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Regulation of Dual-Use Drugs using Blockchain

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ABSTRACT

Dual use drugs are more likely to be tampered with and illegally exported, where they can be combined to create dangerous substances. Drugs that have been tampered with are unlawfully sold on the black market for a greater price. These drugs can be found in both the pharmaceutical and non-pharmaceutical industries. These are chemicals that fall within the pharmaceutical category yet do not have therapeutic purposes. Instead, they labor in other industries including those that produce food, chemicals, and textiles, or they serve as a raw material or intermediate in the production of other pharmaceuticals. The capability to track the supply chain of these dual-use medications from the manufacturer to the end user is absolutely necessary to prevent this. Since blockchain uses the consensus algorithm, it is a great solution to handle supply-chain management quality.

KEYWORDS: Blockchain, Supply chain management, Dual use drugs

1. INTRODUCTION

Dual-use drugs are those that can be used in the pharmaceutical industry as well as various other sectors of the economy. These are compounds that fall under the definition of a drug but aren't employed for therapeutic purposes; instead, they're used in other industries, such as the textile, chemical, and food sectors. They can also be used as a raw material or intermediate in the production of other pharmaceuticals. It is necessary to receive authorization from the CDSCO Zonal Office in order to import medications and to utilize those drugs in two ways, including as a source of raw materials for the production of additional drugs. The acronym CDSCO stands for Central Drugs Standard Control Organization. It is a national drug authority that is responsible for managing and distributing drugs on behalf of the central government and is governed by the 1940 Drugs and Cosmetics Act and Rules. Six Zonal Offices, four Sub-Zonal Offices, thirteen Port Offices, and seven Laboratories are all managed by CDSCO for this organization. Control over the importation of various medications, new drug authorization by the Consultative Committee and DTAB, or Drugs Technical Advisory Board, as well as various licensing authentication under the authority of the Central License Approving Authority, are the main duties of CDSCO.

Several sorts of documents from the manufacturer are needed as part of the Dual-Use NOC application process. These comprise a Covering Letter, Bills of Invoice, Bills of Entry, Bills of Indent, Purchase Order, Bills of Sales Contract, Analysis Certification of All Importing Packages, Copy of High Seas Sales Agreement, and Legal Commitments. Information detailing the details must be included if the drugs being

imported have already been registered with CDSCO. A declaration that the medications won't be used for pharmaceutical or other medical purposes is necessary. Also required is thorough information regarding the number of drugs that were previously permitted.

To avoid penalties, it is advisable for the manufacturer or the authorized agent to obtain the necessary clearance for dual-use before the technical review stage for consideration before the start of the import procedure, ideally before two months of application. Bills, invoices, and other needed documents should clearly describe the purpose of the intended usage.

STRUCTURE OF PAPER

The paper is organized as follows: In Section 1, the introduction of the paper is provided along with the structure, important terms, objectives and overall description. In Section 2 we discuss the need of the system. In Section 3 we discuss the related wor. Section 4tells us about the methodology and the process description. Section 5 concludes the paper with acknowledgement and references.

2. NEED OF THE SYSTEM

Drugs for dual usage are vulnerable to manipulation. These medications are sold illegally on the black market. In order to prevent abuse and boost quality, the government drug regulator is compiling a list of active ingredients, which are compounds used to make medications with a dual purpose and are commonly imported from unregistered businesses. Dual-use APIs are sourced from unregistered businesses and are typically less expensive and of worse quality. The Department of Pharmaceuticals wants to halt the regular importation of such dual-use APIs from unregistered suppliers. NOC must be obtained from the CDSCO zonal office in circumstances involving the importation or use of such medications. Thus, there is a need for a system to regulate the dual use drug services.

