different supply chain participants, serving purposes such as enhancing risk management and streamlining management processes. This ultimately delivers added value to consumers, predominantly in terms of product quality and safety. Beyond ensuring regulatory compliance, this tool enables producers to proactively avert disruptions in market supply that might harm their brand reputation [32].

6. Conclusion

Within a blockchain platform, Distributed Ledger Technology, with a strong focus on cost-efficiency and safety, holds the potential to enhance pharmaceutical cold chains and combat the counterfeiting of medicines. This research outlines how a blockchain-based DLT system can be beneficial for tracking drugs and identifying counterfeit medications throughout the supply chain. To tackle data storage challenges, blockchain platforms can integrate with cloud storage components. Blockchain possesses the capability to integrate vast and diverse data from multiple sources, effectively enabling the tracking of medication fraud. This technology empowers the tracking of various elements within the pharmaceutical supply chain, including medical supplies, prescriptions, and even temperature monitoring, at any given time. Achieving the right blend of technologies for the redesign of an end-to-end channel design that aligns with the organization's strategic plan requires increased coordination and collaboration between engineering and technology experts and key business decision-makers.

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