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Tracing Pharmaceutical Products Utilizing Blockchain Technologies

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Abstract: In recent years, blockchain technology has emerged and gained considerable attention due to its reliability and secure data sharing capabilities in various domains such as supply chain management, finance, the internet of things, agriculture, food, healthcare, and pharmaceutical industries. The track of pharmaceutical supply chains has become more critical in the health society in any country or region to ensure the proper trackability and safety of medicines. With time, it has become more complex and costly to track thousands of various medical products. Without a proper supply chain system, there is a possibility of the availability of counterfeit drugs. Building a traceability system over a blockchain platform would provide a trusted and secured method to track and trace the medical supply chain from the manufacturer to the patient. This work proposes a traceability system for pharmaceutical products in Oman using blockchain technology to maintain the integrity of the data of such sensitive valuable products. In addition to this, different pharmaceutical workflows have been designed and implemented using the Ethereum blockchain platform.

Keywords: Blockchain, Smart contracts, Pharmaceutical, Traceability, Distributed ledger

1. Introduction

The recent decade has witnessed growth in the digital revolution where blockchain technology has emerged and captured the attention of both industry and academia [1]. Blockchain technology which was introduced by Satoshi Nakamoto [1], [2], is resistant to modification of the data due to its decentralized, distributed, and immutable ledger nature where the truncations are recorded securely across various computers, distributed and peer-based networks without the involvement of third-party entities [3]. Blockchain technology was initially introduced for private digital cash such as bitcoin for its various benefits including tamper-resistance, distributed database structure that can record events while ensuring security, and the restriction in recomposing previously generated transactions records [4]. Due to its exclusive benefits, various industries have started to adopt Blockchain technology for different systems.

One of the industries that could reap the benefits of Blockchain technology is the pharmaceutical industry. The pharmaceutical industry discovers, produces, develops, and markets medicines and drugs for curing diseases among patients. In recent times, the pharmaceutical industries are gaining the constant attention of academia and various government bodies due to the stringent regulations from international standard bodies and organizations [5]. In 2006, due to the criticality of counterfeit drugs, the World Health Organization (WHO) established an international task force against counterfeit medical products to engage the stakeholders collaboratively to protect people from using counterfeit drugs [6]. By 2020, the global pharmaceutical market is expected to reach around $1.4 trillion [7]. Pharmaceutical products require a high standard of quality with properly implemented security where products can be traced from the origin due to the involvement of multiple entities such as manufacturers, suppliers, distributors, retailers, and customers [8], [9].

The poor management of tracking and tracing the supply chain of pharmaceuticals may result in serious problems such as a rise in production and distribution of fake drugs, difficulty in auditing the source of drugs, or the number of certain drugs for specific areas [10]. In addition to this, it is difficult to find the root of an issue due to the complex supply chain of pharmaceutical products line when the product has the problem such as identification between original and counterfeit product. Moreover, due to the high possibility of data tempering between the supply chain nodes and within the enterprise is inconsistent which could disrupt the product traceability. However, the implementation of internal traceability can help in tracking the history of the medical drugs including their origin and the related transactions. It will not only increase consumer trust but also guarantee the long-term preservation and searchability

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of information where the history of transactions can be tracked [11]. This could help in mitigating major problems that occur in the pharmaceutical industry. The research aims to propose a decentralized supply chain management model for pharmaceutical industries globally to steer clear of counterfeit medical drugs and promote transparency in the supply chain records. This research illustrates how Blockchain technology can be used to control and track all transactions for pharmaceutical products including capturing activities from production to distribution. The report also discusses how the information can be accessed by authorized stakeholders at any time. In addition to this, the paper reviews governance, operations, and ethical implications for the implementation of the proposed methodology in alliance with the laws of the Sultanate of Oman. Lastly, this paper discusses how to trace and track pharmaceutical products within Omani hospitals under the Ministry of Health using blockchain which facilitates restricting unauthorized entities from accessing sensitive information.

