Towards a Blockchain-based approach to fight drugs counterfeit

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Abstract

A safe supply of drugs is critical to public health. Over the past years, the world witnessed a significant rise in the number of pharmaceutical drug frauds, causing thousands of victims who are affected by poisoning, untreated diseases, premature deaths, and treatment failures. Blockchain technology is currently being proposed as a way to solve the problem of counterfeit drugs by keeping track of the drug supply chain. Blockchain is a distributed, immutable ledger shared between nodes in a peer-to-peer network, where each node stores the same data, and coexists with other nodes without having to trust them. Existing studies have highlighted the need for a robust, end-to-end tracking and tracing system for the drug supply chain. Thus, an end-to-end product tracking system in the drug supply chain is critically needed to ensure product safety and eliminate counterfeits. The majority of existing tracking and tracing systems are centralized, leading to data privacy, transparency and authenticity issues in healthcare supply chains. In this paper, we propose an approach based on Ethereum blockchain that leverages smart contracts and decentralized off-chain storage to ensure efficient drugs traceability and which monitors the consumption of these drugs by patients according to a doctor's prescription. This Smart Contract guarantees data provenance, excludes the middleman need, and provides a secure and immutable transaction history to all involved participants. We introduce the system architecture and detailed algorithms governing the operating principles behind our proposed approach. We present an evaluation of the effectiveness of the approach, in improving traceability within drug supply chains, through testing and validation, and analyzing the costs and security of the approach.

Keywords

Blockchain, Ethereum, Drugs counterfeit, Traceability, Healthcare, Supply chain

1. Introduction

In the Healthcare area, pharmaceutical drug fraud has become a widespread issue due to the complexity of the drug life cycle. Following the completion of the drug manufacturing process, the drug must be transferred from factory stocks to distributors at the wholesale level, who will subsequently transfer it to pharmacies which sell it to patients to consume.

Drug life cycle is a complex process that includes many stakeholders like raw material supplier, manufacturer, distributor, distribution points such as pharmacies and hospitals until drug consumer. Due to lack of information, centralized control, and competing behavior among

Tunisian Algerian Conference on Applied Computing (TACC 2021), December 18–19, 2021, Tabarka, Tunisia
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stakeholders, tracking supplies through this process is not simple. This complexity can lead to the injection of certain drugs that aren't in the manufacturing or packaging standards, whether voluntary or involuntary, thus constitute a danger for the consumer. These drugs may not contain Active Pharmaceutical Ingredient (API), unapproved or poor quality of active pharmaceutical ingredient, harmful substances, or substances which should no longer be used because they were expired. The drugs sold in developing countries are 30% counterfeit drugs, according to the Health Research Funding Organization [1]. Based on these statistics, it is clear that the pharmaceutical industry is very vulnerable to counterfeit drugs. Like indicated by WHO, counterfeit drugs are considered as one of the major causes of deaths in developing countries, and in most cases the victims are children [2, 3]. Counterfeit drugs don't affect human health only, it also cause huge economic loss to the pharmaceutical industry. In America the loss in the pharmaceutical industry is around $200 billion dollars due to counterfeit drugs[1, 4]. Drug supply chain process is sequential. It starts with the API supplier who gives raw materials to drug manufacturers. Drug manufacturers need regulatory agency authorization such as Directorate of Pharmacy and Medicines in Tunisia (DPM) before starting drugs making. Subsequently, drugs are packaged into Lots by manufacturers. Afterwards, these lots are distributed to the pharmacies and hospitals by the distributor so that patients can buy the box. There is always a risk of incorporating counterfeit drugs throughout this supply chain cycle [5]. This is why drug traceability must be an integral part of the pharmaceutical supply chain. Blockchain solutions are currently being proposed to address the problems of traceability in the healthcare area since it can help to keep track of the manufacturing chain of the drug [6]. The blockchain ensures that all transactions are immutable and time-stamped, thus guaranteeing that the information cannot be tampered with or falsified. Pharmaceutical drug industries can use either public or private blockchain systems depending on the requirements of their business. By using blockchain technology, it is possible to obtain the complete trace of the drug. As the drug is transported from one place to another, both its movement information, coupled with its temperature can be stored on the blockchain, thereby improving the traceability of the drug and reducing the risk of its counterfeiting. In this paper, we design a system that uses traceability property of blockchain technology to ensure drugs traceability, monitor drugs temperature, detects a potentially damaged drug and relies on an off-chain InterPlanetary File System-IPFS storage to store user's confidential data. This allows sensitive information to never be leaked to others exploring the blockchain, as the only information stored on-chain is the IPFS hash. The proposed approach pushes back the introduction of counterfeit drugs at all possible access points. The key contributions of this paper can be summarized as follows :

