RESEARCH ARTICLE OPEN ACCESS

A Blockchain-Based Approach for Drug Traceability in Healthcare Supply Chain

Mrs. B.Vijaya MCA M.Tech., [1] , Dasari Swathi [2]

[1] Associate Professor, Department of Computer Applications

[2] Student, Department of Computer Applications

[1],[2] Chadalawada Ramanamma Engineering College(Autonomous)

ABSTRACT

Healthcare supply chains are complex structures spanning across multiple organizational and geographical boundaries, providing critical backbone to services vital for everyday life. The inherent complexity of such systems can introduce impurities including inaccurate information, lack of transparency and limited data provenance. Counterfeit drugs is one consequence of such limitations 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. Therein, an end-to-end product tracking system across the pharmaceutical supply chain is paramount to ensuring product safety and eliminating counterfeits. Most existing track and trace systems are centralized leading to data privacy, transparency and authenticity issues in healthcare supply chains. In this article, we present an Ethereum blockchain-based approach leveraging smart contracts and decentralized off-chain storage for efficient product traceability in the healthcare supply chain. The smart contract guarantees data provenance, eliminates the need for intermediaries and provides a secure, immutable history of transactions to all stakeholders. We present the system architecture and detailed algorithms that govern the working principles of our proposed solution. We perform testing and validation, and present cost and security analysis of the system to evaluate its effectiveness to enhance traceability within pharmaceutical supply chains.

Keywords: - Healthcare supply chains are complex structures spanning across multiple organizational and geographical boundaries, providing critical backbone to services vital for everyday life.

I. 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 behaviour among stakeholders. Such complexity not only results in in-efficiencies such as those highlighted through COVID-19 pandemic [1] 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 [2], [3]. 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 [4].

According to the Health Research Funding Organization, up to 30% of the drugs sold in developing countries are counterfeit. Further, a recent study by World Health Organization (WHO) indicated counterfeit drugs as one of the major causes of deaths in developing countries, and in most cases the victims are children [7], [8]. In addition to the adverse impact on human lives, counterfeit drugs also cause significant economic loss to the pharmaceutical industry. In this respect, the annual economic loss to the US pharmaceutical industry due to counterfeit medicine is estimated around $200 billion [9], [10].

A typical drug supply chain distribution process is illustrated in Figure 1. An API supplier is responsible for delivering the raw materials to manufacture drugs

approved by a regulatory agency such as the US Food and Drug Administration (US FDA). The manufacturer packages the drugs into a Lot or sends it to a re-packager. The primary distributor receives several Lots of the product and is responsible for transferring them to pharmacies based on product demand or secondary distributors (in case the quantity of Lots is very large) who can transfer these Lots to the pharmacies. Finally, a pharmacy will dispense the drug to patients [11] typically based on a doctor's prescription. Throughout the supply chain, the transfer of drugs is usually facilitated by third party logistic service providers such as UPS or FedEx and in some cases the distributors operate their own fleet of vehicles to transport the products.

