

Blockchain-Based Regulatory Proposal for Vaccine Supply Chain

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Abstract: Vaccines are essential special drugs to protect the nation from diseases, and the safety and credibility of their supply chain has an important impact on social stability. Vaccines are characterized by rigorous supply chain, complex process and many risk-prone points, etc. How to comprehensively and effectively supervise the vaccine supply chain has been a key concern in China. Accordingly, this paper puts forward effective suggestions from the perspective of strengthening the information supervision of vaccine supply chain based on the characteristics of blockchain.

Keywords: Vaccine supply chain, Blockchain, Information regulation, Collaboration.

1. Introduction

Vaccination is one of the important measures for effective prevention of infectious diseases, and the regulation of vaccines is related to the health and safety of vaccine recipients [1], as well as to public health and stable development of the country. Nowadays, vaccine incidents continue to occur, such as the falsification of Changsheng vaccine production records and the illegal dumping of vaccines in Shandong [2-3], which urgently require effective safety supervision of the vaccine supply chain.

Blockchain has the characteristics of decentralization, multi-collaboration, openness and transparency, immutability, traceability, and trustworthiness [5-6]; its smart contract can program the logical requirements of vaccine supply chain regulation in code to regulate the logical relationship of matters, powers and responsibilities in regulation, so that regulation can be implemented automatically according to the requirements formulated by smart contract. Accordingly, the information security regulation of the vaccine supply chain can be strengthened and the crisis situation of social distrust in vaccination can be saved.

In this paper, we consider the analysis of the security issues of the vaccine supply chain and explore the stimulation of active autonomy of the internal subjects of the supply chain and collaborative regulation outside the supply chain based on blockchain technology.

2. Literature Study

As a special kind of medicine, loopholes in the regulation of vaccines can lead to major public health incidents, such as the "Shandong vaccine incident" which caused a wide range of social panic [7]. Therefore, we need to pay more attention to the regulation of vaccines, and the following will organize the literature around two aspects: the regulation of vaccines and the application of blockchain in various industries.

2.1. Vaccine regulatory aspects

The exploration of vaccine regulation can be elaborated from various aspects. Thinking in terms of vaccine trust, Wang Jing [8] proposed regulatory recourse through QR codes and combined with information management measures such as Internet feedback to consolidate trust. From the

perspective of collaborative governance, Li Cui-min [9] proposed a collaborative system of online public opinion grooming by applying stakeholder-related theory to analyze the collaborative subjects of safety incidents; Yang Huafeng [10] called for effective cooperation, shared discretion and shared responsibility among government departments to build a "government-led" collaborative governance approach. Analyzing the relationship between vaccine regulation and the market, Yu Jianxing et al [1] advocate that the government should insist on promoting marketization and improving the governance system to improve the regulatory capacity; Bao Jing et al [11] emphasize that they should insist on "governance" reform as a means to return CDC to public welfare and guide enterprises to implement the main responsibility. The above-mentioned vaccine regulation proposed to improve regulation from multiple perspectives, but the vaccine problem still occurred intermittently and failed to be fundamentally solved.

2.2. Blockchain in industry applications

The arrival of blockchain 3.0 emphasizes that blockchain penetrates into all aspects of social life and develops a wide range of application scenarios [12] to implement a full exploration of its application value. Dong Yunfeng et al [13] analyzed the complex, cyclic cycle and risk factors of the cereal and oil food supply chain and used blockchain technology to build a trustworthy traceability model of the whole supply chain of cereal and oil food to complete safe, reliable and accurate traceability; Xu Jiping et al [14] sorted out the information flow characteristics of the rice supply chain and the key information of each link subject, and built a rice supply chain information supervision model driven by blockchain to achieve information interoperability and Zhang Yan et al [15] used blockchain node supervision, collaborative rule governance and technical autonomy embedded in agricultural crowdfunding to break the original trust, security and other restrictive challenges.

Researchers have made many explorations in blockchain applications, but there are fewer blockchain applications in vaccine regulation. This study refers to previous research results and designs a combination of multiple regulatory approaches in the regulatory approach, which is used to explore multi-channel effectiveness regulation under the innovation of technology application.