1. We present blockchain based solution for counterfeit elimination in pharmaceutical supply chain management system that improves the safety, traceability, and transparency of pharmaceutical drugs.
2. We build a set of smart contracts capable of managing various transactions between pharmaceutical supply chain stakeholders.
3. We introduce, implement and test the smart contracts defining the operating principles of our proposed solution.
4. We conduct a cost analysis to evaluate the performance of the proposed solution.

This paper is structured as follows: Section 2 presents a review of existing works with respect to traceability in the pharmaceutical supply chain. Section 3 provides a high level overview of our drug traceability proposed approach, while Section 4 introduces the implementation details. Section 5 provides a discussion and evaluation of the proposed approach and Section 6 concludes this work with future work.

2. Related work

In this section, it is a question of making an overview of some works that have been made with blockchain technology in the supply chain industry. The project MediLedger is a blockchain based network to control drug supply and reduce counterfeit drug distribution [7]. Ambrosus ecosystem based on blockchain technology is designed to confirm manufacturing source, quality and compliance according to product standards. It also assures the respect of good conditions of transport and storage throughout their passage from the producer to the final consumer [8]. In [9] a secure drug supply chain based on Hyperledger Fabric to keep track of each individual in the supply chain to counter drug counterfeiting and to allow doctors, patients, nurses, and pharmacist to enter their data is presented. The system authors describe its performance in terms of throughput and latency. The authors in [10] proposed blockchain platform which offers high transparency and traceability to avoid counterfeiting in drug supply chain and needs supply chain members authorization to create data. The Linux Foundation research on drug counterfeiting prevention resulted in the development of drug control system based on Hyperledger Fabric which maintains, supplies authentic drug supply in drug supply chain, and allows administrators to manage patients and doctors [11, 12]. In [13] authors proposed a drug traceability system called Drugledger which offers authenticity and privacy of stakeholders' traceability information. A system to ensure the efficient traceability of products in the health-care supply chain with the Ethereum blockchain and the IPFS[14] file storage system is being developed in [15]. A smart contract is created for each product to record their movements with events. An Ethereum blockchain-based system for tracing covid-19 vaccines is presented in [16]. This system creates a QR code for each vaccine and for each person who signs up to receive the vaccine. The temperature of the vaccine is constantly checked during transport to ensure that it is within the range of values set in the smart contract. Before injecting the vaccine, the identity of the beneficiary must be verified and the condition of the vaccine must be checked if it has not been damaged during transport. The beneficiary may report possible side effects after receiving the vaccine. Some work has not contented just with ensuring the authenticity of drugs, but also adding a module that offers the drug best suited to users. This is the case in [17] based on blockchain using Hyperledger and machine learning (N-Gram and LightGBM model). Blockpharma is a blockchain based system designed to reduce counterfeit products in supply chain. This system includes a machine learning module to verify drug authenticity before buying [18]. Authors in [19] used blockchain technology using the Hyperledger Project and temperature sensors to track drug distribution and to know about drug status. The proposed framework will therefore record and time stamp the various transfers.

3. Drug traceability approach overview

The present section provides a high-level overview of drug traceability's proposed approach by outlining drug traceability's proposed infrastructure, the actors involved, and the main process for achieving an efficient traceability of the pharmaceutical drug solution.

The infrastructure of the proposed approach consists of two main components: a distributed storage system and private permissioned Blockchain.

