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Blockchain Technology: A Novel Approach to Pharmaceutical Supply Chain

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ABSTRACT

The pharmaceutical supply chain (PSC) contains various nodes including manufacturers, distributors, wholesalers, pharmacies, hospitals, and patients. Thus increasing the complexity of the process and full of loopholes which increases the chances of counterfeiting medicine. This leads to an increase in the need to develop an immutable, trustworthy, transparent and accountable system, more advanced than PSC. The main loophole in the current PSC system is drug changes ownership over every transaction making it hard to trace before it reaches the customer. In the current system, nodes do not exchange information, manufacturing doesn't know what happens to the product, and visibility to regulatory authorities is near zero, recalls are complicated and costly. Problems like traceability, visibility, and security in the current drug delivery systems are explained in this review paper, and methods to solve them are elaborated in the same. Drugs produced by manufacturers can be traced from manufacturing to delivery to the patient and after the administration for survey purposes also. The proposed system will also make it possible to retrieve and store data of patients for future statistics. By using blockchain we can store data of transactions and only certified personnel will be allowed to join and push data on the blockchain.

Keywords: Blockchain, counterfeiting, supply chain, drug traceability

INTRODUCTION

Write Medical product counterfeiting is one of the biggest problems in society today when it comes to health issues and patient care. Counterfeit medicines are copies of genuine medicines, but are not authentic and may be subtherapeutic, have no therapeutic value, or be harmful to patients. According to the World Health Organization (WHO), in developing countries, one in ten medicines is counterfeit. This counterfeit business is worth over $600 billion.[1] Manufacturers have no control over counterfeiting in the current market. This is due to the outdated supply chain system used in today's market. This undermines the market position of manufacturers, hospitals, pharmacies, and wholesalers. These drugs are subtherapeutic or have no therapeutic value. When patients with malaria, tuberculosis, cancer, antibiotics, or other diseases take counterfeit medication, it can lead to drug resistance and serious side effects, and even death in patients taking the wrong medicine.[2] Millions die from counterfeit drugs for tuberculosis and

malaria.[3] In European countries, the number of counterfeit medicines has doubled from the previous year. This is a modernist 21st-century crime according to the FBI.[4]

The current supply chain does not contribute to controlling drug counterfeiting in the current industry, so new systems must be put in place to solve the counterfeiting problem. Blockchain technology could be the solution to this problem. Blockchain is currently in use in Bitcoin and other financial assets, but recently there has been an increase in the use of blockchain in the medical field as well.

PURPOSE

With all the issues mentioned in the abstract section, we realized that the conventional supply chain system in the pharmaceutical industry needs an upgrade. One of the ways to get an upgraded supply system, which will improve the safety and security of the drug's supply chain and add traceability and visibility to both manufacturer and the customer or any individual in the chain, is to incorporate features of blockchain technology. In the current scenario, where we want to protect privacy and allow accessibility at the same time, blockchain technology is the best choice. When the product is released by the manufacturer, the whole journey of a product from the company to wholesaler, distributor, pharmacist, and at the end to the patient, the transactions are documented and a permanent record of the product is maintained. This reduces time, cost, and human errors which would otherwise occur in the conventional transaction.

1. **Improved trust and transparency**

An additional workload of maintaining a separate database would be there for organizations without blockchain. Data in the blockchain is recorded in multiple places as it uses a distributed ledger which is shared with every node and contains the same information. Patients can track product status at any point along the chain, increasing trust and customer satisfaction. Manufacturers can be sure that the products they want to deliver have arrived safely at their intended customers. Customers, on the other hand, get genuine products developed by legitimate manufacturers. The system efficiently manages information such as price, production area, date of manufacture, and expiration date. Counterfeiting can be easily eliminated by using this available information.

2. To improve traceability

When the batch is ready, every product will be registered on the blockchain and then they are released. So at any point in time, products can be traced and authenticated. The manufacturing team digitizes physical assets and the record of all the transactions is decentralized and once it is digitized it cannot tamper. Hence it is immutable. Therefore, end-to-end tracking in the supply chain is achieved.

3. To protect privacy and visibility

Blockchain technology guarantees to verify the authenticity of data that is made available publicly while keeping the private data of an entity secret and no compromise on privacy is made. In the pharmaceutical supply chain system, the manufacturer's method of production and techniques are kept confidential. Also, in the case of medical records, the patient's data will be accessible only to the individual with a key code.

4. Extended security

Blockchain is named one of the top secured ledger systems. Once the information is entered into it, it is immutable. It cannot be modified or deleted. Hence, makes it secure from hacking. Private Blockchain are more secure than public ones. Only allowed participants are granted the privilege to access data.

5. Database for future statistics

Digital ledgers of transactions are duplicated or distributed across the network

of participants. Hence, the same information is stored with each participant. For example, the adverse effect of a drug can be recorded for future studies. Keeping this type of information was not secure in earlier conventional databases. But using blockchain technology it can be securely stored.

WHY SHOULD WE USE BLOCKCHAIN?

