

Blockchain technology in the production and supply of pharmaceutical products

Makarov A.M.

Pyatigorsk State University
Pyatigorsk, Russian Federation
mellin_22@mail.ru

Pisarenko E.A.

Pyatigorsk State University
Pyatigorsk, Russian Federation
gmu41@yandex.ru

Abstract — Blockchain technologies can be used in any industry where verification and logging of certain actions are required. In particular, in the manufacture of medicines it is necessary to have reliable information about the origin of the raw material from which the drug is made, and the process of production of the drug. Blockchain provides protection against counterfeiting and counterfeit drugs. The article describes the model of the contract system blockchain and the work of miners in the chain "manufacturer-pharmacy". According to this scheme, blockchain technology can be implemented in the production and supply of medicines. The proposed model allows us to trace the origin of pharmaceutical raw materials and medicinal products, to guarantee the quality of drugs entering the pharmacy warehouse and pharmacy. This will protect the market from counterfeit medicines.

Keywords — *pharmaceuticals, blockchain technology, mining, counterfeit drugs, digital signature, health information technology*

I. INTRODUCTION

The national security strategy of the Russian Federation among the national interests of Russia includes improving the quality of life and strengthening the health of the population. Health care is a strategic national priority of Russia. One of the strategic goals of the state health policy is to improve the vertical system of quality control, efficiency and safety of medicines [1]. Thus, the issues of quality control of medicines are one of the priorities of the state policy of the Russian Federation.

In the pharmaceutical industry, there is an acute question about the origin of not only the drugs themselves, but also the raw materials for their production. The world health Organization estimates that the global illicit market for counterfeit medicines is about \$ 30 billion [2]. And the world cannot yet completely get rid of counterfeit drugs.

Antibiotics and anti-malaria drugs are the most commonly counterfeited. The use of low-quality antibiotics is particularly dangerous not only for the people who receive them, but for humanity as a whole. Substandard or falsified antibiotics pose a threat of loss of medicinal properties for a whole class of drugs. This can lead to the inability to treat many diseases. Tuberculosis and peritonitis can again become deadly diseases.

And the world can't completely get rid of counterfeit drugs yet.

Pharmacologists analyze and assess the prevalence of substandard and counterfeit drugs, and the results of their work are disappointing [3]. This forces scientists around the world to address the issues of quality control and authentication of medicines entering pharmacies [4]. For this purpose spectrometry and spectroscopy [5, 6, 7], analytical chemistry [8] are most often used.

Manufacturers and suppliers of drugs as methods of combating the counterfeit medicines are developing their own monitoring systems, create a special labeling, analyze complaints from patients and members of the health care system, and so on. So there is no real system that allows us to trace the process of production of medicines from procurement of raw material to packaging, and ensures protection against counterfeit drugs.

II. METHODOLOGY

A. *Ways of appearance of counterfeit drugs in pharmacies*

In order to deal with the undesirable phenomenon, you need to understand its mechanism. Let's analyze how counterfeit drugs can get into pharmacies. There is no exact answer to this question, since the production of counterfeit drugs is illegal, and no one will give reliable information about the origin of such medicaments. However, experts in the field of pharmacy S. Plakhtin (St. Petersburg) and T. Starovoytova (Pyatigorsk) call as possible reasons for the appearance of counterfeit drugs the following:

- manufacture of unregistered drugs in an extra shift;
- purchase of cheap low-quality drugs in other firms and packaging them in new container;
- purchase of expired drugs with subsequent replacement of packaging and shelf life;
- the use of cheap low-quality raw materials for the production of medicines;
- non-compliance with production technology in small pharmaceutical enterprises.

To solve these problems, it is necessary to constantly monitor the process of drug production and record all the information in the register, which cannot be changed in the future. Such opportunities are provided by blockchain technology.

B. Areas of use of blockchain technology

Blockchain technology, which emerged as an economic experiment, was quickly applied in many different areas. For example, based on the blockchain-technologies has developed a system of tracking diamonds from their mining to jewelry sales, which allows you to verify the authenticity of diamonds and the lack of criminal element in their origin. Another promising area of use of new technologies is the system of housing and communal services (HCS) [9]. Here the blockchain is used for automatic allocation of payments for utilities, definition of debt, the appointment and granting subsidies.

