Traceability and Detection ofCounterfeit Medicine Using Blockchain Technology inthe Pharmaceutical Supply Chain

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Abstract

The issue of counterfeiting of drugs has grown as a result of escalating globalisation in both developed and developing nations. As of 2017, "ASSOCHAM" estimates that the bogus medication industry is worth $10 billion annually. WHO estimates that each year, about a million people pass away as a result of fake medications. The pharmaceutical industry's flawed supply chain system is one of the factors contributing to drug counterfeiting. In the current supply chain scenario, either no information is transmitted from one entity to another entity throughout the handoff process, or just minimal or extraneous data about the pharmaceutical formulation is shared within the network. After transferring drugs to another party, the original party is unaware of what will happen to the drugs there. The socioeconomic standing of society is seriously threatened by the counterfeit drug, which also negatively affects patient health and causes legitimate manufacturers to lose money. In this paper we explain how to provide traceability of the pharmaceuticals from their manufacture until their distribution to patients using blockchain technology in the pharmaceutical supply chain, transparency to the drug regulatory body and all the establishment involved in the logistic network. Only trusted parties will be permitted to be the part of network and forward data to the permissioned participants, which will be used to store transactions. In this manner how blockchain can provide security to the logistic

network management system in the pharmaceutical sector is also covered. Legal acts concerning Furthermore explained here are legal actions pertaining to the implementation of this technology.

Keywords: Blockchain, Drug supply chain, Counterfeiting drugs, fake drug, data security

Introduction

Manufacturers in the pharmaceutical sector are facing the challenge of delivering genuine dosage form to the patient which is developed by the legitimate manufacturer, not by counterfeiter.Becausethere is a change in the ownership of drug from manufacturers to wholesaler, distributer and then pharmacist before it reaches the customer. manufacturers are unaware of what is happened to their dosage form, as no information is shared between the entities involved in the current supply chain systems. Regulatory authorities of drughave no access to observe of the system, recollection of therapeuticis complex and expensive for the company, and companies are unable to track down patients**.**This situation of Supply Chain Management leads to the production, distribution, and consumption of counterfeit drugs.Severe consequences of drug counterfeiting include the following:

- Like any other fraudulent economic activity, this crime of counterfeiting of drugs, harms legitimate producers, distributors, and pharmacy businesses since they lose money and occasionally have to compete with distributors of fake items.
- Such injury can range from causing death or major health harm due to the administration of malicious drug and/or the absence of an adequate therapeutic impact, erroneous diagnostic findings, etc. to creating mistrust in physicians as a result of unsuccessful treatment.

Estimation offactitiousdrug

According to the WHO, 30% of all drugs sold in underdeveloped nations are fake.From 75 billion USD in 2009 to 600 billion USD in 2018, the market for counterfeit medications has grown. According to WHO estimates, 0.2 million of the 1 million malaria-related deaths taking place each year are brought on by fake anti-malarial medications. Every year, 0.7 million individuals are killed by fake anti-malarial and tuberculosis medications.For instance, more than 150 tonnes of illegal and counterfeit medicines worth about USD 3.5 million were intercepted in seven African countries in 2015 as part of Interpol's Operation Giboia. In 2015, Operation Pangea, an Interpol initiative, confiscated approximately 20.7 million illicit and counterfeit pharmaceuticals from online sales, including items for cancer, erectile dysfunction, and blood pressure.TheInternational Anti-

Counterfeiting Coalition (IACC) estimates that the annual value of fake drugs at more than US$ 600 billion makes it one of the largest and fastest-getting bigger illicit sectors in the world.[2] The International Criminal Police Organisation (Interpol) organised a five-month operation in 2009 that resulted in the seizure of 20 million pills, bottles, and sachets of illegal and counterfeit medications throughout China and seven of its south-east Asian neighbours; 33 people were detained and 100 retail establishments were shut down. Also last year, a series of searches in Egypt unearthed hundreds of millions of dollars' worth of counterfeit pharmaceuticals and revealed a criminal network that supplied consumers throughout the Middle East. In addition, customs officials in Europe intercepted 34 million fake medicines in just two months of 2009, a quantity that "exceeded our worst fears," according to Guenter Verheugen, the European Union's industry commissioner.[4]

Problems in the existing drug supply chain

The supply chain structure currently in place in the pharmaceutical industry has a number of issues; These are a few of them.Counterfeiting (potential risk to intellectual property rights), decline in trustworthy producers, drug scarcity, sensitive drugs shipping, security for data, drug counterfeiting. Each issue is defined below.