3.1. Involved actors

The principal roles of the involved actors are detailed as follows.

- **Regularity authority (DPM):** is a national agency responsible for overseeing all drug supply chain actors and all their drug-related activities. It has the power to grant or withdraw a license to an actor wishing to participate in the supply chain. It approves the manufacture and marketing of a drug.
- **The manufacturer:** is the one who produces drugs in a defined laboratory, distributes them in batches, and puts them on the market to help the sick to be cured.
- **The distributor:** is responsible for the drug transportation from manufacturer to distribution points accessible to the public. Thus, it acts as an intermediary between the manufacturers and the distribution points.
- **Pharmacies:** are drug distribution/sale points accessible to the public. There are pharmacies in every locality. Their decentralized locations allow easy access to drugs to prevent people from traveling to the manufacturer, a trip that can also be a long journey.
- **Hospitals:** are also distribution points. Normally the hospital is made to treat sick patients. But there are times when the hospital needs medicine right away. So it is necessary that the hospital has its own drug store.
- **Doctors:** are the staff of a hospital. Their role is to diagnose a patient to know his anomaly and provide him with an effective treatment to heal.
- **The patient:** is the client of a hospital. This one is distinguished by an illness that he suffered in his body and decides to consult a specialist in order to get better.

3.2. Main process for drug traceability approach

Figure 1 depicts the main process of our proposed drug traceability approach along with its different steps, which are detailed as follows. Moreover, to clarify the approach, we present the interactions between different actors in a sequence diagram, as shown in figure 2.

(1) **Registration and authorization of supply chain actors:** The DPM registers each supply chain actor in the system by assigning to him an Ethereum address which will allow him to be identified. It also registers an image that represents the license of the actors in the supply chain. This license is an insurance that proves that the supply chain actors are competent in carrying out their work. The image of the actor license will be saved on the IPFS storage system. It will return a hash code which is an identifier allowing to find the location of the file saved on IPFS. The generated hash will be stored on the blockchain to recover the file