Traceability refers to the ability to track and trace along the supply chain [12]. The clearest definition of traceability was made by Olsen and Borit11, who defined traceability as "the ability to access any or all information relating to that which is under consideration, throughout its entire life cycle, using recorded identifications" [13]. According to authors in [14] defined tracing as the ability to determine the origin of an item or group of items through records in the supply chain. Using the principles of traceability allows organizations to create transparency and sustainability [13]. There are three main objectives for traceability namely, better supply chain management, product differentiation and quality assurance, and better identification of non-compliant products [15].

Regarding the pharmaceutical supply chain system, traceability plays a vital role in ensuring the authenticity of data regarding medicine's production and distribution. By creating an immutable drug traceability ledger, the authorized users can investigate and authenticate the drug's source of origin, manufacturer's information, packaging, and distribution entities [16]. Through drug traceability, problems such as distributing counterfeit drugs, fabricating information, and tracking a lost drug consignment can be easily tackled.

2. Related work

One of the fundamental objectives of the quality of life is the availability of quality medical products and services. One of the prime challenges faced by the healthcare industry is the production and distribution of counterfeit drugs and the lack of a traceability system to counter this problem. This section presents the previous work conducted in the field of blockchain-based healthcare systems with an emphasis on traceability as a core module in the implementation of blockchain-based supply chain management systems for pharmaceutical industries.

There are several issues associated with the pharmaceutical supply chain and counterfeit drugs. The distribution of fake drugs can cost millions to pharma companies and put the patients at a high risk associated with the intake of counterfeit drugs. According to [17], there are four checkpoints where drugs are at risk of being counterfeit. The level refers to the stage where the supplier delivers the raw material for drugs production. If the supplier delivers expired or low-quality raw material then it can negatively impact the consumer's health. The second level refers to the manufacturing stage. In this stage, the drug can be counterfeit if the manufacturer uses the wrong ingredients or the wrong dosage. The third level in the supply chain system is the distributor. Once the drug is produced, the next task for the counterfeiters is to distribute those drugs. Lastly, the fourth level is pharmacies. If the counterfeit drugs have been circulated during level three then there's a high probability of the consumers buying counterfeit drugs from the physical pharmacies. In addition to this, another lucrative way for counterfeiters to sell drugs is through online pharmacies. Consumers are often prone to purchasing drugs online for lower prices and as a result, they end up consuming harmful drugs.

Blockchain technology offers an optimal solution for tackling the problems arising due to the countrification of drugs. This problem can be addressed by designing and developing a trackable supply chain management system. Initially, blockchain technology was mainly used for cryptocurrencies like bitcoin and other financial services however with the passage of time, this innovative and distributed ledger technology is being used in a wide variety of applications such as financial, supply chain, auditing, identity management due to its permanent and immutable recording capabilities where transactions are managed in chronological order using encrypted data [13]. Overall, with the challenges and future requirements in the pharmaceutical industry for tracing the products, blockchain provides an effective and secure way for supply chain systems.

Among various blockchain technologies, Ethereum is a widely preferred blockchain technology for designing, developing, and testing decentralized systems. It allows the creation of smart contract agreements between concerned entities by using transaction-based transitions [16]. The authors in [18], introduced Medledger framework for storing all drug-related information, activities, and transactions in a blockchain-based immutable ledger by using chain codes. It obliges all the involved entities to authenticate themselves on the system via cryptographic functions. This framework protects the system against Sybil and Distributed Denial of Service (DDoS) attacks however due to the adoption of new technology such as Hyperledger fabric technology, it faces several implementation challenges related to scalability, governance, identity registration, and privacy regulations. Another researcher introduced distributed trust-based efficient pharmaceutical supply chain using blockchain thataims to provide an integrated and secure supply chain system that promotes business excellence collaboration among

stakeholders while minimizing the costs [19]. The proposed work divides the business ecosystem into application and infrastructure through the creation of institutional trust which decreases the grey market while increasing interoperability and better visibility in the supply chain industry. Similarly, in another work [20] the authors proposed Supply Chain Management (SCM) system for the pharmaceutical industry. In the proposed SCM mechanism, good practices are being shared between supplier and end-user using Radio Frequency Identification (RFID) technology and through the exchange of electronic product codes.

