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Construction of a Visualization System for Anti-counterfeiting and Safe Traceability of Pharmaceuticals based on Blockchain Technology

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Abstract: ***Under the current public welfare donation system, donation data is kept within charities, and it is difficult to ensure the timeliness and authenticity of information disclosure. Blockchain technology is a decentralized distributed database with characteristics such as information traceability, data transparency, and non-tampering, which can effectively resolve the trust crisis in the charity industry. The establishment of a public welfare donation platform based on blockchain technology can effectively connect donors, charities, regulatory agencies and recipients, making public welfare donations safe, credible and documented, and promoting the construction of a healthy development of the public welfare ecosystem.***

Keywords: blockchain technology, pharmaceuticals, Visualization System.

1. INTRODUCTION

In recent years, serious violations of law and trust in China's domestic production and sale of counterfeit, shoddy and illegally operated medicines have been repeated, causing great infringement on the legitimate rights and interests of the general public. According to statistics, in 2017 alone, a total of 369,318 illegal cases of food and drugs were investigated and dealt with nationwide, of which 112,318 were drug cases, and the number of major cases has increased significantly.

China's drug safety supervision has manifested itself in the form of government regulation as the main means, whether it is the direct control of business operations during the planned economy or the implementation of the drug production and operation licensing system and the market access system during the market economy, which all reflect the strong position of government regulation. Formed in contrast, the role of the market, social organizations, and the public in drug safety regulation has been disregarded.

In the centralized bidding and purchasing activities for medicines around the world, the phenomenon of false cost and inflated pricing still exists. Some drug companies in the bidder's identity in the bidding offer times lower than the cost of the offer, disrupting the market order; some enterprises and other enterprises collusion offer, so that other bidding enterprises can not participate in the competition fairly, damage to the legitimate rights and interests of the bidders and other bidders; some to the bidder, bidding agency or bid evaluation experts to bribe the means to obtain the winning bid; some enterprises to provide false proof, or forging the other way to win the bid; worse still, the bidder withdraws its bid within the validity period after the opening of the bid, and the winning bid within the prescribed time. Some enterprises provide false certificates or falsify other means to win the bid; some even withdraw their bids within the validity period of the bidding after the bid opening, and the successful bidders do not sign the corresponding purchase and sales contracts or do not fulfill the obligations stipulated in the contracts within the specified time, and so on.

The essence of blockchain is a secure and trusted distributed database, which is the underlying Internet peer-to-peer technology serving the distributed ledger. Blockchain technology is a technology that uses a decentralized consensus mechanism to maintain a complete, distributed and tamper-proof ledger database, which enables blockchain participants to realize a unified ledger system without the need to establish a trust relationship. Through the super ledger of the coalition chain therein, various production information and logistics information of pharmaceuticals are uplinked and processed, which has the characteristics of decentralization, natural mutual trust, tamper-proof data, and multi-channel, etc. Combined with the traceability of pharmaceuticals, it can not only ensure the trustworthiness of the traceability data, but also provide an architectural foundation for the realization

of credible traceability of pharmaceuticals.

2. BLOCKCHAIN CHARACTERISTICS AND THEIR CONNOTATIONS

2.1 Blockchain Concept

The concept of blockchain comes from the 2008 paper "Bitcoin: A Peer-to-Peer Electronic Cash System" published by a scholar named Satoshi Nakamoto (Satoshi Nakamoto), which exists as the underlying technical support for Bitcoin. Blockchain is a shared ledger with distributed encrypted storage of data, integrating the results of computer networks, probability theory, cryptography and other disciplines, with decentralization, natural mutual trust, data tampering and other characteristics, and has been used in a variety of fields, such as finance, energy, credit, trade and so on.