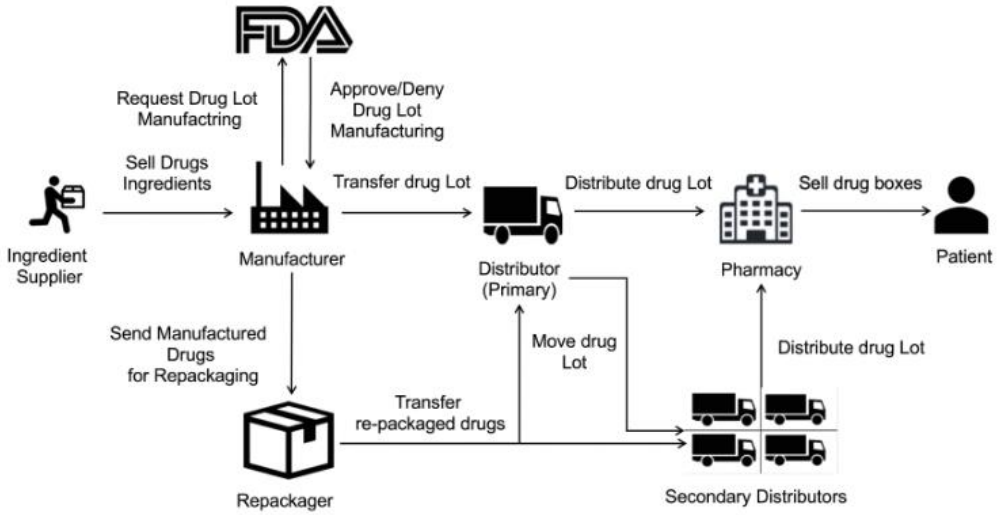

FIGURE 1. Drug supply chain stakeholders and their relationships.

The primary reason for counterfeit drugs to reach end-user marketplace is due to the complex structure of a healthcare supply chain. Leveraging the complexity of this distribution process, medications can easily pass through with little or no trail of information and verifiable documentation [12]. Consequently, monitoring, effective control and tracking of products in healthcare supply chain is fundamental to combating counterfeits.

The importance of drug traceability (track and trace) is increasingly emphasized and mandated by several countries across the world. For example, the U.S. Drug Supply Chain Security Act (DSCSA) has made it mandatory for the pharmaceutical industry to develop an electronic and interoperable system that identifies and tracks prescription drugs as they are distributed across the United States [13]. Similarly, over the last 8 years, China required all the stakeholders involved in the drugs supply chain to record information of individual pharmaceutical products in a specialized IT system whenever drugs are sent to/from their warehouses [14]. Therefore, drug traceability has become an integral part of the pharmaceutical supply chain as it establishes authenticity, and aims to track and trace chain of custody of the product across drug supply chain.

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 [15]. Recently, many real-world applications have been developed in diverse domains, such as the Internet of Things [16], e-Government [17] and e-document management [18]. These applications leverage benefits of blockchain technology due to its self-cryptographic validation structure among transactions (through hashes), and public availability of distributed ledger of transaction-records in a peer-to-peer network. Creating a chain of blocks connected by cryptographic constructs (hashes) makes it very difficult to tamper the records, as it would cost the rework from the genesis to the latest transaction in blocks as illustrated by [19].

Within the context of blockchain-based traceability for pharmaceutical supply chain, [20] presents one of the initial efforts. Although our solution has similarities with this effort due to the focus on pharmaceutical supply chain as well as the use of blockchains, we take a holistic view of the pharmaceutical supply chain, presenting an end-to-end solution for drug traceability whereas [20] only focused on a subset of these challenges.

Firstly, our approach identifies and engages major stakeholders in the drug supply chain i.e. the FDA, supplier, manufacturer, distributor, pharmacy, and patient, whereas [20] is limited to the supplier, manufacturer, and wholesaler as the stakeholders. Consequently, the pharmacists are represented as an external entity which is not the case in a real drug supply chain.

Secondly, we make explicit efforts to identify and define relationships among stakeholders, on-chain resources, smart contracts, and decentralized storage systems which is lacking in [20]. Furthermore, in view of the significance of interactions among stakeholders, we have included precise definitions to remove any ambiguity, whereas such interactions have not been defined as part of [20].

Thirdly, we use the smart contracts technology to achieve real-time, seamless traceability with push notifications so as to minimize human intervention and therefore undesired delays. Specifically, each drug Lot is assigned a unique smart contract that generates an event whenever a change in ownership occurs and a list of events is delivered to the DApp user. However, the smart contracts in [20] are programmed for specific roles such as supplier, manufacturer, and wholesaler which requires each participant to manually confirm which drugs are received. Such approach can introduce delays and inaccuracies in the immutable data stored on the ledger.

Finally, we have conducted a cost and security analysis to evaluate the performance of the proposed solution including discussion on how the proposed solution can be generalized to other supply chains.