To share the information among various stockholders and make the supply chain process transparent and prevent counterfeit drugs in the pharmaceutical industry a blockchain-based technological solution is provided in [21]. The authors used traceability and security to the drugs supply system which tracks the drugs from its manufacturer till they are delivered to the patient. On the other hand, the work in [14], proposed a protocol that provides the data interaction including the integration details among the supply chain nodes through sharing the data in upstream and downstream enterprises. In a similar vein, the authors in [22], proposed a peer-to-peer network architecture that caters to the demand increase through timely delivery of information in a decentralized manner during the logistics phase in the supply chain system, which enables the clients and users of the systems to obtain real-time information about the system. Also, the main advantage is the transparency where users can view the entire transaction at any time.

Among other approaches, the Gcoin blockchain was proposed by [23], to serve as a base of the data flow of drugs which creates the transparent transaction related to drugs data. Besides, traceability is implemented at each stage from the procurement of drug ingredients to production and to distribution which enhances the trust and security of the system. Blockchain technology provides a secure mechanism for transactions through the distributed consensus which verifies the correctness and trustworthiness of data. Also, the addition of traceability at each stage in the supply chain-based systems provides complete transparency which enables the formation of new business models and reliability. Several authors have proposed various methodologies and frameworks for transforming the pharma supply chain system by introducing blockchain technology for implementing immutable ledgers for ensuring reliable and traceable data however some of the problems such as ease of scalability, governance, and privacy issues mostly remain unsolved. These problematic areas need to be further researched to devise effective solutions for the real-life implementation of the frameworks globally.

3. System design & development

The proposed system focuses on designing a tracking system for pharmaceutical products in Oman using a publicly available blockchain. This blockchain allows an identified group of participants to interact with the tracking system. For the proposed case, the Ministry of Health, pharmaceutical factories, warehouses, distributors, hospitals, and pharmacies will be the participants. Data will be visible to all parties and the patient will have read-only access to the tracking system. Figure 1 illustrates the overview of the track and trace system.

A. Main workflow

In the pharmaceutical industry, there are medical drugs buyers such as hospitals, distributors, and pharmacies. On the other hand, there are medicine drugs sellers like factories and distributors. Figure two illustrates the data flow diagram defining the interaction between the external entities such as factory, distributor, hospital, Ministry, and patients with the internal processes such as track and trace process, smart contract, blockchain transaction process, search engine process, and inspect the process. First, the buyers and sellers agree under the Ministry of Health regulation regarding the list of products with details that will be included in the smart contract. After the agreement, the smart contract will be created by the Ministry of Health at a blockchain platform called Ethereum.

Ethereum is a platform that allows the execution of smart contracts and the trading of cryptocurrencies without the involvement of third parties using blockchain technology. Alternatively, bitcoin trades in cryptocurrencies, while Ethereum offers several methods of exchange including cryptocurrencies such as virtual machine (EVM). The great benefit of using Ethereum is the utilization of permissioned and permissionless transactions whereas bitcoin allows only permissionless or censor-proof based transactions with less average block time. Using Ethereum platforms allows individuals and companies to do much more than just performing the financial transactions between entities.

B. Blockchain transaction process

After registering and validating the smart contract, buyers like hospitals and distributors can order medicine products according to the agreement in the blockchain. As illustrated in figure three, once the buyer orders medicine products and sends the payment, Ethereum will confirm the payment after verifying the buyer and its address. The seller will receive a notification from Ethereum about the payment then the seller will assemble the order and ship it. Upon receiving the shipment confirmation from the buyer, Ethereum will deploy the smart contract and send the payment to the seller. Once verified, the transaction will be created and encrypted with a unique transaction ID in a new block in the blockchain. In the end, a chain of blocks will be formed that cannot be modified. Only authorized parties will be able to track the details of the medicine and its real origin. The same scenario can be applied between the factory and the distributor. The distributor, hospital, and every product transfer from one party to another will be added as a transaction in the blockchain platform.