Counterfeiting (potential risk to intellectual property rights)

The brand logos of legal drug makers are occasionally utilised by producers of counterfeit drug to create fraudulent goods for daily use, which is less dangerous to public health.but they frequently have an impact on the treatment drugs for cancer, pain relief, cardiovascular disease, antibiotics, birth control, and of prescription drugs. The emblems of legitimate drug maker are copied by counterfeiters in many cases which is the unauthorised use of another person's invention and it is infringement of intellectual property rights and laws and it is prohibited.

Decline in trustworthy producers

As compared to the productionof counterfeit active pharmaceutical ingredient, the production of original active pharmaceutical ingredient requires greater costs, resources, and labour. In addition, selling of counterfeit active pharmaceutical ingredient is simpler than selling legitimate ones. Such that, drug counterfeiting is detrimental to both consumers and legitimate drug maker.

Drug scarcity

Many times, keeping track of market demand is very challenging for inventory managers because they lack the access of observability in the existing drug logistic network in the pharmaceutical industry. As a result, inventory managers struggle to control the cost

of production, length of time needed to make a finished pharmaceutical, quantity of raw materials required, and variety of developed goods.[3]

Sensitive drugs shipping

Temperature is a factor affecting the safety of most the drugs hence necessitatesthe optimum temperature for stabilityin storehouses while storingand during transfer processtoo. If desired temperature is not maintained during transportation there is a significant risk of degeneration of drug or finished pharmaceuticals before it reaches to the distributor or any other entity involved in the supply chain management system of the pharmaceuticals. This gives rise to the sensitive drug shipping also called as the cold shipping.

Security for data

When assessing the adverse characteristics of centralised databases as a danger to the security of the data, thenit becomes a significant problem to the acquired data because current centralised databases are less secure than blockchain, it is dangerous to store data there.

Drug counterfeiting

The manufacturing and distribution of counterfeit drugs is the biggest problem facing the entire globe today.Theillicit process of creating identical things under the guise of genuine ones is known as counterfeiting. Counterfeiting of s or drugs is a criminal offence as it brutally associates with patient's health.Concept of counterfeit drugs is mentioned below.

FBI(Federal Bureau of Investigation) calls counterfeiting of drugs as a "crime of the21st century", because increase in the production and distribution of falsifiedmedicament within short period of time is facilitated by the advancement in the technology.

Modes of Drug Counterfeiting Include:

1. Drugs lacking the active pharmaceutical ingredient intended to kill the disease which may lead to cause antimicrobial drug resistant strains and where administration of the original drug can't cure infectious disease.
2. Other examples of fake drug include:

   Drug containing the active pharmaceutical ingredients but the amount is too less than the therapeutic dose or too high than the therapeutic dose**,**drug manufactured without following goodmanufacturing Practices or Good laboratory practices, produced by using low quality raw materials,such drug contains impurities, drug dispatched without Quality control checking, may containing toxic ingredients.In those cases,it may cause serious health issues.[2]

3. Falsified therapeutics sold by using brand logo of authorized medicament producer. But that is less harmful.

But here question arises that, how such a large amount of drug is sold in the market?There are numerous points of interaction in the existing drug supply chain that are unsubstantiated and insecure. Any of which might serve as a gateway for illicit drugs. There are a few factors that could be mentioned:

- Supply chain participants could include one or more corrupt parties: Products in the supply chain are being adulterated, replaced, or mislabelled.
- unapproved raw material source. It's possible that a reliable manufacturer is ignorant that the ingredients could have come from an unreliable source.
- imitation medication brands with the aid of fictitious documentation, individuals have successfully created reputable medicine brands and legitimate pharmaceutical companies.
- consumer ignorance and the exorbitant cost of real medications.
- laws against corruption that are not enforced as strictly as they should and use of advanced counterfeiting technique.[10]

Tracking the drug supply chain is extremely difficult due to the numerous access points and lack of a transparent security mechanism. current supply chain system obstacles could be characterised as:

- There is no quick and simple technique to follow a product through the supply chain that can reveal the actual source and locations of transaction.
- inadequate cold chain supply monitoring and management.
- While the drugs are moved between numerous phases, there are handoffs between various parties, including the packager and transport companies. This may serve as entry points for fake medications.
- Various manufacturers have implemented various systems. This causes a related issue, forcing distributors and transportation companies to maintain several types of solutions throughout their supply chain networks. It may result in a misunderstanding of the facts or the way the pharmaceuticals are delivered, putting the customer at risk.

Blockchain a solution in the pharmaceutical logistic network

Pharmaceutical companies require a reliable drug supplying chain management system to prevent the sale of fake medications. Blockchain technology is the finest method

for creating the ideal SCM system currently available.Block and chain, which make up the name "blockchain," can be seen as blocks connected by chains.[43]Blockchain was first introduced to cryptocurrencies by Satoshi Nakamoto.Decentralized or distributed data storage is implemented using blockchain.Immutability and appendonly functionality are two features of blockchain.

In a distributed ledger, each participant in the network receives a copy of all the data. There has been a misconception that Blockchain is primarily useful in the commercial sector becauseit's base is the Bitcoinconcept.

In recent years, the full potential of blockchain technology has been apparent.

Beyond the financial industry,the decentralised platform of the technology can be uti lisedin many practical applications including healthcare, logistics, the Internet of Things (IoT), reputation systems, public services, and supply chains.

When data security and privacy protection are top priorities, blockchain is the ideal s olution.Existing global pharmaceutical supply chains are unable to guarantee the safety of the distribution of medicines and do not provide traceability that are efficient for regulatory compliance.That is why According to researchers, an autonomous drug tracking system should be a useful tool in halting the spread of fake medications thanks to the unique coding of each package.This solution explains how to leverage this technology to trace and cold chain shipping with the assistance of transfer of medications between various establishmentsby using IoT-enabled vehicles to address the challenges of medicine counterfeiting, logistic management, and security of the associated with the drugs & finished pharmaceuticals.

Blockchain-based systems employ various security and privacy measures which includes Anonymous digital signatures are the varieties of digital signatures that can provide confidentiality for the user. These signatures, which include "group signature" and "ring signature" for increased security and anonymity, can be utilised in blockchain-based applications. The unique attribute of homomorphic encryption, a cryptographic method, allows computations to be done directly on the cypher text. The data need not be converted into plaintext in order to be processed in some way, according to this statement. Additionally, it guarantees that when the same operation is carried out on the same encrypted data after decryption, i.e., when the data is converted to plaintext, the result produced is the same as the result produced on the cypher text. Without requiring any modifications to the blockchain's characteristics, homomorphic cryptography can be used on the data in the blockchain to ensure the confidentiality of the data in the public blockchain

and permit only encrypted data to be audited and managed. The other measures include the ,Secure Multiparty Computation Protocol, Algorithm for Attribute-Based Encryption, Non-Interactive System for Zero-Knowledge Proof.[20]

The Council of Europe Convention provides a crucial justification for the adoption of blockchain technology on the counterfeiting of medical products and other offences involving hazards to public health, which was adopted on October 28, 2011.When these rules are put into practise, jail terms are imposed for these offences, and the penalties for people who commit crimes while doing their professional or official obligations (by abusing the trust put in them as producers, suppliers, or professionals) are heightened.Directive 2011/62/EU of the European Parliament and of the Consul of 8 June 2011 amending Directive 2001/83/EC on the Community code associated to medical products for the human consumption with regard to thepreventing the arrival of fake pharmaceuticals into the legitimate supply chain serves as the legal foundation for the adoption of Blockchain in pharmacies.[1]This agreement, which became effective in January 2013, provides that the drug maker can add the distinctive identity to drugs that are sold in the nation.