3. Vaccine Supply Chain Vaccine Supply Chain Status

The possibility of vaccine incidents can occur in each link of the vaccine supply chain, and the ability and behavior of each link body is crucial to vaccine supervision, so it is necessary to analyze its realistic and sensitive issues.

In the centralized procurement process, the provincial CDCs need to be careful in summarizing the vaccine demand of grassroots vaccination units, and conduct bidding and centralized procurement in a fair and impartial manner to ensure that the process is completed in accordance with the rules and regulations; in the subsequent vaccine production process, vaccine production institutions are required to have technical standards of vaccine production and not to do some illegal acts for corporate self-interest, such as unlicensed and unpermitted production, falsified production records, illegal At the same time, in the vaccine transportation link, the transportation unit is required to have a high foundation of maintaining low-temperature facilities throughout the circulation, monitoring the dynamic information of the vaccine, maintaining the whole cold chain, the whole controlled transportation, and eliminating regulatory gaps; in addition, for the vaccination link, the use of vaccine products has a professional threshold of skills, which makes the vaccination unit need to have a certain level of vaccination and relevant vaccination In addition, for vaccinators at the end of the vaccine supply chain, they do not have a fixed and credible source of trust in obtaining information about the vaccine they receive and confirming the safety of the vaccine, and can only be given confidence in vaccination through moral compliance with the vaccine supply chain and the constraints of national laws, resulting in a weak foundation of trust in vaccines, which makes rigorous and credible supervision even more necessary at this time.

4. Blockchain-based Vaccine Supply Chain Proposal

In order to better supervise the safety of the vaccine supply chain from multiple perspectives, four dimensions are considered to jointly constitute the supervision model. Mutual monitoring by production organizations, provincial CDCs, vaccination units and vaccinators within the supply chain, assisted monitoring by mass media and third-party non-profit organizations outside the supply chain with the assistance of blockchain, codified logical regulation under mechanical trust of blockchain itself, and direct realistic regulation by external regulators of the supply chain with their respective roles complemented by smart contracts.

4.1. Mutual monitoring within the supply chain

When the subjects within the vaccine supply chain implement mutual monitoring as regulators, firstly, production institutions, provincial CDCs, vaccination units and vaccinators upload the prescribed regulatory information to the blockchain. Secondly, both subjects involved in the supply chain carry out real-time mutual identification of key authority and responsibility handover between them, i.e., between the provincial CDC and vaccination units, between the production organization and the provincial CDC, between the production organization and vaccination units, and between the vaccination units and vaccinators, and identify

whether the other party is implementing the vaccine supply chain business process in accordance with the requirements by comparing the status of the vaccine traceability content with the reality details. If the requirements are not followed, the previous subject of the vaccine supply chain can be rejected to guarantee the normal handover of rights and responsibilities for vaccines, terminate the process to proceed, and provide feedback on the handover issues of the vaccine supply chain, and subsequently carry out responsibility identification and regulatory implementation through blockchain and regulatory agencies. In order to achieve clear definition of rights and responsibilities between the two subjects of the supply chain and timely cut off the vaccine crisis when a vaccine incident occurs, so as to achieve supervision in the middle of the matter and guarantee clear positioning of rights and responsibilities and accurate rewards and punishments for vaccines in the supply chain from the beginning to the end. If the transportation party delivers the vaccine to the vaccination unit and the vaccination unit is about to implement vaccine storage for the truck, the transportation party and the vaccination unit both implement relevant information traceability to the other party through the blockchain traceability interface at the same time, and when the vaccination unit obtains the traceability information and finds that the transportation vehicle of the transportation party unloads the vaccine in advance, which makes the vaccine exposed to the temperature range of non-stored vaccine for a longer period of time, resulting in possible vaccine This can lead to a vaccine safety incident. The vaccination unit can compare the traceability information with the information occurring in reality and implement the problem feedback through the supply chain feedback interface provided in the blockchain to achieve successful supervision of the vaccine crisis in the supply chain process and stop the loss in time to realize in-the-moment supervision. If both parties involved in the supply chain are negligent in monitoring, resulting in ambiguous definition of rights and responsibilities, both parties will be punished at the same time, so as to motivate the supply chain subjects to actively monitor each other.