3. LITERATURE SURVEY

According to the authors of [1], blockchain technology helps the supply-chain industry in so many ways such as by reducing errors, preventing product delays, eliminating fraud activities, improving management, raising consumer and supplier trust, and so on. They presented a licensed blockchain network solution that entails coordinating all peers to participate in the blockchain network by supplying cryptographic material, such as Certificate Authorities and related data. The minimum and maximum temperature conditions and fines are included in smart contracts and are calculated depending on the input from sensors in various scenarios. This entire data is recorded in a block, and as raw materials are transformed into finished goods and distributed, this entire data is saved in a chain of blocks. The data on the blockchain cannot be changed or removed.

To improve the administration of the pharmaceutical supply chain, the authors of [2] suggested using the Ethereum blockchain. Product traceability is improved when blockchain is used instead of databases without interfering with data. To store data with integrity and flexibility, they used the distributed file system known as Inter Planetary File System (IPFS). The IPFS file system assigns a distinct hash string to each file that is submitted. File retrieval is done using this hash string. Blockchain just stores the hash string, which corresponds to all of the data in the IPFS system. Smart contracts are used to connect the application to IPFS and the blockchain. Users sign up and log in to the application, and a smart contract is used to communicate with the blockchain.

The authors' [3] research revealed that the primary problems with drug safety in the supply chain for fake medications have to do with how the medications are manufactured in the beginning. Their study uses blockchain technology and encrypted QR (quick response) code security to address the problem of drug safety. Sender's public key and digital signature, receiver's public key, and the information being provided by the sender make up a transaction between participants. The participants will exchange information using encrypted QR codes that can only be read by the recipient's public key. All parties involved in the medical supply chain will verify the sender's public key. It will be allocated to all participants once the transaction has been committed.

The authors of [4] discuss blockchain in healthcare supply chains since these networks are intricate systems

that cut over organizational and regional boundaries and serve as the foundation for many services that are essential to daily living. They demonstrated a method for effective product traceability in the healthcare supply chain based on the Ethereum blockchain, utilizing smart contracts and decentralized off-chain storage. The smart contract gives a secure, immutable history of transactions to all stakeholders and ensures data provenance. It also does away with the need for middlemen.

4. PROPOSED METHODOLOGY

The proposed solution is to develop a DAPP (decentralized application) running on the blockchain to manage regulatory issues. Ingredient suppliers, legal authorities (CDSCO), logistical providers, and end-of-line producers are all part of the supply chain. Food, cosmetics, pharmaceutical, and chemical firms are among those that produce final goods. The No Objection Certificate verifies the ingredient supply industry (NOC). The ingredient suppliers must obtain NOC from CDSCO which validates the dual use drugs are authentic and intended to be used in authentic industries. Every actor must register with the company and provide the name, address, phone number, email address, company license, and other required information. At each step of the transaction, a dual authentication mechanism is developed to ensure proper supply chain operation. The system performs a thorough background check with the aid of the NOC supplied by the ingredient supplier. Verification results in the formation of a partnership. The manufacturer of the chemical has a unique QR for each medication they produce. Blockchain stores information about QR codes and drugs. A local blockchain called Ganache, which runs on the Ethereum blockchain, is used to run and deploy projects. With the proof of stake algorithm used by Ethereum 2.0, adding new blocks to the network requires less computational resources and metamask is used as wallet to interact with Ethereum blockchain. Over the drugs are printed the QR codes. The medicine must be verified for each actor's role by scanning the QR code. As soon as a QR code is scanned, blockchain is updated with the timestamp of the medicine that was scanned. The legitimacy of the medicine can be maintained using these transaction logs. The system also verifies the medicine reaches the genuine end user by dual authentication system. The DAPP must authenticate the ingredient manufacturer as well as the end user. A registration mail will be issued to the end user for registration if the DAPP does not authenticate them. After registration, a unique code will be issued to the intended end user and ingredient supplier. The end user will then scan the QR code and input the special code they were sent in the mail. The supply chain is stopped off if the code matches the manufacturer's code for the ingredient.