2.2 Hyperledger as a blockchain implementation

Blockchain is categorized into public chain, private chain and alliance chain according to its openness to the public. The public chain can be participated and maintained by all people, and the information in the blockchain is also open to the public, for example, Bitcoin, and the private chain and the coalition chain can be realized by introducing the identity verification mechanism on the basis of the public chain; the private chain only allows the participation of a small number of people within an organization, and the degree of confidentiality of the information is required to be relatively high, which is usually found in the internal system of the enterprise; the coalition chain, which is in the middle of the public and private chains, can be jointly participated and maintained by several organizations, and the information stored is also shared by these participants. The current mainstream blockchain implementations are Ether and Hyperledger. Ether is a public chain, which has a low level of data confidentiality and is not easy to be managed by the participants; compared to Ether, Hyperledger is a federated chain, which has the advantage of permission control and a high level of security, so this paper takes Hyperledger as the blockchain implementation to design a blockchain-based drug safety traceability system.

2.3 Super Ledger Features

Hyperledger Fabric has the characteristics of decentralization, natural mutual trust, data tampering, multi-channel, etc.

2.3.1 Decentralization

The storage structure of the super ledger is distributed, all nodes in the super ledger keep a full backup of the same ledger, and all nodes jointly maintain this ledger; secondly, there is no centralized manager in the super ledger, all PEER nodes can issue a proposal and synchronize the new data to the backup data of each node after passing the consensus mechanism, which will ensure that the control of the drug traceability system will not be controlled by a controlled by a few users.

2.3.2 Natural mutual trust

The Hyperledger belongs to the alliance chain, which requires it to control user privileges. For this reason, the Hyperledger has a built-in authentication function based on cryptographic mechanisms such as certificates, which ensures that only the organizations specified in the alliance become Only members can initiate operations on the ledger, and in the event of drug quality and safety issues can be directly traced back to the initiator of the traceability data, and the certainty of identity ensures mutual trust among members.

2.3.3 Non-tampering with data

The data is encrypted and saved in the Merkl tree of the block, synchronized with the block into multiple nodes and persisted, and closely associated with the adjacent blocks before and after through the Hash value. This series of encryption measures improves the difficulty of data tampering, thus guaranteeing the security of drug traceability information. First of all, if you want to realize changes to the data in a certain block, you have to continue to modify all subsequent blocks and the corresponding backups in each node; secondly, the super ledger is distributed storage, so if the data in a node is destroyed, other nodes can restore the data to that node, which also improves the fault tolerance of the blockchain system.

2.3.4 Multi-channel

Multi-channel is a unique concept of super ledger, there exists a ledger in a channel, this logical structure can isolate the ledgers from each other; the ledgers can not communicate directly with each other, which ensures the confidentiality of the ledgers; the operation of different ledgers requires different identity encryption information, which ensures the privacy of the data in the ledgers, and the multi-channel provides an architectural foundation for the realization of the subsequent dynamic traceability mechanism.

3. ADVANTAGES OF BLOCKCHAIN DRUG SAFETY TRACEABILITY SYSTEM

First of all, it solves the technical problems of the Internet of Things. Traditional traceability system because the number of nodes is too large, the central platform to centralize the management of data nodes and data, Internet of Things and the central platform data interaction is difficult to achieve, however, blockchain technology can be block and recorded to the blockchain, into the whole traceability system. Secondly, it promotes the unity and effectiveness of product data. All the data in the blockchain are instantly updated and stored in the database of each node. The data of any node in the whole chain can be extracted to verify the correctness of the data of other nodes. In the whole system, only if most of the nodes recognize the transaction and the feedback results are all passed, this transaction can be uploaded to the ORDER node to generate a block and broadcast to all bookkeeping nodes. Under this framework, the transaction information of the quality traceability system is jointly maintained by all nodes, which not only facilitates big data analysis by all parties, but also reduces the risk of the traceability management system being hacked or the central database being tampered with. Third, a new commercial trust mechanism is established. Based on the characteristics of blockchain single node uploading information and multi-node common maintenance, blockchain can create a new commercial trust mechanism. It can truly realize the management concept of "responsible body has a record, production process has a record, the main responsibility can be traced, product flow can be traced, risks and hidden dangers can be identified, the degree of harm can be assessed, and regulatory information can be shared". Fourthly, the responsible body is clear, and the traceability cost is low. Distributed ledger makes destroying part of the node database has no effect on the overall data security of the system, and the data recording process is open and transparent. Based on the characteristics of the reliable database, blockchain data can not be faked, and after the discovery of drug safety and quality problems, the nodes that cause problems are directly clarified through traceability, and there is no need to consider the authenticity of the data, which greatly reduces the cost of responsibility and improves the efficiency of traceability. Fifth, curbing counterfeits from the source. On the one hand, this system adopts electronic labeling technology, so that illegal traders are not able to copy the label content. On the other hand, the blockchain, through the CA access mechanism, has the feature that a transaction is recorded by all nodes, and the database of the whole chain cannot be tampered with, which ensures that counterfeit goods are curbed from entering into circulation at the source.

