SECURE BLOCKCHAIN SYSTEM FOR DRUG RACEABILITY IN HEALTHCARE SUPPLY CHAIN

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Abstract
Healthcare supply chains are complex structures spanning across multiple organizational and geographical boundaries, providing critical backbone to services vital for everyday life. The complexity of such systems can introduce conflicts including inaccurate information, lack of transparency and limited data provenance. Counterfeit drugs are one major problem within existing supply chains which not only has serious adverse impact on human health but also causes severe economic loss to the healthcare industry. Consequently, existing studies have emphasized the need for a robust, end-to-end track and trace system for pharmaceutical supply chains.The existing track and trace systems are centralized leading to data privacy, transparency and authenticity issues in healthcare supply chains. For drug traceability, we've proposed a totally new blockchain system. We present a blockchain-based approach leveraging smart contracts and decentralized off-chain storage for efficient product traceability in the healthcare supply chain. Furthermore, the suggested system can prune its storage effectively, resulting in a robust and usable blockchain storage solution.
Keywords: Supply chain, block chain, industries, drugs, stake holders

Introduction

Healthcare supply chain is a complex network of several independent entities that include raw material suppliers, manufacturer, distributor, pharmacies, hospitals and patients. Tracking supplies through this network is non-trivial due to several factors including lack of information, centralized control and competing behavior among stakeholders. Such complexity not only results in in-efficiencies such as those highlighted through COVID-19 pandemic but can also aggravate the challenge of mitigating against counterfeit drugs as these can easily permeate the healthcare supply chain. Counterfeit drugs are products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product. Such drugs can include medications that contain no active pharmaceutical ingredient (API), an incorrect amount of API, an inferior-quality API, a wrong API, contaminants, or repackaged expired products. Some counterfeit medications may even be incorrectly formulated and produced in substandard conditions.

The importance of drug traceability (track and trace) is increasingly emphasized and mandated by several countries across the world. The existing systems have failed to meet the requirements of drug traceability. Blockchain technology has introduced a new model of application development primarily based on the successful implementation of the data structure within the Bitcoin application. The

fundamental concept of the blockchain data structure is similar to a linked list i.e. it is shared among all the nodes of the network where each node keeps its local copy of all the blocks (associated with the longest chain) starting from its genesis block.Creating a chain of blocks connected by cryptographic constructs (hashes) makes it very difficult to tamper the records.

Objective

The main objective of this paper is to design an effective Ethereum Block chain Solution for Drug Traceability that generates immutable history of transactions, provides security, authentication, traceability of data provenance and to eradicate the conflicts of counterfeit drugs which are hazardous for human beings.

Blockchain technology is an advanced database mechanism that allows transparent information sharing within a business network. A blockchain database stores data in blocks that are linked together in a chain. The data is chronologically consistent because you cannot delete or modify the chain without consensus from the network. As a result, you can use blockchain technology to create an unalterable or immutable ledger for tracking orders, payments, accounts, and other transactions. The system has built-in mechanisms that prevent unauthorized transaction entries and create consistency in the shared view of these transactions.

Blockchain is a shared, immutable ledger that facilitates the process of recording transactions and tracking assets in a business network. Traditional database technologies present several challenges for recording financial transactions. For instance, consider the sale of a property. Once the money is exchanged, ownership of the property is transferred to the buyer. Individually, both the buyer and the seller can record the monetary transactions, but neither source can be trusted. The seller can easily claim they have not received the money even though they have, and the buyer can equally argue that they have paid the money even if they haven't.

To avoid potential legal issues, a trusted third party has to supervise and validate transactions. The presence of this central authority not only complicates the transaction but also creates a single point of vulnerability. If the central database was compromised, both parties could suffer.