Blockchain has many advantages over the standard supply chains used in today's industry. It does not require a third party because every affair which is done over the blockchain is stored with a time stamp. It also does not require a central server because it shares a record with multiple participants. Every registered system has a local copy of the same ledger which detects any major or minor changes in the system. Any change occurring is replicated in the whole network thus if any problem arises in one of the systems the entire network is not affected by it. Blockchain is one of the best technologies which can be used for providing cyber-security in today's pharmaceutical industry. It prevents problems from the old systems in use which was a single person tampering with data and the process, this may very well prevent counterfeiting of drugs and increase the trust and privacy between the industry and the customers. Blockchain makes a product a digital asset and this asset can be exchanged anonymously by the participant's i.e. the Supplier, wholesaler, retailer, customer, etc. Blockchain also provides transparency as the whereabouts and the transfers and every transaction of the product are known and recorded and kept in the database making it easy to find out its origination point and every milestone. By using blockchain a pharmaceutical product becomes just like cryptocurrency. It becomes a digital asset. The participant is anonymous and is assigned a key pair for identification and transactions occur from one public key to another public key of a participant.

Smart contracts are also another huge part of why we should use blockchain and why it is so effective. Smart contracts are automated and self-executing and contain the agreements and terms and conditions of a contract directly in the code. Self-executed when certain conditions are met. This may give an extra edge over the already efficient process.

HOW DOES BLOCKCHAIN WORK?

This section describes how this modern data logging technology works. Blockchain is a node-to-node secure data network that works cooperatively with each other and validates all the transitions. It consists of various nodes i.e. separate databases where all the information is stored and then verified whenever a transaction is being made. Blockchain is like a shared excel sheet where all the nodes have the same copy of the excel sheet and all the data is being shared with each of the nodes i.e. separate server, this excel sheet will display the same information and that can be used for further transaction verification. If any node will tamper with the data present on the blockchain it will reflect in the data of that individual node but when the system will cross-check the data on the blockchain, it will recognize the tamper in data and will not allow that node for further transactions.

Now let's see how we can apply. When a product is manufactured in the industry while handled over to a wholesaler manufacturer will produce a unique hash code that will be a unique ID for that product throughout the journey to the patient. After generating the hash code product will be considered a digital asset and this asset will be transferred throughout the journey from node to node. All the basic information will be available online and excess information can be stored offline as well according to the preference of the manufacturers or the distributing party. Majorly it's convenient to store text data online in blockchain and other heavy data like images, videos, or any other files offline. Once registered the digital asset can

be easily transferred from node to node, thus increasing the traceability of the product and giving trust to the patient and doctor for authenticated medicine.

Let's say that a Manufacturer sells a product to the wholesaler, if it's done using the old PSC system the transfer would take a lot of paperwork and manpower also then the Manufacturer will be cut off the data chain that he will now not know what has happened to the product. But if this process is done using the novel blockchain technology the Manufacturer product first will be registered into the database and converted into a digital asset known by its hash code i.e. unique code for every individual product. Now when the product is to be transferred to the wholesaler the Manufacturer will scan the hashcode and QR code generated by the system. This will record that the Manufacturer has dispensed the product to the wholesaler and this action will be recorded onto the system. Now the wholesaler while receiving the product will scan the same hash code and QR code generated by the system. This will ultimately record that the product has been received by the wholesaler. This same process will be continued further and at every node, the data is fed into the system. Now every step carried out has been recorded and every node in the blockchain can easily review the data and any counterfeiting of the medicine can be detected easily.

IMPLEMENTATION

To implement the features of blockchain technology in the drug supply chain system, we should know how the blockchain ledger works beneath the surface. A ledger records all the transactions and the transaction data is organized into assets. Blockchain has an internal mechanism of identification; the system consist of a key pair, which is cryptographically secure. Each participant is assigned a specific key on the network. A participant can be a system or an individual. The keys represent the original identities of the participants. The identity of the participant is kept confidential. But additional information, for example, name, contact, or professional credentials can be associated with it.[5] To protect the data, the additional information off-chain is merged with on-chain data that is, an assigned key using their IDs. In the case of pharmaceutical supply chain management, the participants can be the manufacturer, packager, distributor, pharmacist, doctor, etc. The participants are identified by their unique key pair on the network. Drugs are considered assets, each with a unique key (or hash). The ID will be related to the drug in the form of a QR Code. The system is implemented in different ways based on one's preferences. A lot of third-party APIs are also available in the blockchain networks.[6-8] The services provided by these APIs are different. Regardless of the APIs we choose, the working of the system will be the same.

It is crucial to select a specific blockchain network for storing transactions. The two major types of Blockchain network are – Public blockchain and Permissioned or private blockchain. [9,10] Permissioned blockchain networks are limited to the participants, who have the key to access. Hence, restricting others from accessing or changing the data. The best choice is to use a permissioned blockchain network in the pharmaceutical supply chain. The next step involves saving the transaction record by using a specific blockchain network, but it comes down to the developer's choice. A few of the types of blockchain networks that are available in the market now are Bitcoin Blockchain, [11] Ethereum, [12] Hyperledger, [13] BigchainDB, [14] etc.

CONCLUSION

The paper proposes the use of blockchain technology in the pharmaceutical sector. The issues of counterfeit drugs in current pharmaceutical supply chain management and how blockchain can be used to overcome the problems faced by consumers/patients by improving the traceability and visibility of pharmaceutical

supplies has been pointed out. The elaboration on the mechanism of blockchain and how it is helpful for manufacturers, wholesalers, distributors, pharmacists, and patients to share data while keeping the important data confidential has been discussed.

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