4.2. Assistance in monitoring outside the supply chain

The supervisors who assist in monitoring outside the supply chain are mainly the mass media and non-profit organizations. Based on the tamper-evident information uploaded on the blockchain by supply chain entities, if vaccine recipients have adverse reactions after the observation period of vaccination, mass media and third-party non-profit organizations can obtain the information on adverse reactions after vaccination released in the society and compare it with the traceability information obtained through the blockchain traceability interface, and if they think that vaccination has caused adverse reactions of vaccine recipients, they can report the problem through the security reporting interface. The problem will be fed back to the blockchain and the regulator to solve the problem. In this way, we can assist in the supervision outside the vaccine supply chain from the perspective of "post-event supervision". If a mass media sees a screen name on the relevant platform disclosing the existence of vaccine incidents, the mass media can trace the information in the traceability interface based on the information provided by the screen name, and compare the humanized traceability information with the real situation, and then provide feedback on the problem through the

security reporting interface. In order to promote the motivation of inoculators, mass media and third-party non-profit organizations to supervise, certain rewards can be given for successful reports.

4.3. Smart contract logic regulation

Based on the information uploaded inside and outside the supply chain, the corresponding regulatory business logic can be realized by setting hierarchical smart contracts [22]. Here, the information uploaded by each subject inside and outside the supply chain is considered to be classified, and the regulatory processing response to the information is logically combined with vaccine regulation and laws, so that the rules of regulatory application can be expressed by computer language. The clearer the rules are, the easier they can be translated into codes, so that the information uploaded can accurately trigger the pre-set trigger conditions of smart contracts, and then realize the regulatory orders under the corresponding conditions. The codification of regulatory logic can replace the regulatory operations with clear regulations, high workload, huge costs, repetitive operations and fatigue in the current manual regulation, and automatically execute them according to the pre-set processes to improve the efficiency of vaccine regulation. For example, for the real-time temperature information of vaccine transportation uploaded by the production organization, when the smart contract identifies that the uploaded information belongs to the content of vaccine transportation temperature, it executes the code board in terms of temperature judgment. When the running code judges that the value range of this temperature data is not within the specified temperature range, it outputs the result of temperature abnormality and sends out a warning to the outside, and when it judges that the temperature data continues to be abnormal for a certain length of time, it executes the corresponding vaccine supply chain interruption instruction and implements the corresponding penalty measures. If the punishment for this vaccine accident is too complex to be codified, the accident regulation is judged to be responsible for which specific regulatory authority it belongs to, and the information is communicated to the regulatory agency, which provides conscious and rational regulation and feeds back the regulatory results to the contract for recording. In order to make the smart contract regulatory content associated with the interests of the supply chain subjects, so that the content of rewards and punishments are valued, here set the parties to submit a deposit to enrich the regulatory means to achieve contract enforcement.

4.4. Direct supervision by regulators

The regulator mainly consists of three departments, dealing with the regulation that cannot be fully covered by smart contracts. Since not all regulation can be handled logically in code, a few incidents inevitably need to be carried out by the non-mechanical automated human component of the regulator. When a smart contract determines that a problem cannot be solved, the smart contract determines the regulatory authority to which the incident belongs and passes the problem down precisely to offline regulation. The contract-assisted regulator can avoid the lack of linkage and unclear responsibility caused by multiple regulators co-regulating each other, resulting in mutual shirking of responsibility and ignoring the handling of accidents, while filling in the content outside the coverage of mechanical regulation of smart contracts. If the mass media reports that the vaccination

process in vaccination units is not strict, and the smart contract is not able to implement accurate limits of punishment through limited information, the problem is judged to be handled by the primary health department, which receives the contract output information and takes subsequent regulatory measures. The setting of the regulator helps to discover where the smart contract considers deficiencies, so that the content of the contract can be further adjusted to increase the contractualization of regulation.

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