Block chain mitigates such issues by creating a decentralized, tamper-proof system to record transactions. In the property transaction scenario, block chain creates one ledger each for the buyer and the seller. All transactions must be approved by both parties and are automatically updated in both of their ledgers in real time. Any corruption in historical transactions will corrupt the entire ledger. These properties of block chain technology have led to its use in various sectors, including the creation of digital currency like Bit coin.

The basic application of the Block chain is to perform transactions in a secure network. That's why people use block chain and ledger technology in different scenarios. It depends on the organization which type it requires to choose for their work. The Fig 1 represents Types of Block chain

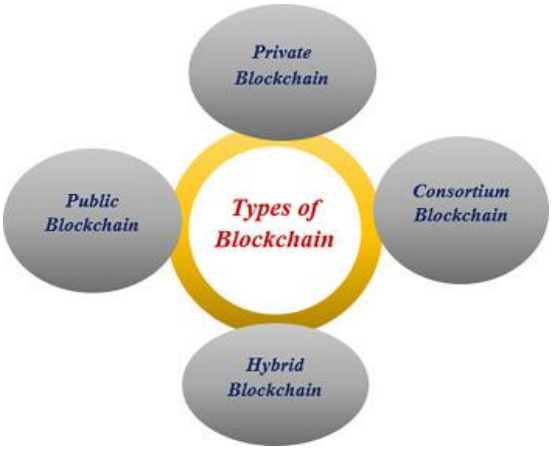

Fig.1. Types of Block chain

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Literature Review

Hyperledger is an open-source collaborative effort hosted by the Linux Foundation, focused on developing blockchain-based solutions for various industries, including healthcare and pharmaceuticals. Hyperledger Fabric, one of the Hyperledger projects, is particularly well-suited for implementing solutions for drug traceability due to its permissioned blockchain architecture, modular design, and support for privacy and confidentiality. Hyperledger Fabric offers a robust and scalable platform for implementing drug traceability solutions that enhance transparency, security, and efficiency in the pharmaceutical supply chain. By leveraging blockchain technology, Hyperledger-based solutions can address key challenges related to counterfeit drugs, product recalls, and regulatory compliance, ultimately contributing to improved patient safety and supply chain integrity. But it is having some scalability and interoperability issues [1].

A drug ledger solution for drug traceability could be designed using blockchain technology, tailored specifically for the pharmaceutical industry [2]. It establishes a permissioned blockchain network where only authorized participants, such as pharmaceutical manufacturers, distributors, pharmacies, healthcare providers, and regulatory bodies, have access. This ensures data privacy, security, and regulatory compliance.a drug ledger solution for drug traceability can enhance transparency, integrity, and accountability across the pharmaceutical supply chain, ultimately improving patient safety and regulatory compliance.

The Smart Track System is a comprehensive solution designed to enhance drug traceability in the pharmaceutical supply chain. It leverages blockchain technology to provide transparency, security, and efficiency throughout the lifecycle of pharmaceutical products. the Smart Track System improves supply chain visibility, combats counterfeit drugs, enhances patient safety, and ensures regulatory compliance in the pharmaceutical industry.It facilitates auditing and reporting by providing auditors and regulatory authorities with access to historical transaction data, supporting compliance with regulatory requirements and industry standards. It records all relevant information, including batch numbers, expiration dates, and shipping details, ensuring complete traceability of drug products. It provides enhanced visibility i.e., allows the stakeholders to observe the movement of drugs. It has complex integration such that when it is integrated with existing IT systems [3].

An NFC (Near Field Communication) based system for drug traceability information utilizes NFC technology to

enable the tracking and tracing of pharmaceutical products throughout the supply chain. Each pharmaceutical product is equipped with an NFC-enabled tag or label containing a unique identifier, such as an NFC chip or QR code. These tags are affixed to the packaging of the drug product during manufacturing [4]. At various points along the supply chain, including manufacturing facilities, distribution centers, warehouses, and pharmacies, NFC-enabled devices (such as smartphones or dedicated NFC scanners) are used to scan the NFC tags on the drug products. NFC tags can be used to authenticate and verify the authenticity of drug products. By scanning the NFC tag, stakeholders can confirm that the product is genuine and has not been tampered with, providing assurance to consumers and regulatory authorities.