4. BLOCKCHAIN-BASED DRUG SAFETY TRACEABILITY SYSTEM

In order to solve the current contradictions faced by China's drug safety, based on the characteristics of blockchain, this paper designs a model of drug information traceability system based on blockchain technology, which provides a solution to solve the drug safety problem to a certain extent. Based on the general aspects of drug circulation in China at present, with full consideration of the scale effect and management difficulty, the participants of the blockchain drug safety traceability system model are set as 7 nodes, including consumers, pharmaceutical factories, logistics centers, hospitals, pharmacies, and regulatory departments. Data is shared in real time among the nodes, and effective tracking and tracing of data is realized under the premise of guaranteeing authenticity.

4.1 System core nodes and collaborative traceability process

Drug safety and quality traceability involves drug production, storage and transportation, bidding, purchasing, sales and other links, and efficient collaboration between the various modules of the system is an important guarantee for realizing effective traceability of drug quality and safety. The drug quality traceability system constructed by applying blockchain technology includes six core nodes, which are: nodes of pharmaceutical factories, nodes of logistics centers, nodes of hospitals, nodes of pharmacies, nodes of consumers and nodes of regulatory departments. The steps of the traceability process are as follows.

Step 1 Pharmacy node information collection.

After obtaining the corresponding production authority, the pharmacy node produces drugs and identifies the

unique traceability code, collects production management and information, and uploads data such as enterprise subject filing, transaction information filing, drug traceability code information and production management information, drug production batch number, and expiration date.

Step 2 Pharmaceutical Sales Company Node Information Collection.

Pharmaceutical sales companies, including the pharmaceutical company's own interests related to the sales company or through the winning pharmaceutical sales company to promote the sale of drugs, in the pharmaceutical company in the pharmaceutical company of each outgoing and incoming information must be uploaded to the distributed database in a timely manner.

Step 3 Pharmaceutical logistics center node information collection.

Pharmaceutical logistics center nodes, after obtaining the appropriate authority, through the collection of management and information collection, will be the main body of the pharmaceutical logistics enterprise filing, as well as the relevant transport information, including shipping address, delivery time, the address of the receipt of goods and other information on the chain.

Step 4 Hospital node information collection.

After obtaining the appropriate permissions, the hospital node will uplink data such as hospital subject filing, information on consultation with consumers, and time of medicine collection through collection management and information collection.

Step 5 Pharmacy node information collection.

After obtaining the appropriate permissions, the retail pharmacy node will upload data such as the main body of the pharmacy filing, information on the batch number of drugs purchased by the pharmacy, commodity information and purchase time of the consumer purchase transaction data through information management and collection.

Step 6 Regulatory and Supervisory Processes.

Drug safety and quality traceability is characterized by public welfare, complexity, chain, system and coverage. The construction of drug safety and quality traceability system cannot be separated from the government's supervision and management, the quality inspection department and other relevant organizations play a leading role in ensuring drug safety and other issues, the government supervision and management functions throughout the entire process of drug traceability. The supervisory authority will accredit pharmaceutical factories, logistics centers, hospitals and retail pharmacies, add their terminals as nodes in the alliance chain, and at the same time upload the supervisory information; and make corresponding adjustments or rewards and punishments to pharmaceutical factories, pharmaceutical sales companies, pharmaceutical logistics centers, hospitals, and retail pharmacies according to the information of the production, processing, transportation, storage and sales of medicines, as well as the feedback from the consumers.

