REVIEW ARTICLE

Blockchain Technology: A Revolutionary Tool Against Counterfeit Pharmaceuticals

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ABSTRACT

Counterfeit pharmaceuticals pose a significant global health threat, with dire consequences ranging from ineffective treatment to severe health complications and death. This paper explores how blockchain technology (BCT) can revolutionize the fight against counterfeit drugs and enhance healthcare integrity. Counterfeit drugs are defined as medications falsely claiming their source, efficacy, or validity, often containing incorrect amounts of active ingredients or harmful substances, leading to various adverse patient outcomes. Counterfeit drugs remain prevalent, especially in countries labeled as LMICs, with 13.6% an estimate of medications being counterfeit, resulting in financial repercussions exceeding $200 billion. Blockchain technology offers a robust solution to these challenges through its decentralized, tamper-proof digital ledger system. Each transaction recorded on the blockchain is immutable and transparent, ensuring data integrity and preventing unauthorized alterations. This technology can significantly enhance drug traceability, allowing stakeholders to verify the authenticity of medications from manufacture to patient delivery. Blockchain technology's promise to enhance transparency, efficiency, and security in healthcare is compelling. Its adoption can lead to a more resilient, equitable, and patient-centric healthcare ecosystem, reducing counterfeit drugs and improving overall patient care. As blockchain solutions mature and gain acceptance, their impact on the healthcare value chain—from drug discovery to patient care—will become increasingly significant, driving innovation and advancing global health and well-being.

Keywords: Counterfeit medication, Blockchain, Pharmaceuticals, Counterfeit drugs, Supply chain.

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INTRODUCTION

Pharmaceuticals have been utilized to mitigate the effects of illnesses, alleviate pain, stop disease progression, eliminate or lessen symptoms, and decrease the progression of illnesses. A rapid increase in the number of false, adulterated, counterfeit drugs has been seen in the past several years. With the progression of counterfeit medications, irrational prescribing of drugs has also been practiced. This leads to severe harm to patients and adversely affects their pathologic conditions. False refers to anything that is not real but is made to look real in order to create or produce something that is not real but is claimed to be so. A counterfeit drug or medication is processed in such a way that might not have API or incorporated certainly in the wrong amount, adulterated with different product form source. This medication pharmacokinetics ADME differs from the original which affects the efficacy of the drug. The validity of such pharmaceuticals falsely clamming is unjustified as they may have hazardous chemicals and come in counterfeit labels & packaging. The shelf life of such a product is modified. Numerous instances of counterfeit drugs have no active component and no hazardous medicine, an excessive amount of active ingredient, a smaller amount of active ingredient, or a drug mixed with chemical or microbiological contaminants. Each can have a different effect on the patient, ranging from no drug benefit at all to a less than ideal effect or, anti-infective case, development of resistance towards medication, which could eventually cause more serious health problems or, in the worst-case scenario, result in death.[1-4]

History

The counterfeiting of drugs has a long and storied past, one among the human crime history. There have been references to a supply of fake antimalarials for several centuries, including quinine in the 1800s and cinchona in the early 1600s.[5] Since then, the issue of phony and inferior medications has persisted and grown unchecked. WHO on first examined issue related to drug counterfeiting worldwide, which is one of the developing problems.

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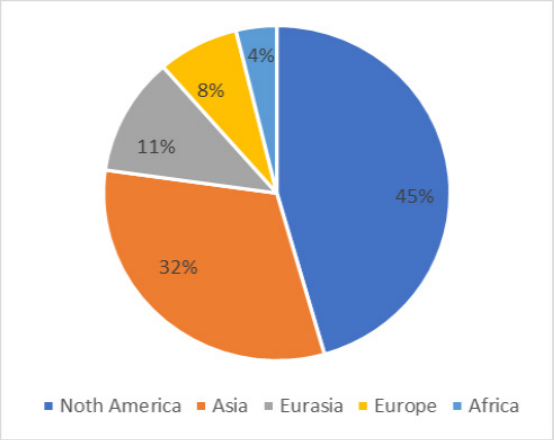

Figure 1: Representation of counterfeit medication in different region

As a response laid by the Conference of Experts held in Nairobi, Nov. 25–29, 1985 on the Rational Use of Drugs, a clearinghouse made by WHO can collect data & literate governing bodies about counterfeiting type and extent. As a reaction, the International Federation of Pharmaceutical Manufacturers and Associations & WHO organized the first-ever worldwide conference titled as counterfeit drugs, which took place from 1-3 April 1992 in Geneva. With financial support from Japan, the WHO initiated an initiative against counterfeit medications in 1995. Furthermore, the WHO created the International Medical Products Anti-Counterfeiting Taskforce in 2006. It has since evolved into the main platform for the organization's efforts to battle counterfeit medications.[6]