An RFID (Radio Frequency Identification) based system for drug traceability information utilizes RFID technology to track and trace pharmaceutical products throughout the supply chain. Each pharmaceutical product is equipped with an RFID tag containing a unique identifier, typically in the form of an electronic chip embedded in the product packaging or label. These RFID tags can store a variety of information about the product, including batch numbers, serial numbers, expiration dates, and manufacturing details. At various points along the supply chain, including manufacturing facilities, distribution centers, warehouses, and pharmacies, RFID readers are installed to capture information from the RFID tags on the drug products. These readers emit radio waves and receive signals from nearby RFID tags [5].

A Data Matrix system-based solution for drug traceability information utilizes Data Matrix codes, a two-dimensional barcode symbology, to encode information about pharmaceutical products and track their movements throughout the supply chain. Each pharmaceutical product is assigned a unique Data Matrix code containing encoded information such as batch numbers, serial numbers, expiration dates, manufacturing details, and other relevant data. Data Matrix codes can store large amounts of information in a compact format.Data Matrix codes are printed on product packaging or labels using specialized printing equipment. These codes are typically small in size but can still contain significant amounts of data, making them suitable for encoding detailed information about each product.When a Data Matrix code is scanned, the scanning device captures the encoded information and transfers it to a central database or cloud-based platform for storage and analysis [6].

Existing Systems

Following are the existing systems for drug traceability in healthcare supplychain:

3.1.1. NFC based system:NFC-based system which affords visibility throughout different stages of pharmaceutical supply chain. Each drug is registered and authenticated by using a key value and an NFC tag is attached to it.Each unit of medication would be equipped with an NFC tag containing unique identification information, such as a serial number, batch number, expiration date, and other relevant data.

3.1.2 Smart Track System:A smart track system enables real-time monitoring and tracking of drug products throughout the supply chain.The system can leverage data analytics and machine learning algorithms to identify patterns of suspicious activity or anomalies in the supply chain, enabling proactive measures to prevent counterfeit drugs from entering the market.

3.1.3 Data Matrix Tracking System:A Data Matrix system-based solution for drug traceability

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Proposed System Model

System Architecture

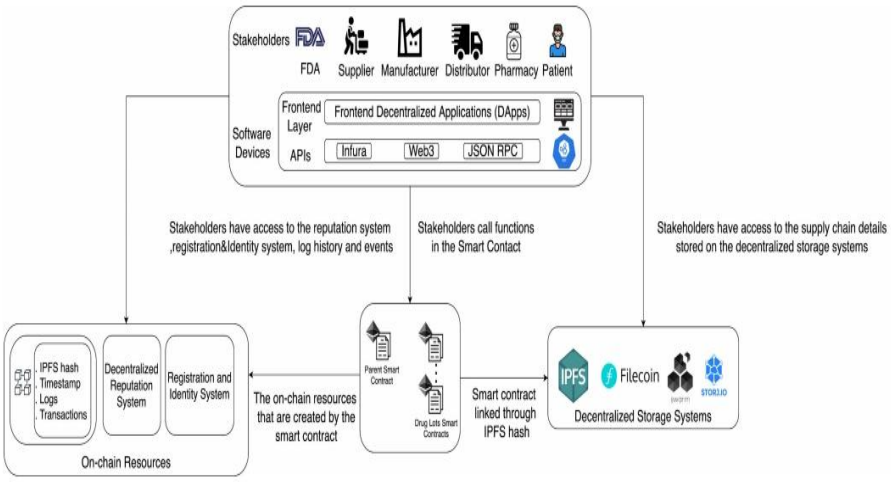

Fig.4. An Architecture for the proposed blockchain-based system for drug supply chain

Above figure shows an Architecture for the proposed blockchain-based system together with the stakeholder and their interactions with the smart contract. The proposed system for pharmaceutical traceability involves stakeholders accessing a smart contract, decentralized storage system, and onchain resources through a DApp connected to an API such as Infura, Web3, and JSON RPC. Stakeholders interact with the smart contract to initiate pre-authorized function calls, access data files through the decentralized storage system, and obtain information such as logs, IPFS hashes, and transactions through the on-chain resources.