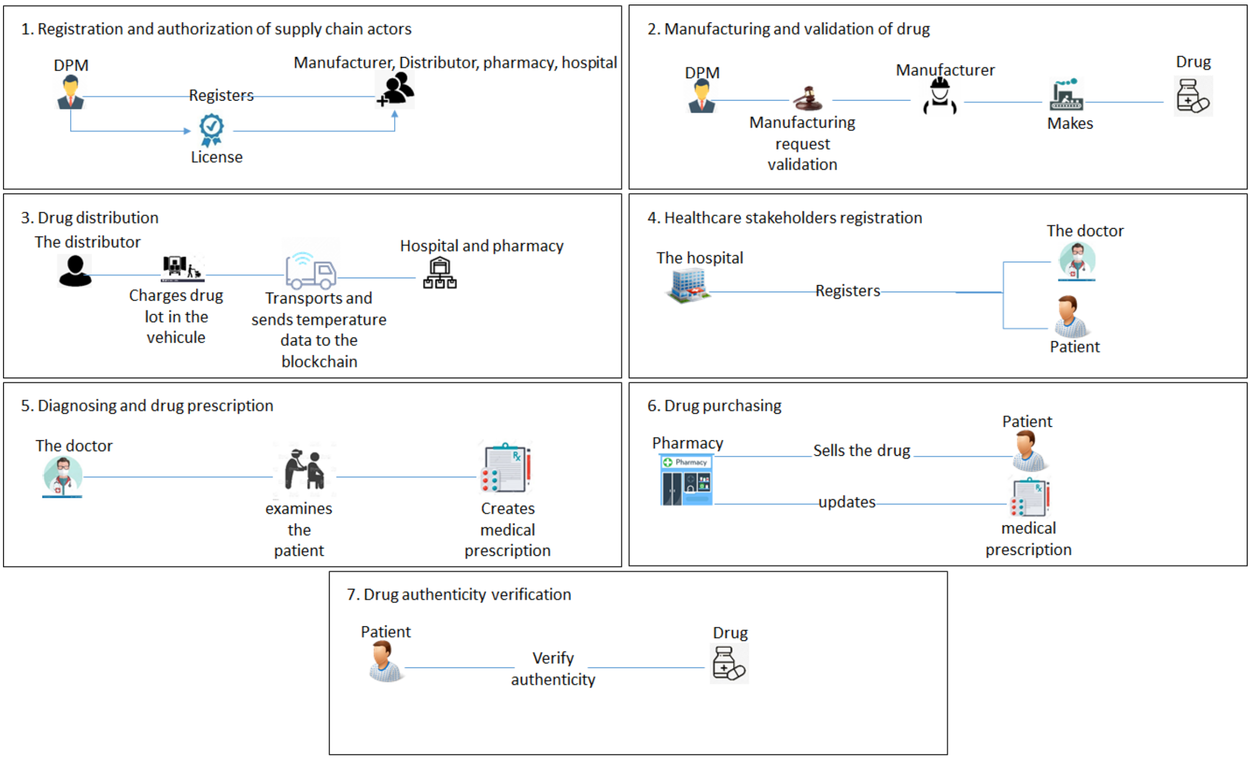


Figure 1: Approach overview

during the verification of a drug. The DPM can withdraw the license and cut off access to the system to an actor who does not do his job well in the supply chain. Actors like manufacturers, distributors, pharmacies, hospitals, and doctors must be registered on the system and have a valid license to perform operations in the system.

(2) **Manufacturing and validation of drug:** The drug manufacturer must have authorization from the DPM to begin making a drug. The manufacturer enters the characteristics of the drug into the system and waits for DPM's approval. After analysis of the drug, the DPM can refuse or approve the request to manufacture the drug. In the event of a favorable opinion, the manufacturer will be able to manufacture batches of the new drug which has been added. Then he calls a distributor who has a valid license and who is available to transport the batches of medication to pharmacies and hospitals where people can purchase the box.

(3) **Drug distribution:** The distributor schedules a shipment of drug batches in the system and indicates which batches are affected by the transport. The lots will be loaded into the vehicle. Some drugs need to be stored within a well-defined temperature range; their effectiveness may decrease if their temperature exceeds the set threshold. To detect these potentially used drugs, the vehicle of the distributor will be equipped with a temperature sensor which will determine the temperature throughout the transport. The sensor data will be collected by a Raspberry Pi single card computer, which will transmit them to the blockchain. The temperature data will not be recorded but will only be used for verification. The blockchain