The challenge of achieving traceability to mitigate against counterfeit drugs is well-established and several efforts have been made to address this within pharmaceutical industry. However, a careful review of literature presents several gaps and opportunities for a comprehensive application of blockchain technology for drug traceability. In this context, the primary contributions of this article can be summarized as follows:

- We propose a blockchain-based solution for the pharmaceutical supply chain that provides security, traceability, immutability, and accessibility of data provenance for pharmaceutical drugs.

- We design a smart contract capable of handling various transactions among pharmaceutical supply chain stakeholders.

- We present, implement and test the smart contract that defines the working principles of our proposed solution.

- We conduct security and cost analysis to evaluate the performance of the proposed blockchain-based solution.

II. LITERATURE SURVEY

RFID based cloud supply chain management

Radio Frequency Identification (RFID) is a key enabler for our proposed Cloud based supply chain management service. The problem area introduced here is to experiment and figure out the less expensive passive RFID in the global supply chain process using the latest cloud-based software infrastructure. This paper embraces briefly the underlying principle of RFID, introduction about supply chain management process and our proposed solution RFID based cloud based SCM services. The purpose of this wok is to provide clarity on how RFID can be used in supply chain management with modern cloud-based platforms by reducing cost overhead to the business. The primary target audiences are actors in the manufacturing, logistics, warehouse and retail industries who are interested in finding cost effective solution for managing their supply chain inventory management system.

Blockchain technology in healthcare: The revolution starts here

Blockchain technology has shown its considerable adaptability in recent years as a variety of market sectors sought ways of incorporating its abilities into their operations. While so far most of the focus has been on the financial services industry, several projects in other service related areas such as healthcare show this is beginning to change. Numerous starting points for Blockchain technology in the healthcare industry are the focus of this report. With examples for public healthcare management, user-oriented medical research and drug counterfeiting in the pharmaceutical sector, this report aims to illustrate possible influences, goals and potentials connected to this disruptive technology.

Drugledger: A Practical Blockchain System for Drug Traceability and Regulation

Drug traceability system is essentially important for public drug security and business of pharmaceutical companies, which aims to track or trace where the drug has been and where it has gone along the drug supply chain. Traditional centralized server-client technical solutions have been far from satisfying for their bad performances in data authenticity, privacy, system resilience and flexibility. In this paper, propose a scenario-oriented blockchain system for drug traceability and regulation called Drugledger, which reconstructs the whole service architecture by separating service provider into three independent service components and ensures the authenticity and privacy of traceability data. Drugledger is more resilient than traditional solutions with its p2p architecture. Furthermore, Drugledger could efficiently prune its storage, achieving a finally stable and acceptable blockchain storage. Besides, algorithms reflecting the real drug supply chain logic (e.g, package, repackage, unpackage, etc.) are designed based on the expanded UTXO workflow in Drugledger

III. EXISTING SYSTEM

Existing solutions within supply chain management have traditionally used barcodes and RFID tags as identification techniques, Wireless Sensor Networks (WSN) to capture data, and Electronic Product Code (EPC) to identify, capture, and share product information to facilitate tracking of goods through different stages. In this context, Smart-Track utilizes GS1 standards barcodes containing unique serialized product identifier, Lot production and expiration dates. The information contained in the GS1 barcode is captured across various supply chain processes and used to maintain a continuous log of ownership transfers. As each stakeholder records the possession of the product, an end

user (patient) can verify authenticity through central data repository maintained as Global Data Synchronization Network (GDSN) by using a smartphone app. In the downstream supply chain at the warehouse, pharmacy and hospital units can scan the barcode to verify the product and its characteristics. Similarly, Data-Matrix tracking system creates a Data-Matrix for each drug which includes the manufacturer ID, Product ID, Unique ID of the package, the authentication code, and an optional meta-data. This allows the patient to verify the origin of the drug by using the attached Data-Matrix.

Disadvantages

- Non-Robust
- Ineffective Drug Traceability.
- Authencity Issues

IV. PROPOSED SYSTEM

Within the context of blockchain-based traceability for pharmaceutical supply chain, presents one of the initial efforts. Although our solution has similarities with this effort due to the focus on pharmaceutical supply chain as well as the use of blockchains, we take a holistic view of the pharmaceutical supply chain, presenting an end-to-end solution for drug traceability.