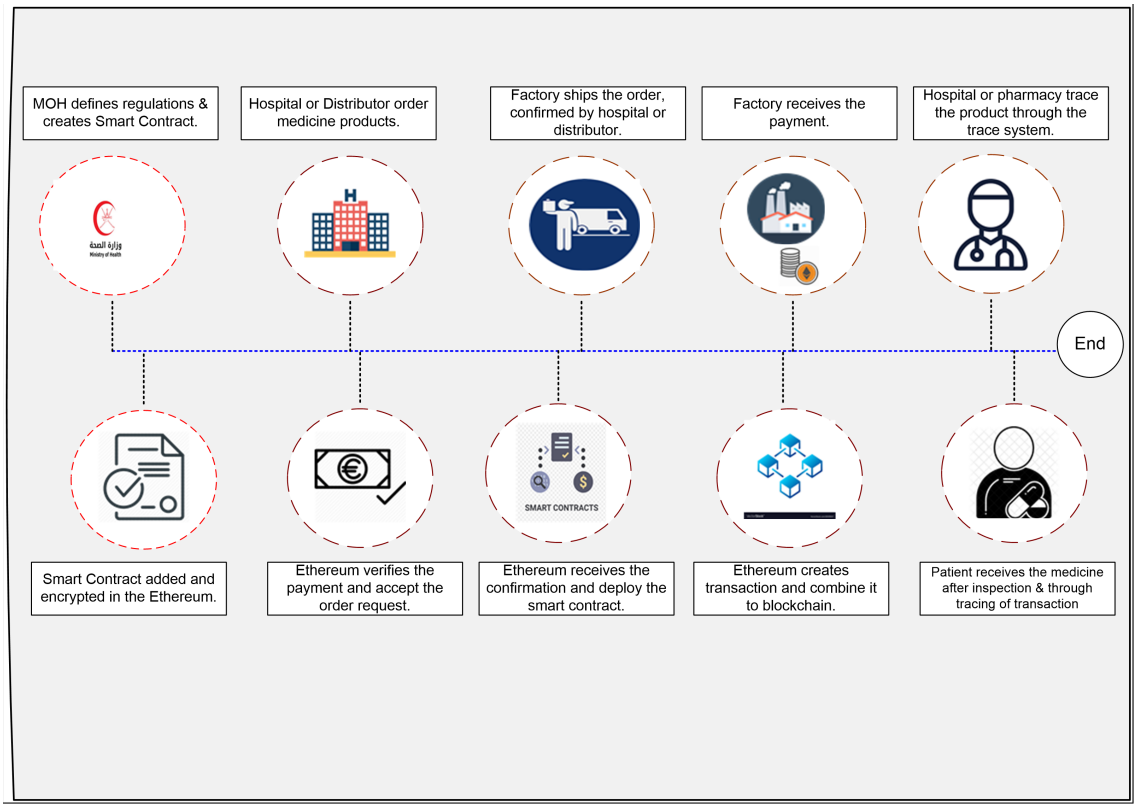

Figure 1. Workflow of the track and trace medicine system in Oman

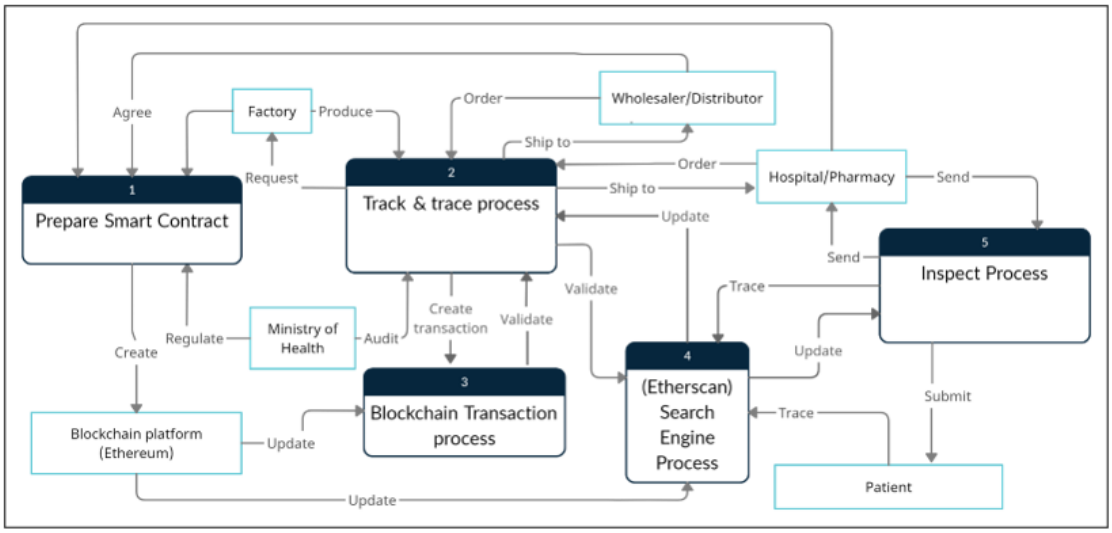

Figure 2. Level-0 physical dataflow diagram

C. Tracking and tracing medicine transactions

The main function of the blockchain in the proposed system is to provide immutability and security to the traceability system. Figures four and five depict the working mechanism of the tracking and tracing system. Requesting medical products is offered through the track and trace system application, which will interact with the Ethereum blockchain platform. This application will be the medium for interaction between the participants and the Ethereum platform. Reaching this information by the parties through the application will create more transparency and integrity in tracing the medicine products. Also, through a search