Blockchain suggested model

In essence, there are six stakeholders involved in the medication supply chain,frommakers to consumers.

(1) Manufacturer (2) Distributor (3) Transporter (4) Pharmacy (5) Hospital (6) Patient

In the present drug supply chain (without blockchain), drug moves from the producer to the customer.The description of this model is as follows:

Depending on the amount of drug requirement, drug maker will send the drug to the distributor or the shipping company. Drug might be received by the distributor through a shipping company or immediately collected from the manufacturer. The transport companies are used once more by the distributor to deliver medications to the wholesaler, retailer and hospitals.If the hospital needs a large numberof pharmaceuticals, it can either buy them directly from the distributor or order them straight from the manufacturer through a transportation company.

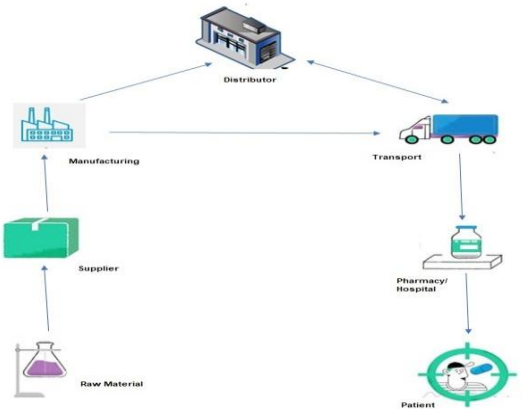

Figure 1: Blockchain based drug supply chain framework

Finally, either the hospital or the pharmacy will provide the patient or client with their medication.The first five stakeholders can work together to develop a blockchain architecture without the consumer.The following list includes explanations for why the last party(consumers) was excluded from the blockchain.

- The consumer population is quite diversified, ranging from low literacy rates to high levels of education and from young adults to geriatrics. They are all unable to take part in the transaction verification process, from a person who lives a long away from any towns or cities to a person who lives in the urban areas.
- The Blockchain architecture will be significantly laden if we add every consumer because there are billions of consumers in our country.
- It will be costlier and more difficult to manage such a large amount of data.[10]

Perhaps in the near future, all customers will be able to participate in the blockchain, but for the time being, they are kept consumers out of it.The legitimacy of the medicine may be verified by any consumer on a platform, nevertheless that is covered in the STEP 6.Our current dug supply system is imperfect, as we've already discussed. With adigitally distributedshared ledger containing among five entities, blockchain has created the framework in a decentralised manner.Four Pillars of Blockchain system are decentralization,accessibility to the general public, lack of an intermediary, consensus among participants.

Initially, the CDSCO (Central Drugs Standard Control Organization India) must certify that all drug maker arelegitimate. The accountability for the drug's authenticity rests on the Indian government. The drug manufacturer ought to be a reputable company because using the proposed blockchain infrastructure, drug counterfeiting cannot be stopped if genuine drug producers make fraudulent products. The main functions of this government body are as follow as:[10]

Give the real and legitimate drug maker and distributors operating in the pharmaceuticalindustry a unique ID, control the flow of batches, watch how producers and distributors are operating, describe the uniform criteria for genuine active pharmaceutical ingredient manufacturing and its systematic distribution to the drug makers and drug distributors respectively.

Step 1:

A unique ID should be provided by the authorized body to each legitimate drug maker and distributor who has registered on the Blockchain.In accordance with distributor's order, manufacturing companies will dispatch the finished medications to the distributors. All the establishments in the network will be aware of to this deal as part of the blockchain's functioning system. Before adding a new transaction, all Blockchain entities should confirm the previous one, in order to prevent future fraud or denial of this deal. The digital ledger will provide the subsequentdetails of drug. drug's manufacture date, expiration date, chemicalsubstances usedin the manufacture of drug, manufacturer's unique ID, name of manufacturing firm, and delivery date.

