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Requirements Identification for a Blockchain-Based Traceability Model for Animal-Based Medicines †

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Abstract: In this paper, the traceability of heparin medicine will be studied. Currently, the registration of traceability data is conducted in a decentralized manner. With blockchain implementation, the traceability systems that use this data could become semi-automated, increasing the quality, security, and confidence of the information generated in the supply chain. This paper presents the essential requirements and activities wherein information must be collected within the heparin drug supply chain, focusing on the animal raw materials production link and its requirements. Blockchain technology is proposed to increase traceability and reliability in relation to the current situation. It also fulfills all the requirements identified if used as part of a traceability system. These requirements are: the existence of a consensus mechanism; anonymity; protocol, efficiency, and consumption; immutability; ownership and management; and approval time. We conclude the paper by presenting the mapping of requirements and entities and critical activities for adopting blockchain technology to support the traceability of raw materials from animals used in heparin production.

Keywords: blockchain; livestock; supply chain; medicine; traceability

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1. Introduction

Livestock systems contribute significantly to national economies worldwide, and the value of livestock production accounts for 20 to 40 percent of the total agricultural output in developing and developed countries, respectively [1]. The food chains worldwide contain a considerable number of actors in their links. Some of their main links or entities are: farmers, processing industries, shipping companies, wholesalers and retailers, distributors, and retailers [2]. The drug supply chain is also global and complex, presenting problems related to counterfeit products and raw materials [3]. Blockchain is a technology that could improve decision-making on these supply chains and guarantee product quality. Drug supply chains can use this technology to establish product and raw materials' provenance in the context of fraud and counterfeit products [3]. Blockchain has shown its potential for transforming traditional industry with its key characteristics: decentralization, persistence, anonymity, and auditability [4]. It can also monitor social and environmental responsibilities and facilitate real-time management of the supply chain [2]. However, few works in the literature evaluate the use of this technology on animal-based drug supply chains. In this paper, heparin, an important anticoagulant that uses components extracted from cattle lungs and intestines [5], was used as a case study for evaluating the use of blockchain technology. The main objective of this paper was to: (i) identify the main requirements for implementing blockchain on this supply chain, (ii) identify the main entities or links and services involved, and (iii) map the requirements and the entities identified, allowing for better decision-making.

2. Use of Blockchain Technology for Supply Chain Traceability

Bitcoin is considered the first real-life application of blockchain technology [6]. Blockchain leads to technology development that allows for ubiquitous financial transactions among distributed untrusted parties [2]. In supply chains, its use could allow for trustworthy data gathering, storage, and visualization, even if some agents are untrustworthy. The primary use of this information is for traceability purposes [7]. Blockchain can be described as a digital transaction ledger maintained by a network of multiple computing machines that are not relying on a trusted third party [2]. It is essential to observe that it allows transactions to occur in a decentralized manner [4]. Blockchain traceability solutions are widely recognized in food and agricultural supply chains [8]. Several serious problems such as tampering of products, delay, and fraud exist in the traditional supply chain management system, and blockchain technology can provide essential features such as decentralization, transparency, product traceability, and trust-less environment anonymity and immutability [7]. Agriculture and food supply chains are well interlinked since agriculture products are almost always used as inputs in some multi-actor distributed supply chains [2], and this concept was applied in this article considering animal-based medicines. Animal-based medicines are described as medicines with one or more critical components extracted from animal products. The primary animal-based medicine for most countries is heparin, widely used to inhibit blood coagulation [5].

3. Methodology

The methodology used in this paper was composed of three main steps: (i) requirements gathering, considering an in-depth literature survey on the following domains: blockchain models used for product traceability, animal products supply chains, medicines supply chains, and animal-based medicines supply chains. The main entities of the heparin supply chain were also identified in this step; (ii) identification of main supply chain blockchain models, considering both theoretical models and models currently being implemented in real-life scenarios; (iii) model assessment, considering a mapping of the requirements identified in Step 1 with each supply chain entity. Three forms of traceability were explored: pre-production, production, and distribution.

4. Supply Chain Entities of the Heparin Supply Chain

Supply chain management is related to managing the production, flow of goods, data, and finances and oversees the processes from origin to consumption [7]. A supply chain often intersects business functions and national boundaries with an extensive network of trading partners, and these interactions increase the vulnerability of the supply chain and can lead to its disruption [9]. It is essential to observe that the heparin supply chain operates differently from other animal products supply chains because product delivery is subjected to various kinds of comprehensive regulations and rules to guarantee product quality [7]. Blockchain technology can track the physical movements of medicines and monitor their quality and authenticity through all supply chains [8].

Figure 1 represents the main entities and processes of the animal-based medicines' supply chain, focusing on the heparin supply chain. Its main entities are: (i) farmers and consultants involved in planning, breeding, feeding, and health maintenance of animals; (ii) the slaughterhouse, which is responsible for slaughtering and packaging, and storing the animal organs such as intestines and lungs; (iii) the pharmaceutical industry, which is responsible for the production of the medicine; (iv) distributors, retail, and hospitals, which are responsible for acquiring, storing, and supplying the medicines; and (v) patients, which will consume the medicine.