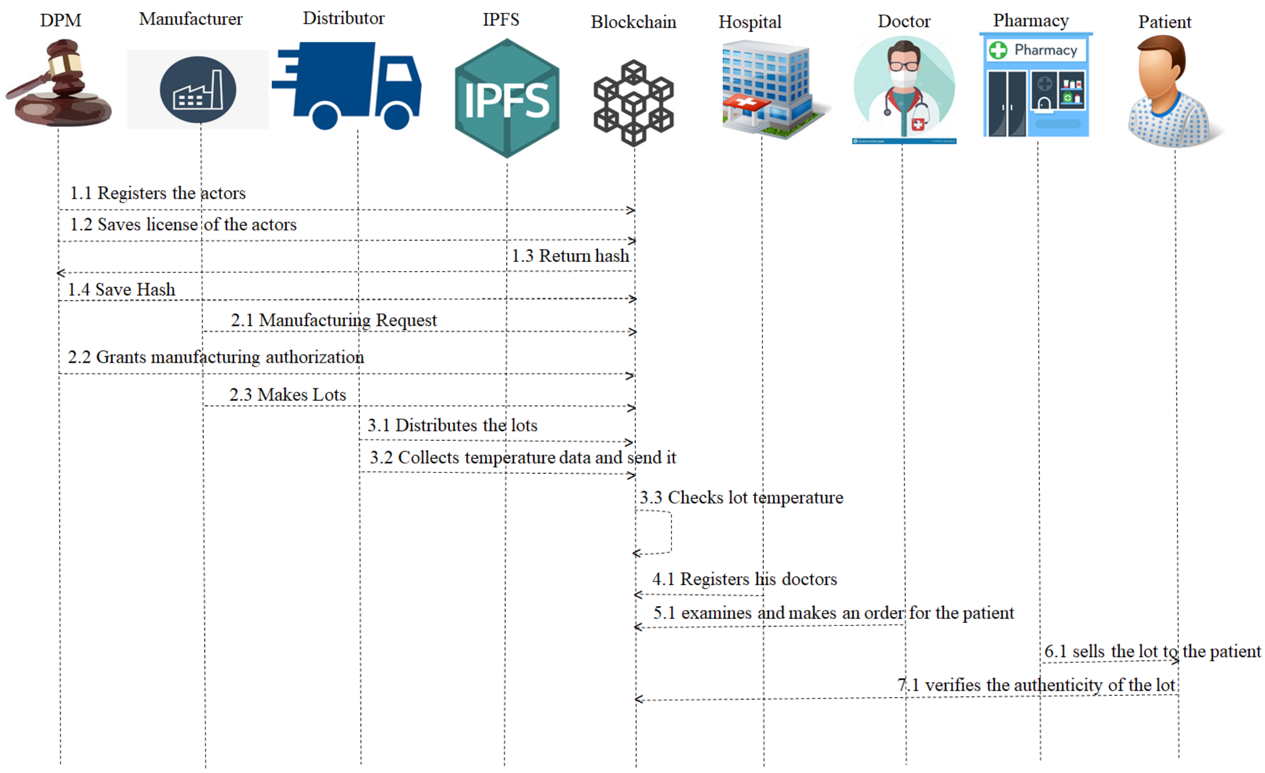


Figure 2: The actors interactions

matches the temperature of the transport in the temperature range of each batch of drugs being transported. The batches which will exceed their temperature will be marked and the consumer will have a warning during the verification indicating the conditions of transport. The distributor at the end will mention the points of sale (pharmacies and hospitals) where he delivered each batch.

(4) **Healthcare stakeholders registration:** The hospitals will manage their staff by registering in the system the doctors who work in their homes. They will also register patients if they have not been added previously by another hospital. This will allow to have all the medical data of a patient in a global way and to constitute a complete medical file.

(5) **Diagnosing and drug prescription:** Following a medical diagnosis of a patient, the doctor will prescribe a prescription containing the list of drugs that the patient must buy and consume. A consumption limit will eventually be defined on each drug of the prescription.

(6) **Drug purchasing:** To purchase drugs, the patient must go to a pharmacy. The pharmacy checks the patient's prescription to make sure that he has not reached the dose prescribed by the doctor. If this is the case the patient buys the drugs and the pharmacy accesses the patient's medical file to quote the drugs purchased. Otherwise, the pharmacy will refuse the sale of drugs to the patient.

(7) **Drug authenticity verification:** After purchasing the medicine boxes, the patient can verify their authenticity by indicating the name of the medicine purchased and its batch number. If the drug batch is genuine, it will have a complete history containing the information of the manufacturer, distributor, packaging of the batch according to temperature and the points where the batch was delivered. Otherwise, he will have no information about the lot.

4. System Prototype

In this section, we are implementing the drug traceability approach based on IoT and Ethereum blockchain which is publicly available in Github repository[1]. Specifically, we explain the details of the system components, including smart contracts, and their implementations.

4.1. Drug traceability approach component

In order to realize our system, several technologies are used. The system is divided into three parts: a user interface, an IPFS storage space, and a blockchain.

- **User interface:** We use the Vue.js framework [20] to develop our user interface. Vuejs is a versatile javascript framework. It's easy to learn and allows to make easy, testable and maintainable code. Vuejs provides the libraries and ecosystems needed to build client-side business logic. To build a web page with Vuejs, we split it into parts called components, each containing their own HTML, CSS, JavaScript code.
- **IPFS storage space:** The players' licenses will not be able to be put on the blockchain because of their large size. However, the images will be saved on IPFS. The IPFS server will return a hash that we can use to find the location of the file. In our case we will save the hash on the blockchain. The IPFS server that we use is provided by Infura [21]. To use it you just have to install the ipfs-http-client [22] package from Node [23].
- **Blockchain :** We use a test blockchain to build our framework. The blockchain used is Truffle develop [24]. It is useful to test and debug our smart contract, or to execute transactions by hand. The interaction with the blockchain is done with a JavaScript library called Web3. In our project we use version 1.2.11.