Currently, blockchain technologies are being developed in the fields of education, notary services, oil production, production and bottling of mineral water, and others.

C. Blockchain in medicine and pharmaceuticals

Modern digital technologies allow solving the problem of authentication of medicines and their components using fundamentally different methods - using blockchain technology. The easiest way to use blockchain in pharmaceuticals is to track the origin and transportation of drugs and raw materials. The transparency of blockchain technology will protect drugs from counterfeiting. In addition, blockchain technology reduces the number of intermediaries in the pharmaceutical process, which will reduce the cost of drugs.

Using blockchain technology seems like the only solution to the problem. Full logging in the blockchain of all actions (transactions) that occurred during the moment of production and purchase of medicinal raw materials and before the drug was delivered to the pharmacy and to the patient, will ensure the legal origin of the drug of good quality. Thus, the new technology will make it possible to solve the problem of counterfeit and fake drugs. In addition, the blockchain can document the test results of new drugs, which will provide tremendous material for research in the field of pharmaceuticals and ensure the safety of personal data of patients participating in the trials of new drugs.

Currently, a number of companies are trying to solve the problem of the high cost of developing and testing new drugs. Three competing companies Pfizer, Amgen and Sanofi intend to use blockchain to solve this problem [10]. Blockchain sharing is expected to help reduce the duration and cost of clinical trials, as well as increase the percentage of successful developments. For example, currently accessing data from patients who would like to participate in the study is a difficult task, because the data is stored in different, unrelated institutions. The blockchain system, in particular, will allow interested patients to make their data available to representatives of pharmaceutical companies. In addition, the blockchain will help ensure the unity of data on new drugs, which is especially important for their approval by regulatory authorities.

To date, some measures have already been taken to solve these problems. For example, DHL and Accenture created a prototype based on a blockchain with nodes in six geographical areas to track pharmaceutical products in the

supply chain by product serial numbers [11]. A registry that tracks these drugs may be open to some individuals, including manufacturers, warehouses, distributors, pharmacies, clinics, and doctors.

The microchip manufacturer Intel, together with medical companies, is striving to introduce blockchain technology to track drugs that contain narcotic substances [12].

Blockchain technology is a solution to the above problems, but currently only attempts are being made to introduce it into pharmaceuticals and medicine.

We propose a scheme for introducing blockchain technology into the manufacturer-pharmacy chain to track the origin and composition of drugs delivered to the pharmacy.

III. RESULTS

A. The blockchain-contract for the supply of products

One of the possible ways of introducing blockchain technology in pharmaceuticals is a blockchain contract when concluding contracts for the supply of pharmaceutical products and exchanging contracts between pharmacies and pharmacy warehouses. The proposed model allows you to track the production and supply of drugs and ensure the legality of their origin. The structure of the blockchain contract is shown in figure 1.

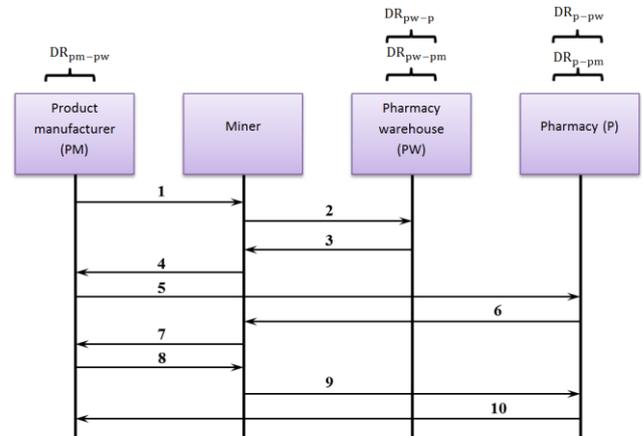


Fig. 1. The block diagram of a contract for the supply of products

DR_{wp-p} – distributed registry between pharmacy and warehouse pharmacy

1. The product manufacturer forms its internal block with an internal hash:

$$h_{pm} = f(D, K_{pub(pm)}, K_{pr(pm)}, S_{pm}, Z_{pm}) \quad (1)$$

D – block data;

$K_{pub(pm)}$ – PM public key;

$K_{pr(pm)}$ – PM private key;

S_{pm} – PM digital signature;

Z_{pm} – block header.