Fig 1 depicts the architecture diagram of supply chain management of dual use drugs. The supply chain initially begins with ingredient supplier and progress to next actor role. The NOC for validation must be submitted by the ingredient supplier. Verification of the NOC results in the formation of a partnership. For drugs, QR codes are created, and these codes are printed on the medication. The supply network for these pharmaceuticals develops, and the next actor is regulators. The regulators must scan the QR code and register in the DAPP. The blockchain is updated with a new timestamp when the QR code is scanned. When the medications reach the logistics provider, they are verified by scanning the QR code. When a medicine reaches the end user, it is validated along with the end user by examining the unique code that the end user entered. The complete supply chain is terminated and the transaction log is stored in a blockchain if the QR code entered by the end user matches the QR code provided to the ingredient provider.

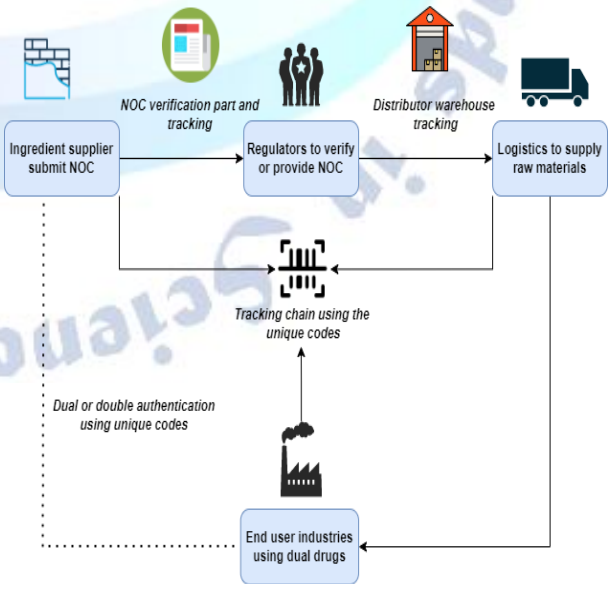

Fig 1. Architecture Diagram

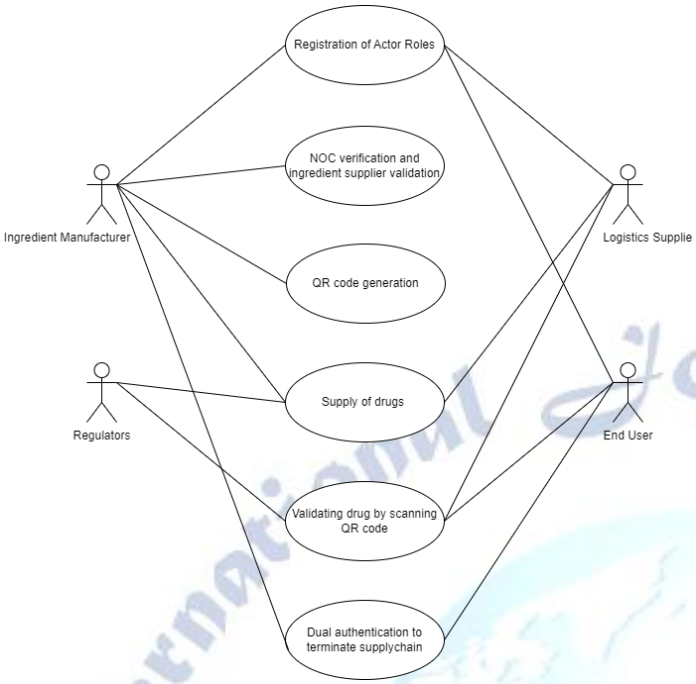

Fig 2. Use Case Diagram

Fig 2. shows the use case diagram of the supply chain of dual use drugs.

5. CONCLUSION

In this paper, we have examined the problems with dual-use drug regulation and ways that blockchain technology can help. The blockchain-based DAPP follows the movement of drugs from their manufacturing to their final consumer. Ethereum based DAPP uses proof of stake algorithm which requires less computation power as it eradicates the issue of solving complex cryptographic puzzles which requires less gas fee, as a result blocks are created easily and validated by validators in an effective way. Through this project, it will be possible to ensure security and transparency throughout the supply chain.

Conflict of interest statement

Authors declare that they do not have any conflict of interest.

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