4.2. Smart contracts

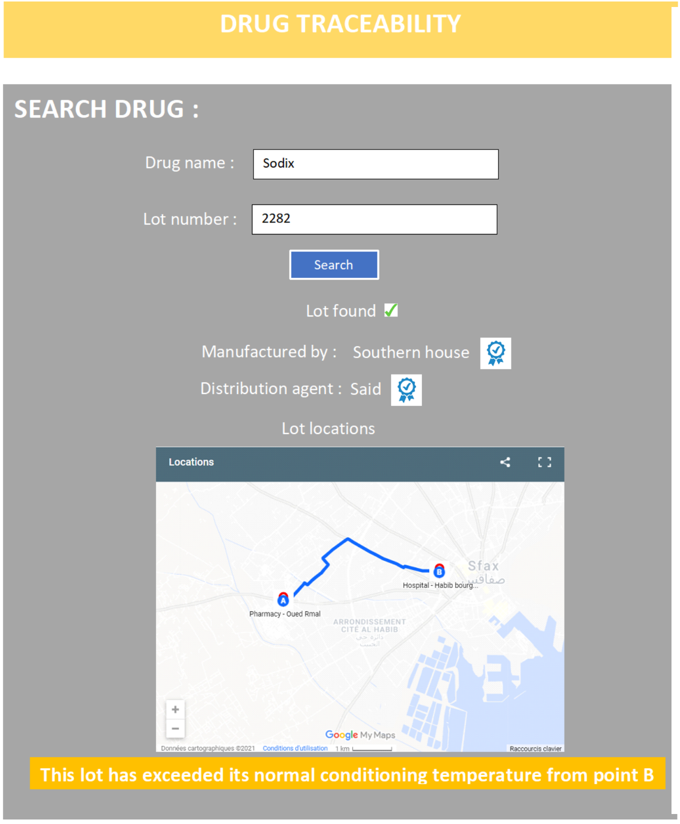
The smart contract is a program that runs on the blockchain. It is like a key that one must have to manipulate data in the blockchain. We use three smart contracts developed with the Solidity language for the realization of our system: a smart contract to manage the actors, a smart contract to handle all the activities concerning the drugs, their batches, and their distribution channels, a smart contract to monitor the drugs consumed by a patient. For conciseness reasons, only a snippet of code of the implemented function which allows finding and tracing the drug is illustrated in listing 1.