Then it sends the internal block to the network for embedding into the external blockchain network.

2. The miner, having accepted the block, forms an external hash:

$$H_{pm} = f(h_{pm}) = f(h_{pm}, D, K_{pub(pm)}, K_{pr(pm)}, S_{pm}, Z_{pm}) \quad (2)$$

This hash is a function of the internal hash and the external hash of the previous network block.

The miner sends it to the pharmacy warehouse (PW).

3. Pharmacy warehouse signs it with its digital signature S_{pw} , forms internal hash h_{pw} and sends it to miner.

$$h_{ppm} = f(H_{ppm}) = f(h_{pm}, D, K_{pub(pm)}, K_{pr(pm)}, S_{pm}, Z_{pm}, H_{ex}, h_{pw}) \quad (3)$$

4. The miner, based on h_{pw} , forms the final external hash using information from the previous block.

$$H_{pw} = f(h_{pw}, H_{ex}) \quad (4)$$

Then he sends it to the product supplier and embeds it into the external blockchain network.

5. The manufacturer of products sends this block to all pharmacies in the form of a distributed registry.

6. The pharmacy concludes a direct contract with the supplier of products, produces an internal block with a hash:

$$h_p = f(D_p, K_{pub(p)}, K_{pr(p)}, S_p, Z_p) \quad (5)$$

Then the pharmacy sends it to the miner. The miner generates an external hash and sends it to the product supplier.

$$H_p = f(h_p) \quad (6)$$

7. The manufacturer forms the internal block with its hash and sends it to the miner.

$$h_{pm} = f(H_p, H_{previous}) \quad (5)$$

8. The miner forms an external final hash and embeds it into the blockchain network.

$$H_{pp} = f(H_p, H_{previous}) \quad (9)$$

9. The miner sends the block to the pharmacy.

10. The pharmacy sends the block to the supplier of products.

B. An exchange of the blockchain-contracts between pharmacies and pharmacy warehouses

The exchange of contracts between pharmacies and pharmacy warehouses should also occur using blockchain technology.

Consider the scheme of exchange of contracts between a pharmacy and a pharmacy warehouse (Figure 2).

DR_{wp-p} – distributed registry between pharmacy and warehouse pharmacy

1. Product manufacturer creates internal block with hash h_{pm1} :

$$h_{pm1} = f(D_1, K_{pub(pm)}, K_{pr(pm)}, D_{pm}, Z_{pm1}) \quad (10)$$

D_1 – product data;

$K_{pub(pm)}$ – PM public key;

$K_{pr(pm)}$ – PM private key;

D_{pm} – PM digital signature;

Z_{pm1} – the header of the internal block with the products.

Then he sends it to the miner.

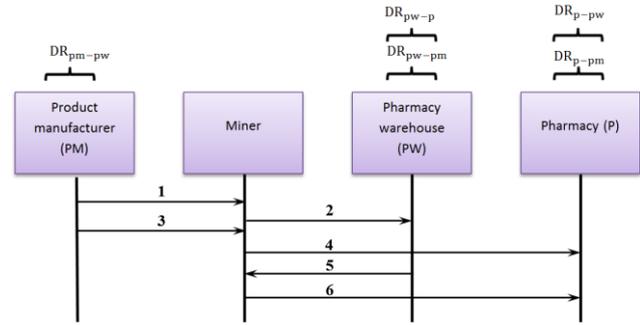


Fig. 2. An exchange of contracts between a pharmacy and a pharmacy warehouse

2. Miner finds the external hash of the previous block and forms the external hash H_{pm1} :

$$H_{pm1} = f(h_{pm1}, H_{previous}) \quad (11)$$

Then he sends it to the pharmacy warehouse.

3. Product manufacturer creates an internal block with hash h_{pm2} :

$$h_{pm2} = f(D_2, K_{pub(pm)}, K_{pr(pm)}, D_{pm}, Z_{pm2}) \quad (12)$$

D_2 – product data;

$K_{pub(pm)}$ – PM public key;

$K_{pr(pm)}$ – PM private key;

D_{pm} – PM digital signature;

Z_{pm2} – the header of the internal block with the products.

Then he sends it to the miner.