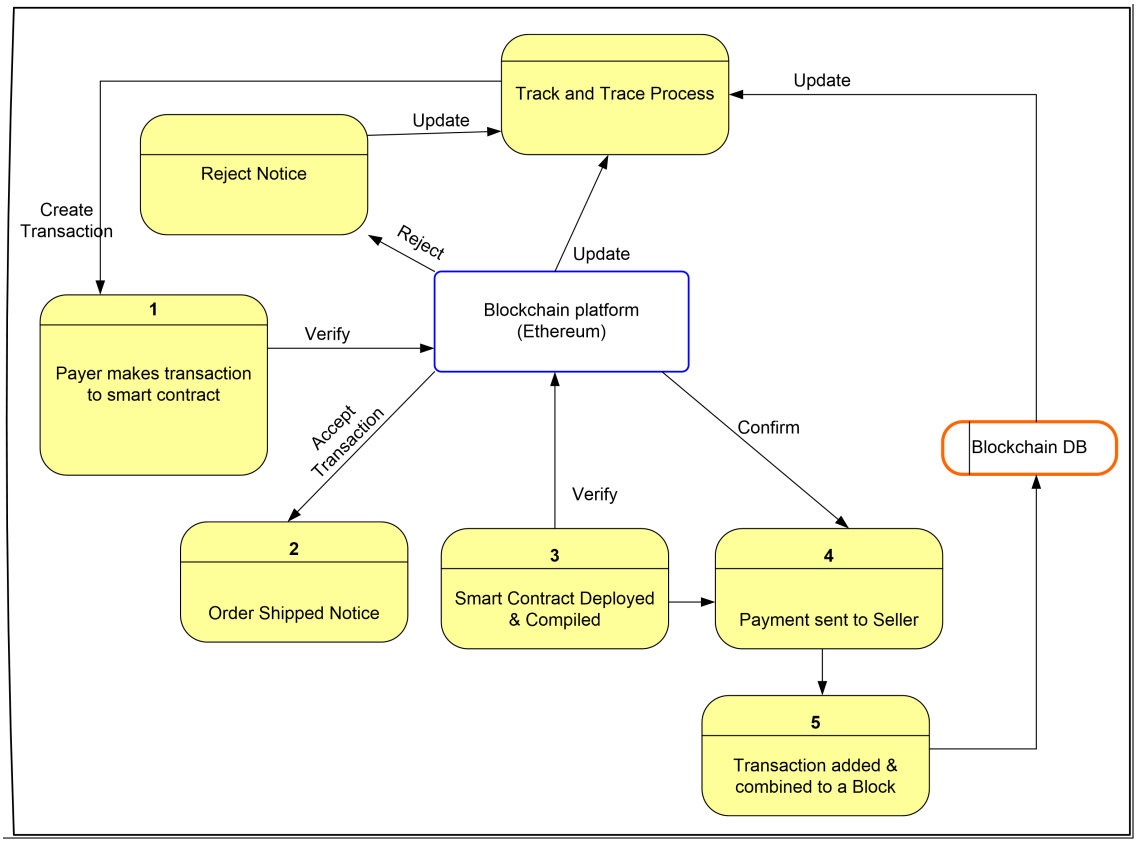

Figure 3. DFD- Blockchain transaction process

engine called Etherscan, the allowed participant can track any transaction by entering the details or the address, transaction id, or block id. Etherscan lets you search and track transactions, addresses, tokens, and prices related to all activities on the Ethereum Blockchain platform.

4. Analytical Review

An Analytical review refers to the analysis and evaluation of different aspects related to a particular topic. This section discusses and highlights important aspects such as governance, operations, technology, social, ethical, and legal implications.

A. *Governance*

This distribution of pharmaceutical products comes under the Ministry of Health's responsibilities and regulations in Oman. The ministry is responsible for ensuring the supply of pharmaceutical products locally. The system has been designed and analyzed according to the vision and goals of the Ministry of Health. By using this proposed system, the Ministry can:

- Establish a decentralized electronic system between all parties related to the pharmaceutical industry in Oman.
- Smooth information flow and availability between pharmaceutical parties under the governance of the Ministry of Health.
- The system will enable the authorized party to track the medical products.
- Sharing information without breaching the private information for each party.

Governance of the track and trace system for pharmaceutical products should ensure transparency and accountability by the Omani government which is also the goal of the proposed system.

B. *Operations*

There will be a challenge in making an efficient tracking system for the pharmaceutical industry in Oman. The system won't be productive and achieve all its targets unless all parties related to the supply chain management collaborate. The following operation related issues could arise with regards to this project:

- Legal (Governance) Ensure government support (Ministry of Health), and regulations for the project, with consultancy from
  - Information Technology Association ITA
  - Ministry of Laws Affairs