Global Scenario

The WHO in the year 2017 calculated that counterfeit & Low-quality pharmaceutical global sale is 10.5%. As per a survey, approximately 13.6% prevalence is from low- and middle-income countries (LMICs). The estimated financial repercussions might rise up to $200 billion in such case.[7] The effects of an increase in fake medications are being seen globally. Counterfeit medications are more common in LMICs, but nonetheless in the global supply chain. Through an attack laid by Interpol's global Operation Pangea on pharmaceuticals which are counterfeit with medical equipment, MHRA & UK as partners found >3 million medications & medical devices in the supply chain of the UK were forged, costing business of £9 million medication in October 2018.[8] A recent Europol operation called Shield II resulted in the seizure of almost 25 million medication units, valued at approximately €63 million. Earlier in 2009, the European Union (EU) seized 34 million fake pills in just two months, including ones that included antibiotics, chemotherapy drugs, and sildenafil citrate (ViagraTM).[9]

India, in particular, is the country that produces counterfeit medication in numbers is 35-75 percent.[10] Nonetheless, the highest proportion of fake medications found was larger in North America Asia-Pacific, followed by, according to reports from the PSI (Pharmaceutical Security Institute), an organization with a non-profit membership. 4 cough syrups from Maiden Pharma, India, were recently warned by WHO in September 2022 because of the alleged death incidence of 66 children in the western African country Gambia. It was eventually discovered that the product included high concentrations of pollutants, specifically ethylene and diethylene glycol.[11] This is not the first instance of a death brought on by subpar or counterfeit medication; numerous other cases involving the use of subpar or counterfeit medication have been reported, resulting in fatalities and disabilities. In general, these instances of drug counterfeiting will damage the reputation of pharmaceutical companies, healthcare systems, and stakeholders in general. The goal of this review is to analyze the global issue of drug counterfeiting and find the use of blockchain technology to examine anti-counterfeit mechanisms for pharmaceuticals.[12]

Definition

A database distributes & maintaining a list of records in form of blocks referred to as a blockchain. A digital Ledger that is public and decentralized, spanning multiple computers, is called block chain. Preventing record tempering without compromising network consensus and all subsequent blocks is its goal. To connect these blocks, cryptography is employed.[13]

A timestamp, a cryptographic hash & transaction data all in one inclusive block. On the blockchain, each transaction is first recorded before being stored in a block. The process of connecting each block to the previous one and encrypting it for security is known as blockchain and it results in a chronological sequence based on codes. This suggests that information stored in can't be changed/altered or unpublished without the consent of entire network. These contemporary databases facilitate transparent and trustless data interchange across a network of connected machines by acting as a single point of trust.[14]

Blockchain is a data recording method designed to make information stored on the blockchain safe and immutable. Every computer containing transaction records in order to prevent a single point of failure. All copies also go through concurrent validation and updates.[15,16]

Importance

Preserving the distribution network to enhance the quality of different channels and shield patients from errors or malfunctions that occur during repackaging or relabeling is the primary goal of pharmaceutical companies. Clinical research, development, manufacturing, distribution, and a broad range of healthcare services are all included in the pharmaceutical supply chain, indulging a number of stakeholders such as wholesalers, retail managers, and manufacturers. The healthcare and pharmaceutical industries are very complex because of the intense scrutiny from regulators, businesses, and consumers. By opting for a decentralized, non-breakable system of transactions, BCT lessens the concern by creating one ledger for every party. Each transaction needs consent from everyone which gets upgraded autonomously in their respective ledgers in real time. The entire ledger gets impacted if any transaction gets tainted or recorded already.

BCT's characteristics have made it to be applied across several industries, whether virtual currencies creation e.g., Bitcoin.[17-19]

BCT Solutions in Pharmaceuticals

Traceability of drugs

Over 15% of pharmaceuticals medication in underdeveloped countries are sold being fake, making Drug counterfeiting is a major concern. Anti-counterfeiting costs bear by pharma corporations is over $200 billion a year.[20] Blockchain's security, drug traceability & visibility feature can help address the issue of counterfeit drugs. Through the use of technologies that include verification of originality and step-by-step tracking capabilities to address the fake issue, the system makes sure that once a drug is manufactured, it is authentic. Verification by a user can be the legitimacy of medications before buying. BCT has the potential to trace medications not only from the manufacturer's point but to the patient's delivery point, but also to document the post-utilization effects of the drug in a database for statistical purposes in the future.[21,22]

Clinical examinations/trials

A new drug's efficacy is tested in a controlled setting through clinical trials, which generate a tone of data. The procedure is costly, requires several years to finish, and is not free from fraud. Ensuring that the trial results are not manipulated with requires a transparent method that allows anybody to evaluate the clinical reports. Because blockchain ensures data integrity, it can be a useful tool for clinical studies; nevertheless, the documents' legitimacy must be confirmed. No data may be altered without permission, thanks to the distributed network.[23]