Several methodologies are employed in blockchain-based drug traceability to ensure accuracy, transparency, and security. With the following methodologies blockchain provides immense security, traceability among all existing systems.

Serial Numbering

In thiseach drug unit is assigned a unique serial number recorded on the blockchain, allowing for precise tracking of individual products throughout the supply chain. So that the stakeholders can access information easily.

Smart Contracts:

Smart contracts automate and enforce predefined rules and agreements, such as verifying the authenticity of drugs, triggering alerts for suspicious activities, or enforcing compliance with regulations. Smart contracts are only responsible for everything in Blockchain network.

Consensus mechanism:

Consensus mechanisms ensure agreement among network participants on the validity of transactions, enhancing the integrity and reliability of the data stored on the blockchain. It is the mechanism that allows blockchain to store only the valid transactions. Through consensus mechanisms blockchain provides data integrity.

Immutable Ledger

Blockchain's immutable ledger ensures that once data is recorded, it cannot be altered or deleted, providing a trustworthy record of every transaction and movement of drugs.Once a transaction stored in blockchain it will never be changes even by the stakeholders.

Workflow of Blockchain

The workflow of a blockchain system involves a series of steps and interactions among participants to achieve consensus, validate transactions, and maintain the integrity of the distributed ledger. Here's a high-level overview of the typical workflow of a blockchain system.

Ethereum Blockchain System

For the pharmaceutical supply chain, we suggest a Ethereum blockchain-based system that offers data provenance confidentiality, traceability, atomicity, and accessibility for pharmaceutical medications. We create a smart contract that can handle numerous transactions between parties involved in the drug supply chain.

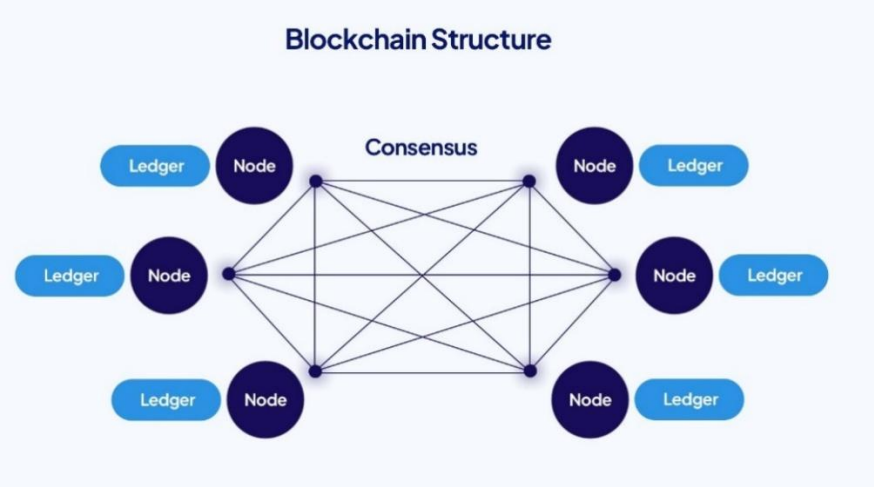

Fig.2. Structure of Block chain

The proposed approach for drug traceability in the pharmaceutical supply chain involves identifying and engaging major stakeholders, defining relationships among them, and using smart contracts technology for real-time traceability with push notifications. This is an improvement over previous efforts, which had limitations in terms of stakeholder representation, lack of defined interactions, and manual confirmation of received drugs. The proposed solution also includes a cost and security analysis and can be generalized to other supply chains. Overall, the approach presents a comprehensive application of blockchain technology for drug traceability.