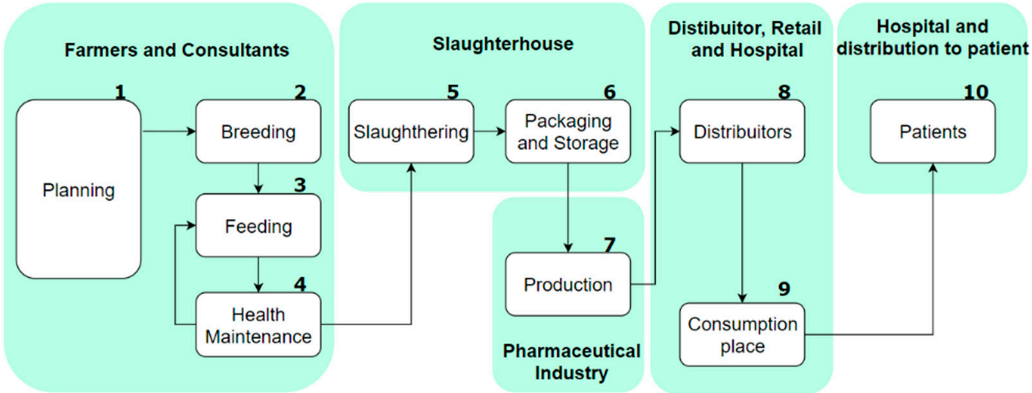

Figure 1. Supply chain of animal-based medicines.

5. Mapping of Requirements and Entities for Using Blockchain Technologies on the Heparin Supply Chain

Table 1 illustrates the main requirements for implementing blockchain technology for heparin traceability. The first is a consensus mechanism, which decides the block-validation process, and provides consensus among all the nodes [7]. This guarantees that the information is trustworthy. There are several common approaches to reach a consensus in a blockchain, such as: proof of work, proof of stake, practical byzantine fault tolerance, delegated proof of stake, Ripple, Tendermint, and others [4]. The second is anonymity, which guarantees that it is impossible to establish, a priori, to which users are involved in a specific transaction [6]. The third is protocol, efficiency, and consumption, and it is linked to convenience, energy use, computational resources consumption, and the costs of operating the system [4]. The fourth is immutability, which is related to the capacity of guaranteeing that the information cannot be changed once it is added to an information block in the blockchain [7]. The fifth is ownership and management, and it is linked to aspects of governance, maintenance, and policies to operate the blockchain [10]. Lastly, the approval time is linked to how long it takes to create a block or register a transaction in the blockchain [9].

Table 1. Mapping of the main requirements and entities for blockchain-based traceability for the heparin supply chain.

Requirements	Farmers and Consultants	Slaughtering	Pharmaceutical Industry	Distributor, Retail and Hospital	End Users
Consensus mechanism			X	X	
Anonymity	X	X			X
Protocol, efficiency, and consumption			X	X	
Immutability	X	X	X	X	X
Ownership and management	X	X	X	X	X
Approval time			X	X	

Source: based on the works by [2,4,6–10].

It is important to observe that these requirements are addressed differently by the different blockchain models and that their importance is relative to each supply chain entity. Therefore, we also included in Table 1 which requirements are considered the most important for each supply chain entity. It is critical to observe: (i) immutability and ownership are essential for all entities; (ii) consensus mechanism, protocol, efficiency, and consumption, and approval time are more relevant for the pharmaceutical industry and the distribution, retail, and hospital entities; (iii) anonymity is essential for farmers and consultants, slaughtering, and end-users; and (iv) end-users consider critical the requirements of anonymity, immutability, and ownership and management.

Lastly, it was possible to identify three main types of traceability: (i) pre-production, related to all aspects that guarantee raw materials quality, from farm to the pharmaceutical industry; (ii) production, related to all the production aspects and the internal traceability in the pharmaceutical industry; and (iii) distribution, related to all the aspects related to transporting, storing, and distributing the products to the end consumers. The blockchain technology used must gather information from all those traceability systems.

6. Conclusions and Future Works

Animal-based medicine supply chains are essential for healthcare. However, several problems related to counterfeiting exist in those supply chains. In this work, we evaluated the use of blockchain for improving product traceability, information visibility, and end users' trust in those products, focusing on the heparin supply chain. The main entities, processes, main requirements for those entities and traceability types necessary for guaranteeing product quality were identified. A mapping between requirements and entities was also conducted based on an in-depth literature review to identify the most critical requirements for each entity and traceability type. It is essential to observe that the methodology used can be applied in other supply chain studies, such as plant-based medicines or high-cost medicines. Future works are related to: (i) using computer simulation to evaluate the potential impacts of adopting blockchain on the heparin supply chain; and (ii) implementing a pilot project to evaluate this technology in real-life scenarios.

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