Supply chain for healthcare

Pharmaceutical companies are using blockchain for a supply chain to monitor the movement of raw compounds, or component parts in every step of the supply chain from manufacturer to end user. The pharma research community potentially uses BCT for securing data related to the medical and health supply chains. Supply chain security is thought to be enhanced by blockchain's capacity to identify the provenance and validity of medical goods.[24,25] With the rising prevalence of controlled substance misuse, blockchain also enables the complete range of issues associated with pharmacological therapy to be detected. The pharmaceutical sector uses blockchain-based technologies to communicate data in a more reliable manner. One such instance is the Zurich-based startup Modum.io, which uses blockchain technology and sensors to increase the effectiveness in the supply system of pharmaceutical goods. MODSense is a BCT code created by Modum.io that monitors the temperature of delicate pharmaceutical items in the supply chain, with assistance from Swiss Post and SAP Software Solutions. MODSense makes sure that the temperatures that are recorded are unchangeable and that interested parties are aware of the handling that a particular product underwent while in transit.[26] Medical supplies, vaccine delivery, clinical studies, medical samples, and perishable foods are just a few of the many uses for this system. As an additional illustration, the pharmaceutical business Bayer created a blockchain solution to trace chemicals as they moved through its ecosystem of supply chains. The technology enabled the pharmaceutical supply claim to attain a higher degree of efficiency and security by locating the product faster than usual.[27,28]

Some software platforms and projects implementing blockchain technology in pharmacy and healthcare:

MediLedger

A BCT-based platform aimed to enhance the efficiency & security of the supply chain in pharmaceuticals. It enables stakeholders to monitor and validate the authenticity in medication mentioned in the prescription, ensuring compliance with regulations and preventing counterfeit medications.

ProCredEx

This platform utilizes blockchain technology to streamline the credentialing process for healthcare providers, reducing administrative burdens and improving data accuracy. It offers a decentralized network for sharing and verifying provider credentials securely.

GemOS

GemOS is a blockchain-based platform designed to facilitate interoperability and data exchange in healthcare. It allows healthcare organizations to securely share patient data across disparate systems while maintaining privacy and compliance with regulations.

Patientory

Patientory is a BCT-based healthcare data management system that lets patients securely store and exchange their medical history & records with doctors and hospitals. It utilizes blockchain technology to ensure data integrity and patient privacy.

SimplyVital Health

SimplyVital Health offers a blockchain-based platform called Health Nexus, which aims to improve care coordination and data sharing in healthcare. It provides secure access to patient data for healthcare providers and supports value-based care initiatives.

Hashed Health

Hashed health develops blockchain-based solutions for numerous healthcare implications, which include credentialing, interoperability & management in the supply chain. These platforms aim to improve transparency, efficiency, and security in healthcare operations.

FarmaTrust

FarmaTrust utilizes BCT to combat counterfeit drugs and improve traceability in the supply management chain. Its platform enables instantaneous observation of drug shipments and verifies the authenticity of pharmaceutical products.[32-34]

Table 1: Application & advantage of block chain in different aspects[29-31]

S.N.	*Division*	*Application*	*Advantage*
1.	Patients	Patients are able to monitor their medical history access to their most recent prescriptions. Patients can safely exchange their data with all of their providers Empowerment of the patient	Builds patient confidence. Enhances patient access to reliable information.
			Encourages improved teamwork. Enhances openness.
			Enhances and customizes the experience for patients.
			Decreases operating expenses and boosts efficiency.
			Permits global accession to the medical record of patients.
			Permits patients to view their most recent prescriptions.
2.	Regulatory Compliance	Monitoring compliance Smart contract-based verification	Creates a reliable audit trail that is instantly verifiable.
			Creates a framework that proactively protects privacy laws.
			Permits information tracking of who with whom, without any disclosure of information.
3.	B2B	Money Transfer Supply chain for medical devices Temperature-regulated supply networks	Makes automated payments possible using smart contracts.
			Accelerates the payment process. Gives the patient complete transparency regarding all assets across the supply chain.
			Permits private and certified communication between service providers and medical devices
			Combines all of the transactions onto one platform.
4.	Front offices and back offices	Managing Revenue	Increases the effectiveness of tracking and tracing the locations of leaks.
			Lowers administrative costs. Improves auditability and dependability.
			Expedites the procedure of financial transactions.
5.	Pharmaceut-icals	Confirms the provenance of drugs Establishes a single, industry-wide source of aggregate data	Monitors and follows medications.
			Verification of genuineness for anti-counterfeiting methods. Aids in stopping the sale and transportation of fake goods. Allows for the detection of the entire range of side effects associated with medication
6.	R & D	Obtaining Clinical Trials	Stops intellectual property theft. allows users to verify the presence of any document and authenticate it.
			Permits access to a sizable patient database that is authenticated and anonymized.