Relationship between stakeholders within supply chain:

A typical medicine supply chain distribution mechanism is depicted in below Figure 3.2(b).An API supplier is responsible for delivering the basic materials needed to manufacture pharmaceuticals approved by a regulatory body such as the United States Food and Drug Administration "US FDA". The producer places the drugs in a lot or sends them to a re-packager.Demand of customers the primary distributor moves the Lots of products to the pharmacies usual the pharmacist will distribute the drugs to the patients depends upon the doctor's prescription. The Major factor that getting counterfeit drugs to end user market is intricate design of Supply chain

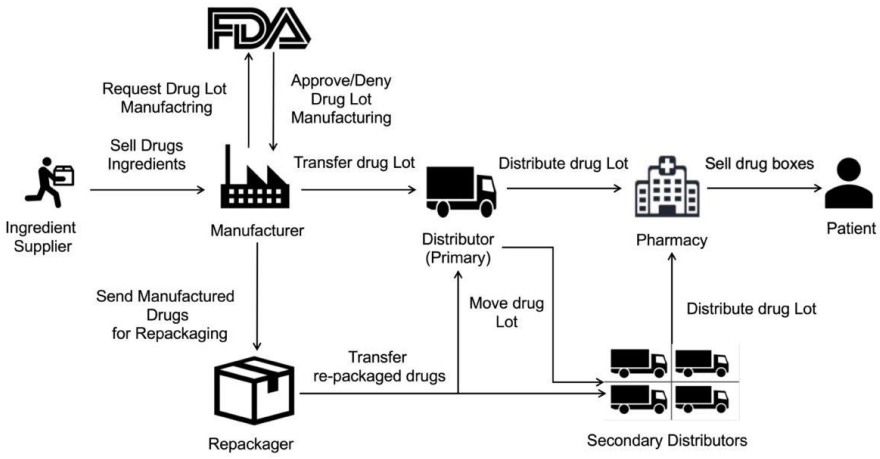

Fig.3. Stakeholders in the drug supply chain and their ties

Comparison of Proposed Solution with Existing Solutions

The following table represents the Comparison of Proposed Solution with Existing Solutions:

Features	Smart Track System	NFC based system	Data Matrix Tracking System	Proposed solution
Decentralized	No	No	No	Yes
Resilience	No	No	No	Yes
Integrity	No	No	No	Yes
Tracking and Tracing	Yes	Yes	Yes	Yes
Security	No	No	No	Yes
Transparency	No	No	No	Yes

Table.1. Comparison between our proposed solution and the existing solutions

Transparency of transactions is ensured and all solutions in Table 1 have the track and trace feature, but decentralized storage, integrity and transparency are also important for a trustworthy system. The proposed solution offers decentralization, resilience, data integrity and security through blockchain technology.

IMPLEMENTATION

Tools used in System Implementation

Following are the different tools used in system:

Ganache

Ganache is a personal blockchain emulator that you can use for Ethereum development and testing. It provides a local blockchain environment that mimics the behavior of the Ethereum mainnet, allowing developers to test their smart contracts and DApps in a sandboxed environment without incurring any actual transaction costs or waiting for block confirmations. Ganache is an essential tool for Ethereum developers, providing a convenient and efficient way to develop, test, and debug smart contracts and decentralized applications in a local environment.

Truffle

Truffle is a popular development framework for Ethereum blockchain. It offers a suite of tools that make the

process of developing, testing, and deploying smart contracts easier and more streamlined. Truffle is a powerful tool for Ethereum developers, offering a comprehensive suite of features to streamline the development, testing, and deployment of smart contracts and DApps.