[1]https://github.com/Jiddou-Youssouf/vue-app

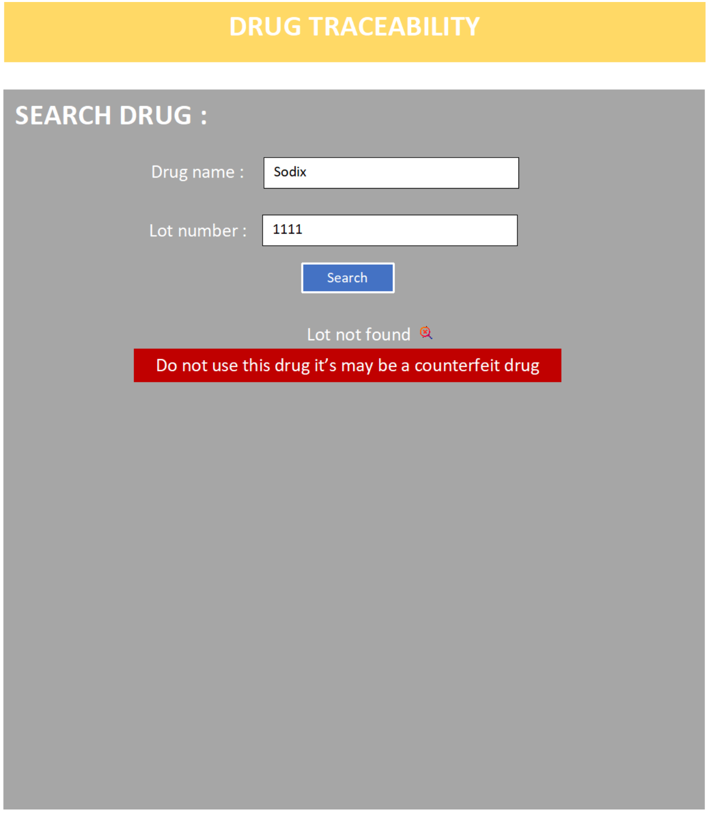
```
function findDistributionsByLot(delivered_Lot memory _lot) public view returns(int256) {
    for(uint i=0; i < distributions.length; i++) {
        for(uint256 j=0; j < distributions[i].delivered_lots[_lot.drug_name].length; j++) {
            if( keccak256(abi.encodePacked( distributions[i].delivered_lots[_lot.drug_name][j] )) == keccak256(abi.encodePacked( _lot.lot_number )) ) {
            return int256(i);
            }
        }
    }
    return -1;
}
```

Listing 1: *findDistributionsByLot* function of DrugManagement smart contract

- **Actors management smart contract :** All the functions implemented in this smart contract are totally controlled by regulatory authority. This authority registers each actor, which is represented by a data structure, by giving a unique Ethereum address, as an identifier. It is also charged of granting and revoking access to an actor. For the management of actors, a data structure is built for each type of actor containing a unique Ethereum address to connect and interact with the system and additional information to identify the actor. The regulatory authority will be in charge of granting addresses.
- **Drugs management smart contract :** The smart contract for drugs and their various treatments contains data structures related to drugs, batches, and their distribution channels. Among the information in the data structure of a drug, we have the minimum and maximum temperature in which the drug should be stored. The data structure of drug batches contains the batch number, the drug to which the batch belongs, the date of manufacture, the expiry date, and the condition of the batch that will be examined during its transport. The last data structure for tracing the life cycle of drug lots contains the identity of the actor who carried out the transport, the lots he transported, the list of points where he made deliveries, and the list of delivered lots for each point. We identify six major functions in this smart contract: a function to add drugs, a function to authorize the manufacture of drugs, a function to refuse the manufacture of drugs, a function to add batches to drugs, a function to record the distribution circuit of the batches and a function to check the temperature of the transported batches.
- **drugs consumption monitoring smart contract :** This smart contract contains 2 data structures. The first one is for medical prescriptions containing a unique number, the day of the consultation, the identity of the patient, the identity of the doctor, the report of the doctor's consultation, the list of drugs prescribed to the patient, possibly the quantity of the necessary dose to be consumed for each drug and the address of the points where the drugs were purchased. The second one is for register a patient containing a identity number, a name, a phone number, a date of birth, a nationality and a birth place. The smart contract contains functions to add a patient, to create a new consultation for the patient and to modify the prescription. Figure 3 shows how a patient can verify if the drug is counterfeit or not with the two different cases.



(a) Drug traceability : Drung found.



(b) Drug traceability : Drung not found.

Figure 3: drug Traceability : Found and Not Found cases

5. Discussion and Evaluation

In this section, we firstly discuss the generalization of the proposed IoT and Ethereum blockchain-based solution, then present a cost analysis of the proposed blockchain-based pharmaceutical drug traceability approach, and finally discuss the limitations of blockchain in the supply chain.