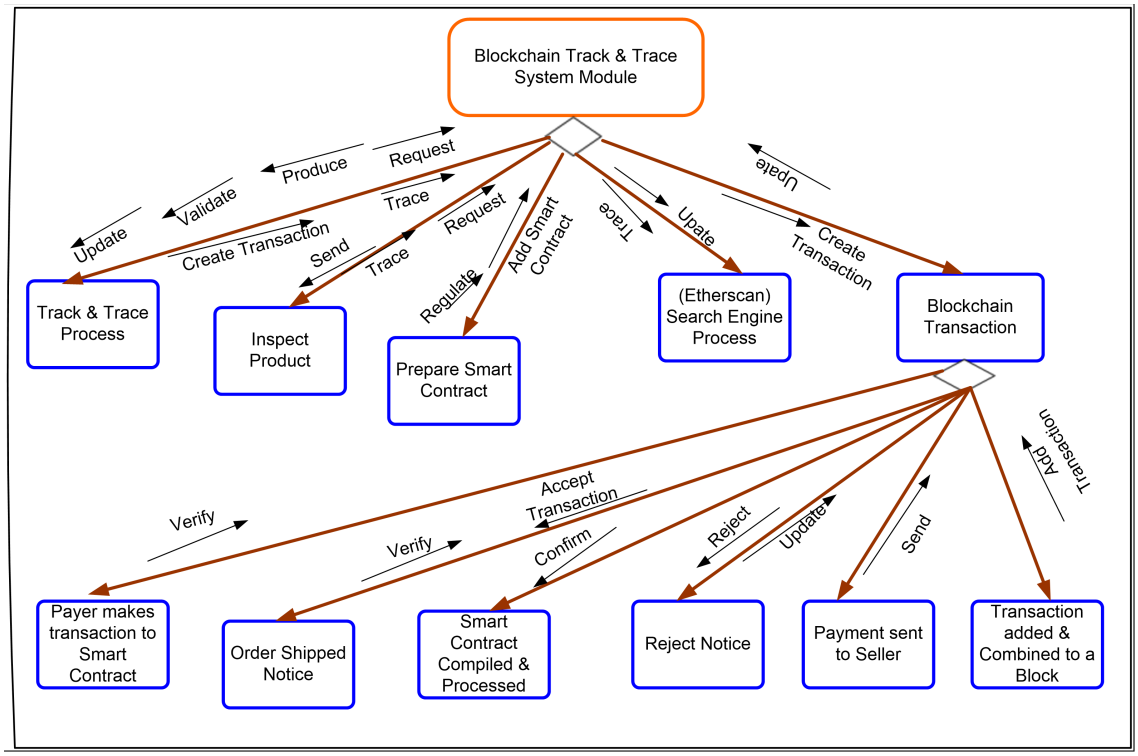

Figure 4. Track and trace process

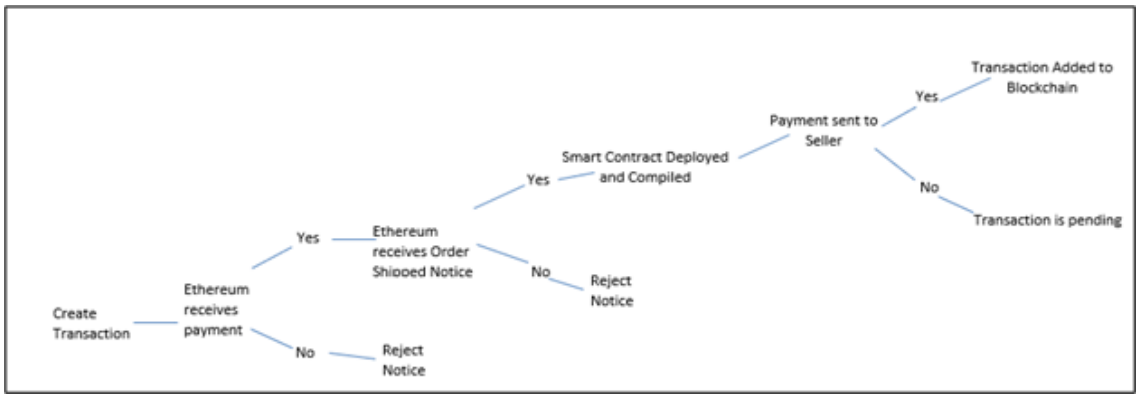

Figure 5. Decision tree for creating and adding transactions

- Ministry of Finance

- Ensure cooperation with all local parties including the government, factories, distributors, hospitals, and pharmacies. The factories only in Oman would be suggested to join the proposed system because it would be difficult for the ministry to force factories globally to follow their rules. The same issue lies with the hospitals. The hospitals that are under the Ministry of Health will be suggested to join the proposed project. In the future when the system's efficiency in tracking the medical products is proven, then we will recommend other hospitals from different sectors like the Ministry of Defense hospital, ROP hospital, Diwan hospital, and even private hospitals to join the system.
- Training the staff of the related local parties.
- Change management and convincing the key staff in every party about the effectiveness and importance of the proposed system.

C. Technology

Ministry of Health needs to work closely with ITA to come up with the technical requirements for the project. They should consider the availability of the technical re-

sources and ensure they are compatible with the Blockchain technology to run the system smoothly with no technical risk of uncertain issues that might appear before and after implementing the project. Other technical considerations that should be taken into consideration before approving the project are:

- The government must discuss whether the technical experts are capable and experienced in using a blockchain platform for coding, deploying, and mining. This can be achieved by searching for IT companies who have experience with blockchain here in Oman or our neighbors' companies.
- Identify the required hardware, software, and IT infrastructure for the project, and if they will be capable to handle all procedures and processes currently and in the future. We suggest getting recommendations about the proper IT infrastructure from ITA as a neutral non-profit organization aiming to support government organizations confidently.
- Identify which project methodology fits this project. We suggest implementing the hybrid (waterfall and agile methods) methodology for this project because it will have a proper planning phase with accumulated versions of a prototype that ensure acceptance by the Ministry of Health.
- Get a consultant from ITA about the location of physical nodes. For security purposes and the ease of reaching these nodes in any case, we recommend locating them locally.