The challenge of achieving traceability to mitigate against counterfeit drugs is well-established and several efforts have been made to address this within pharmaceutical industry. However, a careful review of literature presents several gaps and opportunities for a comprehensive application of blockchain technology for drug traceability. In this context, the primary contributions of this project can be summarized as follows:

- ❑ Propose a blockchain-based solution for the pharmaceutical supply chain that provides security, traceability, immutability, and accessibility of data provenance for pharmaceutical drugs.
- ❑ Design a smart contract capable of handling various transactions among pharmaceutical supply chain stakeholders.
- ❑ Present, implement and test the smart contract that defines the working principles of our proposed solution.

- ❑ Conduct security and cost analysis to evaluate the performance of the proposed blockchain-based solution.

Advantages

- ❑ Robust
- ❑ Effective Drug Traceability
- ❑ Secured

V. IMPLEMENTATION

- ➢ Pharmacy Seller
- ➢ Patient

Pharmacy Seller

In this module, the seller has to login by using valid user name and password. After login successful he can do some operations such as View & Authorize Users,AddCategories,AddDrug,View all Drugs, View all Purchased Drugs, Find Total Bill On Purchased Drugs, List All Drugs by Chain Tree, List All reviewed comments on Drugs,List All Search and View Details History,View All User's Drug Search, View Drugs Rank chart,View Search ratio in chart.

Patient

In this module, there are n numbers of users are present. User should register before doing any operations. Once user registers, their details will be stored to the database. After registration successful, he has to login by using authorized user name and password. Once Login is successful user will do some operations like My Profile,AccountManagement,Search Drugs and Purchase,View my search History,View Drugs by Chain Tree,View Other Patient Comments On Drugs,View Top K Drugs Purchase,View Top K Query Details.