MetaMask

MetaMask is a popular browser extension that serves as a cryptocurrency wallet and a gateway to the Ethereum blockchain. It allows users to interact with Ethereum decentralized applications (DApps) directly from their web browsers. MetaMask is a versatile tool that provides a seamless experience for interacting with Ethereum DApps and managing Ethereum assets directly from the browser. Its user-friendly interface and robust security features have made it a popular choice among Ethereum users and developers alike.

Experimental Results

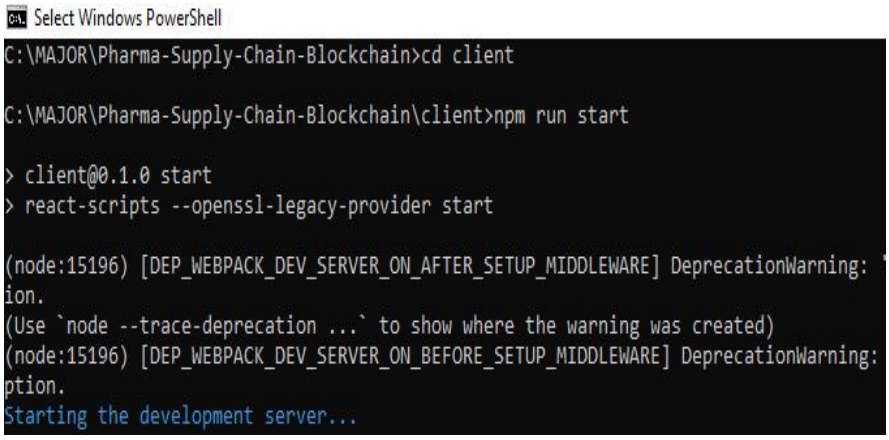

Fig.5. Launching Application

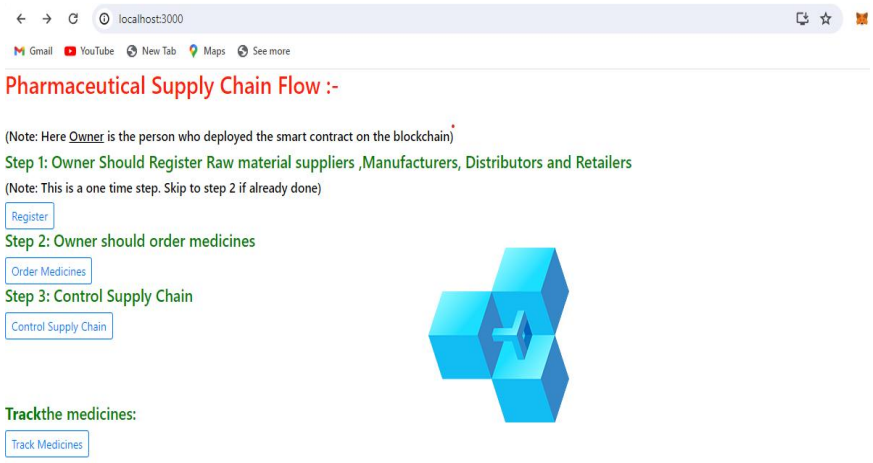

Fig.6. DApp Home Page

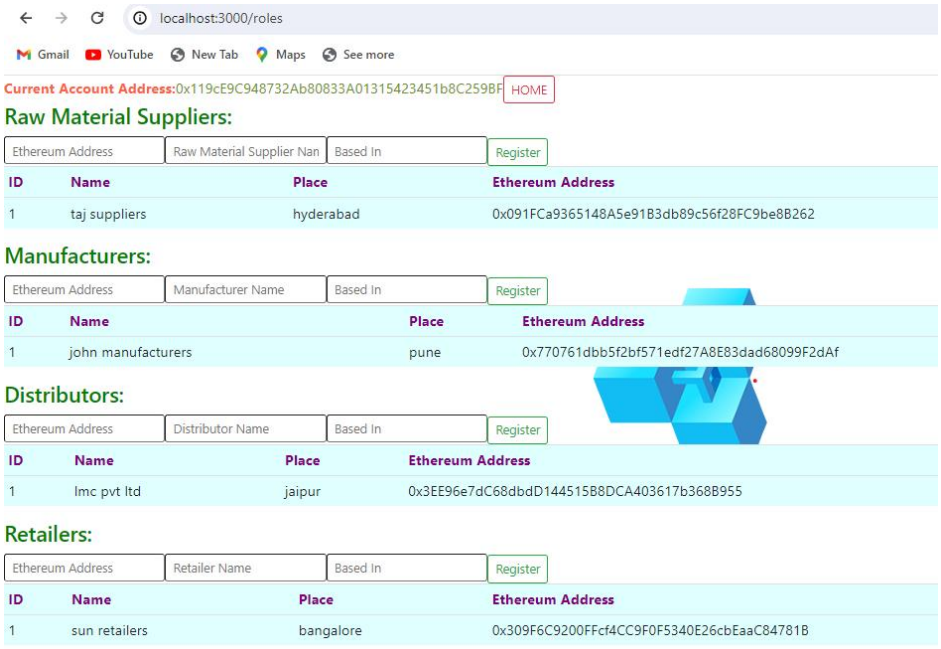

Fig.7. Registration page

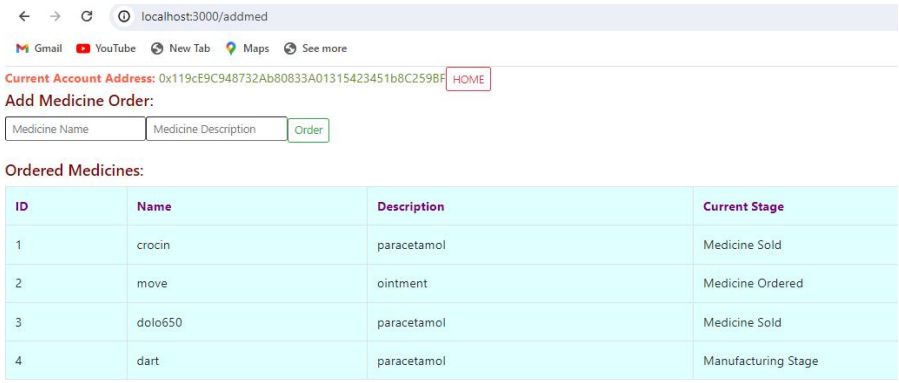

Fig.8. Ordering Medicines

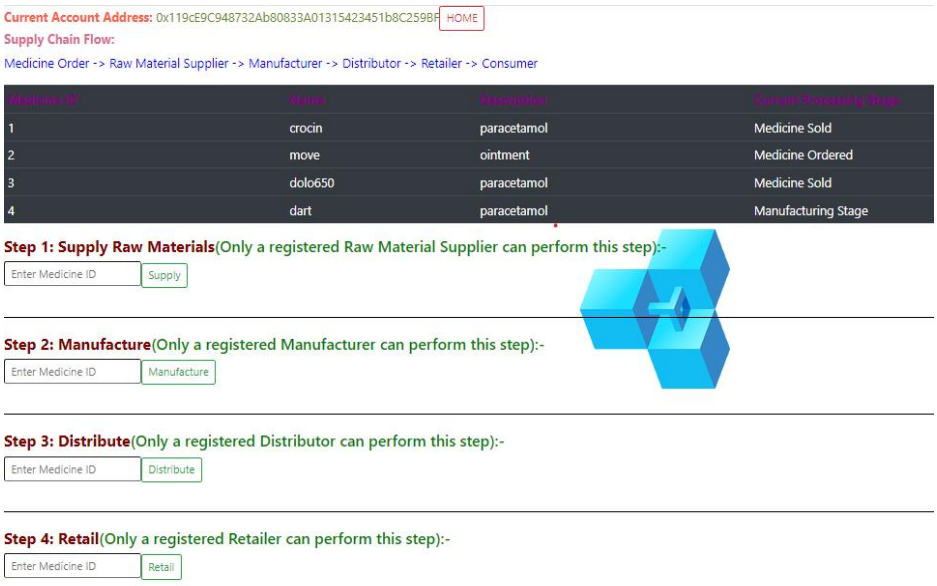

Fig.9. Controlling Supply chain

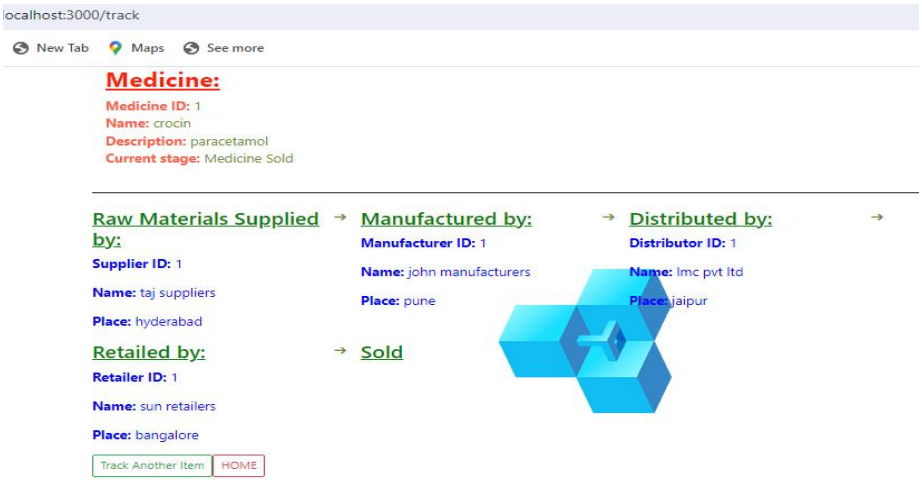

Fig.10. Tracking Medicine

CONCLUSION

In this paper, we discuss the challenge of drug traceability within pharmaceutical supply chains and proposes a blockchain-based solution to track and trace drugs in a decentralized