D. Social, Ethical, and Legal

Implementing a trace and track system would gain many social and legal benefits. Society will eliminate the non-ethical actions of dealing with medical drugs. In addition to this, accountability and auditing of transactions related to pharmaceutical products would be easier than before.

Although Information Technology Authority in Oman made a special forum about the blockchain future in Oman in 2018 [24], blockchain is still considered new technology, and its regulations and rules are under development. For eliminating counterfeit drugs from the Sultanate of Oman and promote a healthy society, the Ministry of Health must develop a tracking system using the blockchain platform. Even though there will be high expenditure for this project but if the government prioritizes saving patients from the risk of counterfeit medicine drugs, then it would be worth the cost.

Adoption of blockchain technology helped Oman to achieve its digital transformation aim by developing national capacities, strengthening infrastructure, developing the IT industry, and increasing the quality and efficiency within the public sector, the digital transformation program aims to create a sustainable knowledge-based society.

5. Discussion

multiple stakeholders such as suppliers, manufacturers, and distributors, these links can be lured into counterfeiting drugs for monitorial gains for counterfeiters. Based on the literature review conducted, most of the researchers consider blockchain technology as an ideal solution for developing a track and trace system. An article published by [20] discussed the importance of a blockchain-based supply chain system for increased trust and transparency, traceability, and security however they did not analyze the system's modules in detail and the paper also lacks a discussion on governance. Another research conducted by [19] discussed an overview of the supply chain management system however they chose radio frequency identification technology (RFID) and electronic product codes (EPC) for designing a supply chain management system. In addition to this, they didn't discuss the traceability module for the development of the pharma supply chain management system.

There are number of alternatives to blockchain technology which can be utilized in supply chain. Some of the technologies are highlighted in Table I. In addition to employing blockchain technology as a solution towards pharma supply chain management system, business still requires having proper track and trace based systems' solutions.

This research article discusses the issues associated with this problem, the importance of traceability for ensuring the production and distribution of safe and authentic drugs. Overall, this research paper provides an end-to-end analysis of the existing problems and a blockchain-based track and trace system's development solution.

6. Conclusion

The exponential growth in usage of Blockchain technology for creating permanent and transparent ledgers of records has paved a way for numerous industries to opt for decentralized storage systems. It can serve as a beneficial technology for introducing trackability and traceability in pharmaceutical supply chain management systems. The model proposes to use Ethereum Blockchain technology which is an open-source technology and a popular choice for development among the Fortune 500 companies[25]. The proposed model did not implement and test the complexities involved in pharma chain management system. In addition, it is important to test and validate the inclusion of regulations associated with pharmaceutical industry while using blockchain technology. Overall, the implementation of an efficient supply chain management system for the pharmaceutical industry will result in safe and secure manufacturing and distribution of medical drugs and assist in detecting and discarding counterfeit drugs.

TABLE I. Alternatives to blockchain technologies

Technology	Description
Blockchain	Blockchain technology considered as a type of a distributed ledger.
Centralized Databases	Storage solutions focuses on centralized Databases.
Centralized Ledgers	General ledger contains all the accounts for recording transactions.
Cloud Storage	Storage of data over the cloud.
Decentralized Storage	Peer to peer decentralized data storage solution.
Distributed databases	Database solutions to store data that consists of two or more files located in different sites on same or on different network.
Other distributed ledgers	Iota Tangle: stores data across a Directed Acyclic Graphs (DAG) in which each node, or vertex, represents a transaction. Open source, designed for Internet of Things (IoT) environment. Hashgraph: another DAG ledger, patented, and the Hedera Hashgraph is the only authorized ledger. R3Corda: peer to peer distributed ledger technology model which help to record and process financial transactions.

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