4. The miner finds the external hash of the previous block and generates the external hash H_{pm2} :

$$H_{pm2} = f(h_{pm2}, H_{previous}) \quad (13)$$

Then he sends it to the pharmacy.

5. Pharmacy warehouse creates an internal block with hash h_{pw} :

$$h_{pw} = f(D_3, K_{pub(pw)}, K_{pr(pw)}, D_{pw}, Z_{pw3}) \quad (14)$$

D_3 – block data;

$K_{pub(pw)}$ – PW public key;

$K_{pr(pw)}$ – PW private key;

D_{pw} – PW digital signature;

$Z_{pw,3}$ – block header.

Then he sends it to the miner.

6. Miner finds the hash of the previous H_{pw} and generates an external hash:

$$H_{pw} = f(h_{pw}, H_{previous})$$

Then he sends it to the pharmacy. As a result, the miner forms distributed registries of all interested structures.

Thus, the miner certifies the contract between the manufacturer of medicines, the pharmacy warehouse and the pharmacy. Pharmaceutical warehouse has accurate information, from what manufacturer he gets the products and where these products send. The pharmacy has reliable information about the manufacturer of the drug and has a guarantee of quality and legal origin of drugs.

C. The result of the blockchain system

In the proposed scheme, the miner controls and certifies the passage of all transactions, sends information about transactions to all participants of the blockchain contract system. Once the miner has attached a document about the next transaction to the blockchain, it is impossible to change it. This means that it is impossible to change in the documents the number of packages in the batch, add an extra batch, legalize products made from illegal or untested raw materials. This can all be checked against documents that are stored in a distributed registry. Check the information can be any member of the system-manufacturer, supplier, pharmacy, consumer (through the pharmacy).

An attacker can attach copied documents registered in the blockchain system to fake medicines. But in this case, the registered number of packages of the drug will not match. This will immediately require checking the actions of those participants in the system that are associated with the discovered packages. Thus, the appearance of counterfeit drugs will be immediately recorded and their sale and use will be prevented

IV. CONCLUSIONS

As a result of work according to the presented scheme, the manufacturer of the medicinal product, pharmacy warehouse and pharmacy will have complete reliable information about the origin and quality of medicines registered in the blockchain chain. This information can at any time be received, verified and issued to the consumer - the patient or medical institution. A feature of blockchain technology is the inability to make changes to past contracts and transactions, the inability to correct documents added to the chain. This makes it impossible to legalize batches of medicinal products obtained from illegal sources or not registered in the chain at the initial stage of production. Thus, fake or counterfeit medicines will not be able to get to the pharmacy warehouse, the pharmacy, and then to the patients.

The discussion question is the method and algorithm for solving the problem of implementing the mechanism for generating private keys to subscribers of service consumers

and distributing them to subscribers who provide services. The second task is the adoption of a law on participation in the blockchain system of public services and notary cryptographers (miners) and on the payment of remuneration for the performance of services.

When solving the problem of introducing the described technology into the work of pharmaceutical institutions, the question necessarily arises of legislative, organizational and methodological support for such technology. On the one hand, the proposed scheme provides control over the production and full accounting of all drugs produced and sold in the country, therefore consumers, drug manufacturers, and the state should be interested in such technology. On the other hand, the production of counterfeit medicines gives a very big profit, so there will always be people who do not like tight control technology. The solution to this problem is seen in attracting to the introduction of blockchain technology large pharmaceutical companies that are interested in cleaning the drug market from fakes.

Blockchain technology is low-cost compared to analytical laboratories that determine the authenticity and quality of drugs. The introduction of such technology requires appropriate computer equipment and software that implements the work of a distributed registry, as well as hashing, cryptographic encryption and decryption, verification of digital signatures and data transfer. In addition, it is necessary to provide for the payment of the work of a cryptographic miner. At the same time, the effectiveness of the blockchain system will be significantly higher than that of a laboratory that performs selective quality control of drugs.

In conclusion, we note that the skills, knowledge, limitations, duties imposed on the models can be simplified for the tasks solved by the blockchain technology in each specific case, e.g., for local structures, global structures, critical facilities, corporate systems, and other systems and structures. The given example illustrates the creation of a global structure for the pharmaceutical industry within the borders of one state.

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