Step 7 Consumer Traceability Process.

The consumer node, after obtaining appropriate privileges, inquires about the entire transaction process by scanning the drug electronic label on a specific device, and uploads feedback information (e.g., complaint information, evaluation information of the product, etc.) through this device.

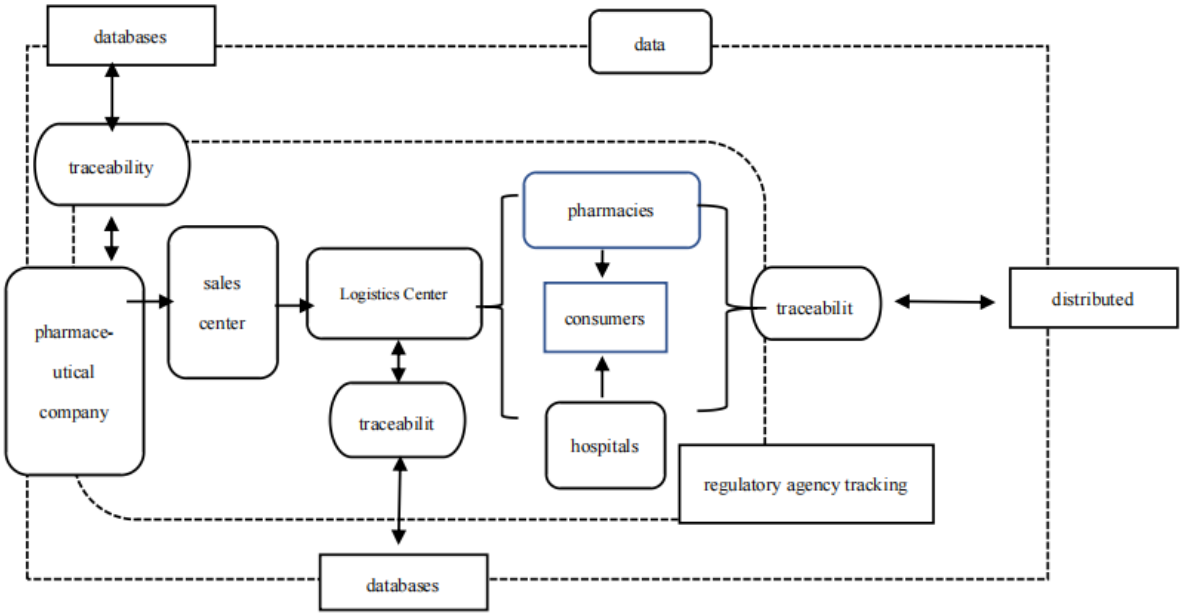

Figure 1: Drug anti-counterfeiting and safety traceability system model

4.2 Overall Architecture of Pharmaceutical Anti-counterfeiting and Safety Traceability Platform under Blockchain

By introducing blockchain, each participant controls the nodes on the network. A consensus is required for each transaction to ensure that the product starts from production, and at all stages of the supply chain, so that pharmaceutical products from production, quality control, warehousing, out of warehouses, distribution, use and other aspects of the blockchain gradually establish standards to comply with the blockchain traceability. In terms of information flow, all information is in the blockchain and supports access to it by authorized nodes. Access to information depends on the roles and functions of the participants in the supply chain. Another core feature is the privacy protection of special and private data in pharmaceutical product traceability. Pharmaceutical companies are reluctant to share a lot of special information with others, blockchain technology enables information that exists in different pharmaceutical companies to be shared through the blockchain while keeping the information secure.

In the model, each link in the industry chain and module management service are composed of appropriate number of independent modules, and the modules are integrated with backend service programs and peer nodes with operation rights to the account book of the link, which can independently handle the transaction requests of the link subjects and store the traceability data securely; the link modules interact directly with the module management service, and the link modules communicate indirectly with each other through the service; the module management service is at the core of the traceability model. The module management service is at the core of the traceability model, which is responsible for managing and deploying the links in the system, handling the query requests from the quality supervision department and consumers, and realizing the dynamic combination of the links to achieve flexible traceability.