Step 2:

The distribution centre will get the requested batch of medications.Transportation companies will deploy IoT enabled vehicles to keep the cold chain shipping intact. By using IoT sensors built into the vehicle, will guarantee that the therapeutics get to the clients in their authentic form and at the correct, controlled temperature.This related data will be updated as a current block and will include details like the car numberand name of the travel agency.[3]

Step 3:

Distributors will now receive medications with the manufacturer's unique ID and other helpful information. Both the entities should digitally sign using their confidential keys in the distributed digital ledger at the hand off from manufacturers to distributors, and the transaction is then put to the block.The IDs of the manufacturer and the distributor will serve as a private key between them in this hand off. All the parties involved in the network will be aware that the distributor has collected the medications when the arrival time is noted and the transaction details of the current deal is updated by the distributor. The following new details have been added: the transaction ID of distributor, the arrival time, name of the distributor company, and the number of medications.[21]

Step 4:

When the deal between the manufacturer and the distributor is finished, the travel agency will be notified. In order to get the medication to hospitals, retailer pharmacies, and wholesaler pharmacies, travelling agency will take it from the distributors. The likelihood of counterfeiting is higher at this time. This block will include information. Details about the travel agency, the vehicle number, and the time of shipment from the distributor's warehouse. The likelihood of counterfeiting is highest at this moment. IoT and wireless sensor devices can be used in this situation to track the current location & examine it. The medicine package can be equipped with a GPS device, which can be tracked continuously until it reaches its next entity. Because some medications are temperature-sensitive and higher temperatures would ruin the medication, a wireless sensor can also be inserted within the box to continuously monitor temperature, humidity, and other conditions.

Step5:

The step 4 description will be followed when handing off medications between a transportationfirm and a health care centre or a transportationfirm and a pharmacy. Following delivery and inspection of the pharmaceuticals, the hospital and the shipping company will digitally sign by using their respective private keys.

Step6:

The medication is now available for its last application. Patients can now receive drug for administration or purchase their medications from pharmacies. How can patients be sure the drugs they have purchased are genuine if they are not allowed access to the Blockchain?The Blockchain technology can be used to construct a cloud platform with access controls where all the information about the drug is stored during its complete journey from producer to customer.Consumers can learn all the information about a drug, from where it was made to who will use it, by simply scanning a QR code or entering a unique serial number found on the drug package.

Manufacturers will be able to direct the inventory in accordance to address the issue of medicine scarcity if information is properly tracked at each deal in the supply chain. This will notify manufacturers regarding the market demand. By utilising blockchain technology's traceability capabilities, counterfeiting will also be resolved.Blockchain makes it possible for data to be shared while maintaining privacy and giving pharmacists the opportunity to confirm the origin of the medication.Information cannot be changed or deleted after the data has been saved there in the block or digital ledger& it is a is immense advantage of blockchain in comparison to the standard database where transaction related

information can be effortlessly manipulated to be false as well with denying that any alterations have been made.

Huge pharmaceutical giants like Pfizer and Genentech, who together have a market capitalization of over $300 billion, announced the launch of the blockchain project MediLedger. its foundation is the Ethereum-based Quorum platform, where the intention of creation of a blockchain is to obstruct the flow of fake therapeutics into the supply chain.Experts believe that the concerns with confidentiality and transparency in clinical trials of drugs could impede upcoming trials of development of drug and driveup expenses. Clinical research can beneficial from the aspect of blockchain technology like decentralised transaction verification and information transparency. And that is the reason why the development of a blockchain programme for clinical trials was announced by the pharmaceutical corporations Pfizer, Amgen, and Sanofi in January 2018 in an effort to lower the price of developing and testing new pharmaceuticals.[1]