manner. The proposed solution uses blockchain technology to achieve tamper-proof logs of events and utilizes smart contracts within Ethereum blockchain to achieve automated recording of events that are accessible to all participating stakeholders. The solution is cost-efficient and offers protection against malicious attempts targeting its integrity, availability, and non-repudiation of transaction data. The authors envision future work to extend the proposed system to achieve end-to-end transparency and verifiability of drugs use.

Specifically, our proposed solution leverages cryptographic fundamentals underlying blockchain technology to achieve greater security within the supply chain and utilizes smart contracts within Ethereum blockchain to achieve automated recording of events that are accessible to all participating stakeholders.

FUTURE SCOPE

Blockchain-based solutions for drug traceability offer significant potential for enhancing transparency, security, and efficiency in the pharmaceutical supply chain. There are several enhancements are available to make blockchain more efficient in drug traceability. Incorporating Internet of things devices to track movements and conditions of drugs in real-time for traceability. So that real time tracking can be done very easily. By enhancing the use of smart contracts and automation can streamline supply chain processes, reduce administrative overhead, and improve compliance with contractual agreements and regulatory requirements. Future enhancements may involve the development of smart contract templates, oracles, and decentralized autonomous organizations (DAOs) to automate key processes such as authentication, verification, and payments. Leveraging artificial intelligence (AI) and machine learning (ML) technologies can enhance the capabilities of blockchain-based drug traceability systems in areas such as anomaly detection, predictive analytics, and decision support. Future enhancements may involve integrating AI/ML algorithms to analyze supply chain data, detect fraudulent activities, optimize inventory management, and identify potential risks or opportunities.By incorporating these enhancements, blockchain technology can further strengthen drug traceability efforts, patient safety in market.

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