5.1. Generalisation

The approach proposed in this paper proves the potential application of both blockchain and IoT technologies for drug traceability in a pharmaceutical supply chain. The functions of the smart contract were defined to specifically meet the needs of the pharmaceutical supply chain, although they can easily be extended for other types of supply chains since it differs in the products/items that are shipped, distributed, sold and how they are handled throughout the process. As an example, some drugs require highly specific conditions that include temperature and humidity during their transfer between locations, whereas a supply chain of car components, for example, would need extremely different conditions. Depending on the specific supply chain application, such as food, spare parts, or any other application, the supply chain actors and their roles need to be modified. Furthermore, using a decentralized storage system is not often necessary where storage and access to large off-chain data files are not required. Eventually, the resources on-chain could be adjusted to suit the needs of the specific proposed application. For instance, setting up a reputation, payment and funds transfer system would sometimes be useless. In such cases, on-chain storage will be widely adequate to keep transaction logs between the involved parties. Furthermore, creating multiple products simultaneously may require extending functions to accommodate additional products, which can be achieved by modifying the existing smart contract, with reference to similar algorithms in various other supply chains.

5.2. Cost analyzing

In this subsection, we provide the cost analysis of the Ethereum smart contract code and function calls. On Ethereum blockchain, to conduct a transaction, it costs gas to send it to the Ethereum blockchain. MetaMask wallet provides a very useful and easy-to-use way of estimating the execution and transaction costs as the main types of costs. The execution cost corresponds to the cost of executing the different functions of the smart contract, while the transaction cost considers several factors such as contract deployment and data sent to the blockchain network. Table 1 illustrates the gas costs of each function used in the smart contract, along with the costs converted to fiat currency (USD). Table 1 shows a very low cost of the functions in USD. The highest cost function is the *Add distribution points to lots* function which is executed by the distributor . Such a relatively high cost could be explained by the changing of different variables in the function that requires storage. Alternatively, the *Remove access to the actor* function costs the lowest, since it only revoke access from an actor in the supply chain. The above observations demonstrate that gas charges are proportional to the number of times the smart contract status has changed, which also indicates that storage can significantly increase costs, thus it is critically important for the user to upload the correct details, as once the function is executed, it cannot be reversed and the gas charges are permanently lost.

6. Conclusion

In this paper, we proposed an Ethereum blockchain based approach for drug traceability in the pharmaceutical supply chain to prevent counterfeit drug issues. Our proposed approach ensures efficient drug traceability and which monitors the consumption of these drugs by patients according to a doctor's prescription. The proposed solution provides a way for the patients to verify the authenticity of the provenance of the drug they are consuming and thus his protection from counterfeit drugs which may cause harmful effects. Indeed, our approach relies on a set of emerging technologies such as Blockchain and IPFS storage to guarantee the security and the traceability for pharmaceutical supply chains. We have outlined the architecture of the proposed approach and its components, with details of the operating principles behind it. We have implemented and evaluated the effectiveness of this approach, including improving traceability in pharmaceutical supply chains by conducting tests and validations, as well as analyzing the costs. For some reasons, we couldn't implement the IoT part and provide real time data collected from sensors. For future work, we are continuously focusing on improving

Table 1
Gas Costs of the Smart Contracts Functions

Function caller	Function name	Gas used	Cost in Ether	Cost in USD
DPM	Register an ator	423693	0.000847	$2,85
DPM	Give access to an actor	48303	0.000097	$0.33
DPM	Remove access to the actor	18348	0.000037	$0.12
Manufacturer	Manufacturing request	190492	0.000381	$1.28
DPM	Grant manufacturing request	33708	0.000067	$0.23
DPM	Refuse manufacturing request	33729	0.000067	$0.23
Manufacturer	Add lot for a drug	169013	0.000338	$1.14
Distributor	Plan a new distribution	317590	0.000635	$2.13
Distributor	Check drug temperature	95745	0.000191	$0.64
Distributor	Add distribution points to lots	426031	0.000852	$2.86
Distributor	Complete a distribution	47421	0.000095	$0.32
Hospital	Add doctor	342041	0.000684	$2.32
Hospital	Add patient	192571	0.000385	$1.31
Doctor	Create medical prescription	251236	0.000502	$1.70
Pharmacy	Update medical prescription	71693	0.000143	$0.49

the effectiveness of pharmaceutical supply chains and plan to focus on extending the proposed system with an IoT layer to achieve more transparency and verifiability of drug use.

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