Another application of the blockchain includes IoMT systems are essential to the growth of medical and health information systems. IoMT stands for the Internet of Medical Things. IoMT technology allows medical devices like body scanners, heart monitors, and wearables to collect, process, and transmit data via the Internet in real time. With the development of AI, for instance, healthcare providers can now take an image using the IoMT paradigm, spot worrisome cells or even cancerous portions, and communicate this information with people who have the legal right to access it. The progress in IoT for healthcare and smart medical devices in the field of AI is mostly covered in the following topics. Following steps are involved.[11]

Step 1: The patient is the source of all data in the world of IoMT.

Step 2: Medical IoT devices are typically either intimately attached or remotely monitoring patients' bodies,producing a significant amount of data.

Step 3: Blocks or cloud storage are used to store the data generated in step 2 in step 3. Blockchain will benefit from AI in order to develop intelligent virtual agents, which can automatically generate new ledgers. Decentralised AI systems may be able to assist block chains in achieving the highest levels of security when dealing with sensitive medical data, when security is the top priority.

Step 4: Healthcare providers are the final users who request access for a secure delivery of care that has been approved by the owner.

Utilising integrated BC-IoT in the pharmaceuticals is also possible. The security of Pharmaceutical Supply Chain is ensured by the integration of blockchain technology and the

internet of things (IoT). By following the supply chain from the point of origin to the final consumer, integrated blockchain-IoT can promote trust, transparency, and visibility. By transmitting information between many stakeholders, blockchain technology can be utilised to address the security and supply of fraudulent pharmaceuticals in the pharmaceutical supply chain. The integration of BC and IoT serves as a complementing technology for each other since it addresses Pharmaceutical Supply Chains shortcomings in terms of transparency, scalability, visibility, audibility, and immutability. Despite the benefits of smart contracts and real-time tracking, BC-IoT integration is still largely constrained by factors including information transaction capabilities, data security/privacy, and corrupted data.[18]

This Blockchain technology will enable impacted patients to share theirpersonal medical information accessible to pharmaceutical corporations and facilities of research. To prevent any risk of fraud or manipulation, the research findings will be offhandedly stored in the platform of blockchain of respective organisation at the same time.Hence, blockchain technology enables: 1) to improve medication clinical trials; 2) to improve the process of pharmaceutical product licencing; 3) to monitor the amount of pharmaceutical items produced by the manufacturer and their subsequent sales; 4) to keep tabs on the places where pharmaceutical items come from and how to use them; 5) to keep track of the registration period, expiration date, and storage and transportation conditions for pharmaceutical products; 6) to restrict the operations of unlicensed online pharmacies; 7) to lessen the potential for a shortage of pharmaceutical products; 8) to ensure the transparency to all partners.[1]

Drawbacks of blockchain technology include the advantages that blockchain offers have a price, just like any other technology. To decide if blockchain is the best option for a comprehensive solutions architecture, its disadvantages must be fully taken into account. Due to the fact that blockchain technology is still relatively new, it is continuously changing and expanding, there are few individuals trained in it, and if there are any, it is quite expensive. Best practises, appropriate use cases, and suggested patterns are continuously being created.[39]

Conclusion:

Discussed are a number of problems with the medication supply chain management system, including drug shortages, medicine adulteration, the transportation of sensitive drugs, and compromises that could have a negative impact on a patient's health. Blockchain technology can be a key component of the answer to these significant issues by enhancing

visibility and traceability. Also, the working mechanism of Blockchain is mentioned here. The implementation of blockchain technology not only reduces the risks of giving patients fake medications, but also lowers logistics expenses. As a result, patients can purchase the medication for lower price. Enough legal backing is necessary for the full implementation of blockchain technology in pharmacy.The architecture can be further enhanced by include all consumers(patient) in the Blockchain in the future, albeit this could be an enormous task for data storage. The removal of the middlemen between patients and manufacturers through the use of smart contracts will also help consumers in the long run.

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