4.3 System Architecture of Pharmaceutical Anti-counterfeiting and Safety Traceability Platform under Blockchain

Based on the above analysis, this paper tries to construct a pharmaceutical anti-counterfeiting and safety traceability platform based on blockchain technology, and the overall architecture of the platform is mainly composed of interaction layer, application layer, storage layer and data collection layer.

4.3.1 Data Acquisition Layer

The data collection layer, which consists of pharmaceutical factories, pharmaceutical sales companies, pharmaceutical logistics centers, major public hospitals, retail pharmacies and other participants in the intermediate links of the industrial chain. The pharmaceutical traceability code is a code used to uniquely identify

the packaging unit of pharmaceuticals at all levels of sales, and consists of a column of numbers, letters and/or symbols. The composition of the drug traceability code shall meet the following requirements: a) it can be composed of numbers, letters and/or symbols, including all the characters in the table of GB/T 1988-1998; b) it contains the drug identification code and ensures that the drug identification code is kept unique at all levels of the sales package of the drug; c) it contains the production identification code: the production identification code shall contain the serial number of the single product, and can, according to the actual demand, contain the drug production lot number, production date, expiration date or expiration date, etc.; d) Contain check digits to verify the correctness of the drug traceability code. Through the traceability code of the drug and the supporting drug scanning equipment, the data of each link is exhaustively collected to realize the information input of the complete drug industry chain.

4.3.2 Storage layer

The storage layer consists of the super ledger and the traditional centralized database, which keep the traceability data and non-traceability data respectively. Each link in the industry chain has its own specific identity in the corresponding ledger, and the publisher can be directly located according to the encrypted information of the traceability data, which ensures the non-repudiation of the data from the source; each link in the industry chain corresponds to a specific ledger, which reduces the complexity of the system and improves the expandability and flexibility; the ledger interacts with the module management service directly and is uniformly managed by the ledger, and the status information of each link module is also uniformly kept by the module information ledger, which realizes the standardized management and flexible management of the links and modules through the centralized management mechanism. The information is also saved by the module information ledger, which realizes the standardized management and flexible deployment of the links and modules through the centralized management mechanism. The super ledger cooperates with the traditional centralized database to store all the data in the drug traceability system.

4.3.3 Application layer

The application layer provides services for four types of roles: system administrator, data provider, quality supervision department, and consumers. The system administrator is responsible for maintaining the drug traceability system and the super ledger to ensure their stable operation; the data provider, i.e., the participant in the middle link of the industry chain, is responsible for collecting the traceability data in the industry chain and uploading them to the system; the quality supervisory department is responsible for supervising whether the drugs on the chain comply with the quality and safety standards, and warns about problematic agricultural products; and the consumer is the last link in the agricultural products industry chain, and he can inquire the traceability data of the agricultural products he purchased. traceability data of the purchased agricultural products.

4.3.4 Interaction layer

The interaction layer includes Web application, mobile APP, WeChat applet, traceability terminal, etc., which is the interface between blockchain drug anti-counterfeiting and safety traceability system and users, and provides fast and convenient way to operate the system.

5. CONCLUSION

While the use of blockchain technology can ensure that uploaded data is not tampered with, it cannot ensure that the data itself is not untrue due to human factors. In addition to legal and ethical constraints, it is also necessary to work with other IoT and sensor technologies to collect raw data. In addition to this, the pharmaceutical supply chain is a complex system that involves multiple organizations working in tandem. The prerequisite for blockchain application is the willingness of various stakeholders to share, so a certain amount of educational work is needed to guide enterprises onto the chain. Blockchain is only as a tool, and can not change the phenomenon of artificial counterfeiting, but through the introduction of a transparent system that includes multiple parties and more technical means, it can allow producers, regulators, and consumers to form a more binding supervision mechanism through the cross-validation of data. To solve the security problems in the field of drugs can not rely solely on technology, traceability is easy to break, anti-counterfeiting is difficult to attack. Solve the "traceability" is not difficult, how to solve the "source" is a long way to go.

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