Implementation Challenges of Blockchain Technology in Pharmacy and Healthcare

Regulatory Compliance: The healthcare and pharmaceutical industries are heavily regulated, and implementing blockchain technology necessitates adherence to a number of regulations and legislation, including the US's Health Insurance Portability and Accountability Act (HIPAA). Making sure blockchain solutions follow these rules can be challenging and time-consuming.

Interoperability and Standards: The challenge rises in achieving interoperability within various BCT platforms and the traditional system. Developing common standards for data exchange and integration of BCT in healthcare and pharmacy is crucial in realizing the potential.

Scalability: Networks in BCT shall be designed in a manner wherein a vast pool of transactions can be generated, particularly in industries dealing with health, where data generality is wide on a daily basis. Scalability issues, such as transaction throughput and latency, need to be addressed to accommodate the requirements of the medical field.

Data Privacy and Security Concerns: While blockchain offers enhanced security, concerns remain regarding the privacy of sensitive health information stored on the blockchain. Balancing the need for transparency with patient confidentiality is essential to maintain trust in blockchain-based healthcare solutions. Integrated Legacy Version: Many pharmacy & health systems depend on antiquated structural frame that might not be BCT compatible. Integration of BCT with the current system while ensuring data integrity and security can be a significant technical challenge.

Addressing these implementation challenges requires collaboration between stakeholders, including healthcare providers, pharmaceutical companies, regulators, and technology developers. Despite the hurdles, the strategic values offered by blockchain technology make it a compelling tool for transforming healthcare and pharmacy operations in the future.[35-37]

DISCUSSION

Within the constantly changing environment of medical care and pharmaceuticals, the advent of BCT emerged out to be driven energy, promising to restructure different facets of the industry. Throughout this discourse, we have delved into the multifaceted implications of blockchain technology, exploring its profound impacts on supply chain management, data integrity, patient empowerment, and beyond. Blockchain's

potential to overhaul the pharmaceutical supply chain cannot be overstated. By leveraging its immutable ledger technology, blockchain enables the creation of transparent and tamper-proof records of drug provenance, thereby combating the pervasive issue of counterfeit medications. Through solutions like MediLedger and FarmaTrust, stakeholders can trace the path of pharmaceutical goods through manufacturer-patients, establishing legitimacy and regulatory compliance at every step. Moreover, blockchain facilitates real-time monitoring of drug shipments, reducing the risk of diversion and enhancing the efficiency of logistics operations.[38] Furthermore, blockchain holds immense promise in safeguarding the integrity of healthcare data a cornerstone of patient care and clinical decision-making. In a time when privacy concerns and data breaches are common, BCT cryptographic mechanisms offer unparalleled security, protecting sensitive medical information from unauthorized access and tampering. Platforms such as Patientory and GemOS empower patients with greater control over their health data, enabling secure sharing and interoperability across disparate systems. By fostering a patient-centric approach to data management, blockchain not only enhances privacy but also facilitates more personalized and collaborative care delivery.[39] However, amid the promise of blockchain technology lie formidable challenges that shall be addressed to accomplish the highest possible in pharmaceuticals and healthcare. Regulatory hurdles, interoperability concerns, scalability limitations, and data privacy considerations pose significant barriers to adoption and implementation. Achieving regulatory compliance, establishing common standards for interoperability, and navigating the complexities of legacy systems require concerted efforts from industry stakeholders, policymakers, and technology developers. Moreover, ensuring the ethical use of blockchain technology and safeguarding against unintended consequences demand ongoing vigilance and ethical foresight.[40,41]

CONCLUSION

Despite the challenges, the momentum behind blockchain's integration into pharmaceuticals and healthcare continues to accelerate, driven by a shared vision of additional transparency, efficacy, & a compassionate system of healthcare. As blockchain solutions mature and gain widespread acceptance, the potential for transformative impact across the entire healthcare value chain from drug discovery to patient care—becomes increasingly tangible.[42] By fostering innovations & collaboration, the power of blockchain can be harnessed to disguise the most crucial challenges facing the pharmaceutical & healthcare industries, ultimately advancing the cause of global health and well-being. In conclusion, the implications of blockchain technology in pharmaceuticals and healthcare are profound and far-reaching, offering unprecedented opportunities to reimagine the future of medicine and patient care.[43] By embracing blockchain's principles of transparency, security, and decentralization, we can catalyze a paradigm shift towards a more resilient, equitable, and patient-centric healthcare ecosystem—one that empowers individuals, fosters innovation and delivers value at every touchpoint along the healthcare journey.

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