VI. RESULTS

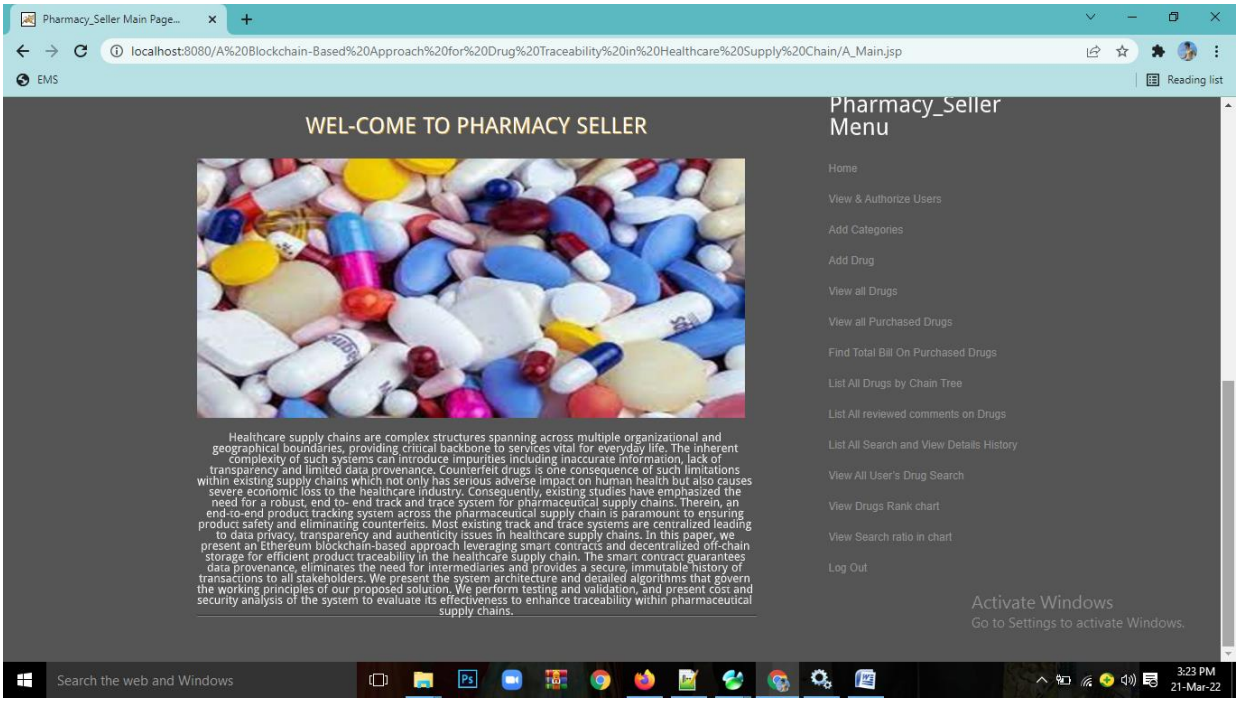

Fig 2. admin page

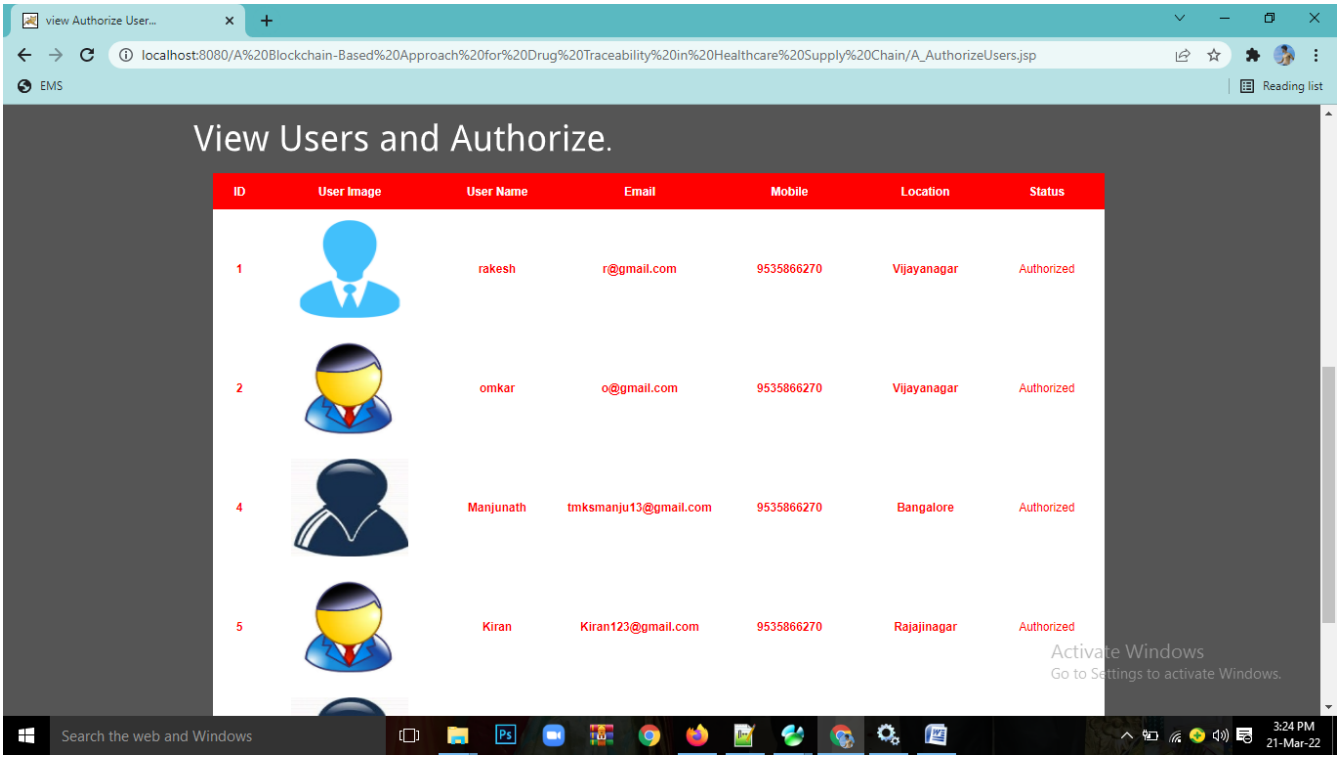

Fig 3. view users and authorize

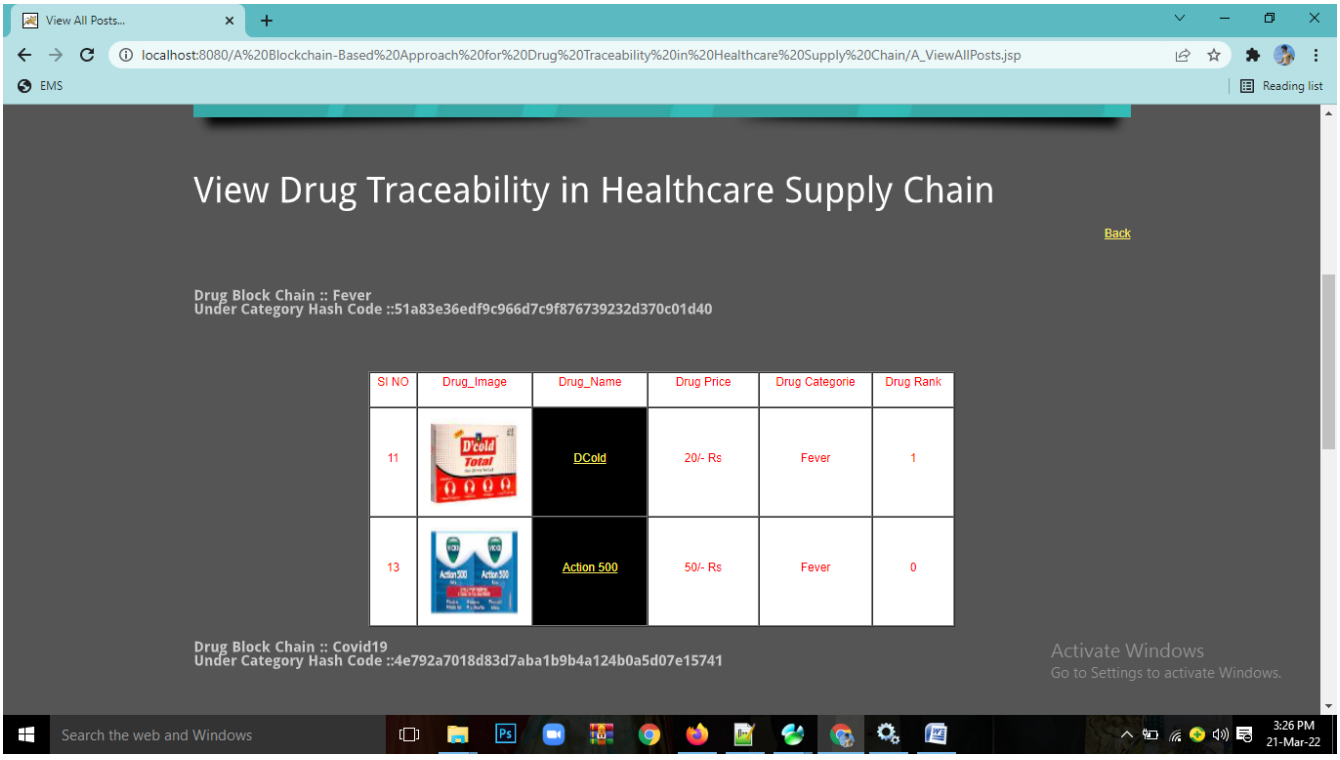

Fig 4. View Durg

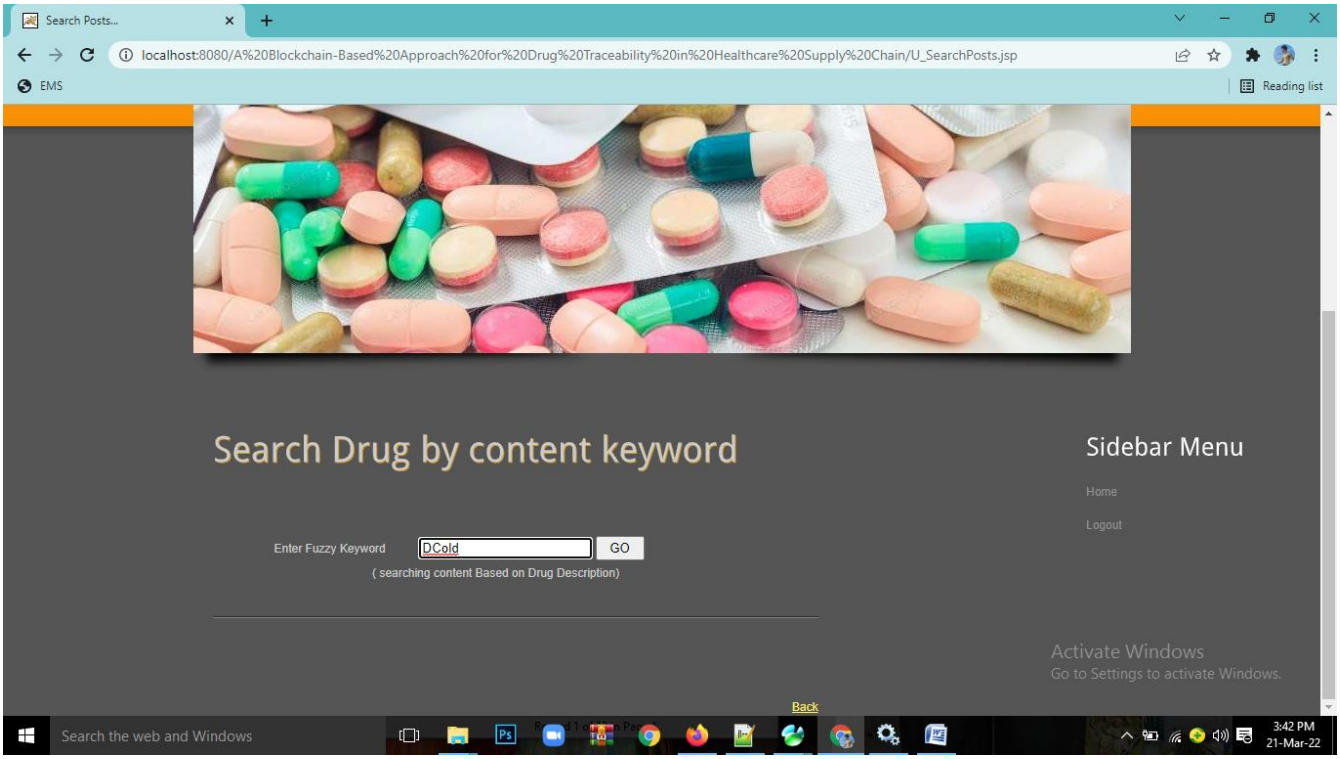

Fig 5 search drug

VII. CONCLUSION

Investigated the challenge of drug traceability within pharmaceutical supply chains highlighting its significance especially to protect against counterfeit drugs and have developed and evaluated a blockchain-based solution for the pharmaceutical supply chain to track and trace drugs in a decentralized manner. Specifically, our proposed solution leverages cryptographic fundamentals underlying block chain technology to achieve tamper-proof logs of events within the supply chain and utilizes smart contracts within Ethereum block chain to achieve automated recording of events that are accessible to all participating stakeholders and have demonstrated that our proposed solution is cost efficient in terms of the amount of gas spent in executing the different functions that are triggered within the smart contract.

REFERENCES

1 "Shortage of personal protective equipment endangering health workers worldwide" https://tinyurl.com/v5qauvp. [Accessed on: 3-June-2020]

2 Chambliss W, Carroll W, Yelvigi M, el al. "Role of the pharmacist inpreventing distribution of counterfeit medications". J Am pharm Assoc.2012;52(2): 195-199.

3 Ziance RJ. "Roles for pharmacy in combating counterfeit drugs". J Ampharm Assoc. 2008;48: e71-e88.

4 Toscan P. "The dangerous world of counterfeit prescription drugs".Available: http://usatoday30.usatoday.com/money/industries/health/drugs/story/2011-10-09/cnbc drugs/50690880/1.[Accessed on: 3-June-2020]

5 T.Adhanom,"Health is a fundamental human right",2017 valuable at. :https://www.who.int/mediacentre/news/statements/ fundamental-human-right/en/. [Accessed: 26- May-2020].

6 World Health Organization, "Growing threat from counterfeitmedicines", 2010.

7 Daniela Bagozzi, C.L. "1 in 10 Medical Products in DevelopingCountries Is Substandard or Falsified". 2017. Available: https://www.who.int/news-room/detail/28-11-2017-1-in-10-medical-products-

indeveloping-countries-is-substandard-or-falsified.[Accessed: 3-June-2020].
8 The Guardian. "10% of Drugs in Poor Countries Are Fake, SaysWHO". 2017. Available: https://www.theguardian.com/globaldevelopment/2017/nov/28/10-of-drugs-in-poor-countries-are-fakesays-who.[Accessed: 3-June-2020].
9. H. R. Funding, 20 Shocking Counterfeit Drugs Statistics, Jun. 2017, [online] Available: https://healthresear.chfunding.org/20-shocking-counterfeit-drugs-statistics.
Show in Context Google Scholar
10 A. Seiter, "Health and economic consequences of counterfeit drugs", Clin. Pharmacol. Therapeutics, vol. 85, no. 6, pp. 576-578, Jun. 2009.
Show in Context CrossRef Google Scholar
11. A Drug Supply Chain Example, Jun. 2020, [online] Available: https://www.fda.gov/drugs/drug-shortages/graphic-drug-supply-chain-example.
Show in Context Google Scholar
12. A. Marucheck, N. Greis, C. Mena and L. Cai, "Product safety and security in the global supply chain: Issues challenges and research opportunities", J. Oper. Manage., vol. 29, no. 7, pp. 707-720, Nov. 2011.
Show in Context CrossRef Google Scholar
13. U.S. Food and Drug Administration, Jun. 2020, [online] Available: https://fda.gov.
Show in Context Google Scholar
14. On suspension of drug electronic supervision system, Feb. 2016, [online] Available: http://www.sda.gov.cn/WS01/CL0051/144782.html.
Show in Context Google Scholar
15. M. Andrychowicz, S. Dziembowski, D. Malinowski and L. Mazurek, "On the malleability of Bitcoin transactions", Proc. Financial Cryptography Data Secur., pp. 1-18, 2015.
Show in Context CrossRef Google Scholar
16. A. Suliman, Z. Husain, M. Abououf, M. Alblooshi and K. Salah, "Monetization of IoT data using smart contracts", IET Netw., vol. 8, no. 1, pp. 32-37, Jan. 2019.
Show in Context CrossRef Google Scholar
17. K. M. Khan, J. Arshad and M. M. Khan, "Simulation of transaction malleability attack for blockchain-based E-voting", Comput. Electr. Eng., vol. 83, May 2020.
Show in Context CrossRef Google Scholar
18. N. Nizamuddin, K. Salah, M. Ajmal Azad, J. Arshad and M. H. Rehman, "Decentralized document version control using ethereum blockchain and IPFS", Comput. Electr. Eng., vol. 76, pp. 183-197, Jun. 2019.
Show in Context CrossRef Google Scholar
19. S. Nakamoto, Bitcoin: A Peer-to-Peer Electronic Cash System, 2009, [online] Available: https://metzdowd.com.
Show in Context Google Scholar
20. M. Muniandy, O. Gabriel and T. Ern, "Implementation of pharmaceutical drug traceability using blockchain technology", Int. J., vol. 2019, pp. 35, Jun. 2019.
Show in Context Google Scholar