



REVIEW ARTICLE

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Blockchain: A Perfect Security Check for Medicines

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ARTICLE INFO ABSTRACT



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Introduction: Counterfeit medications pose a significant global health threat, resulting in ineffective treatment, adverse reactions, and fatalities, with an estimated 1 million deaths annually worldwide. Despite considerable investments in protective measures, the pharmaceutical industry struggles to curb counterfeiting, with approximately half of fake medications evading prevention measures.

Methods: This review highlights how blockchain technology is helping to guarantee medication authenticity and traceability in the pharmaceutical supply chain. Counterfeit drug detection is made possible by blockchain's decentralised ledger system, which provides an immutable, transparent, and safe platform for recording and verifying transactions.

Results: By leveraging blockchain, stakeholders can create a transparent tracking system for drug validity, enabling better testing, maintaining temperature control, and ensuring pharmaceutical legitimacy.

Discussion: Blockchain technology shows promise in reducing counterfeit drug circulation and improving traceability, as supported by research findings and case studies. However, challenges such as stakeholder agreement, interoperability, implementation costs, security vulnerabilities, and regulatory considerations must be addressed for widespread adoption.

Conclusion: Despite challenges, blockchain emerges as a beacon of hope, offering a secure, transparent, and traceable solution to combat drug counterfeiting in the pharmaceutical industry.

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Introduction

A serious public health concern that hurts both treatment outcomes and human lives is counterfeit medication. The World Health Organisation (WHO) defines counterfeit medications as goods that are fraudulently and knowingly mislabeled concerning their identity or source. Falsified information, including incorrect labelling and packaging, as well as inadequate, inaccurate, or erroneous ingredients, can be found in counterfeit medications (Mackey, 2011).

Each year, an estimated 1 million deaths occur worldwide due to counterfeit medications, presenting a global health crisis. The distribution of fake medicines is pervasive, affecting not only less controlled areas but also penetrating more strictly regulated regions. Shockingly, in low- and middle-income nations, approximately 1 in 10 medical medications are of inferior quality or counterfeit (Substandard and falsified medical products, 2018). The consequences are dire, with up to 155,000 children perishing annually due to counterfeit



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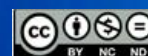
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antimalarial drugs alone (Karunamoorthi, 2014). Following purchase, thousands of cancer patients in the US received subpar Avastin® anti-cancer medication, increasing the risk of side effects from treatment (Mackey et al., 2015).

Today, the complexity of the drug supply chain, spanning various nations, is exacerbated by the rise of e-commerce and e-pharmacy. This complexity makes it easier for consumers to purchase drugs online from dubious sources, leading to the distribution of counterfeit drugs that mimic genuine products but often lack effectiveness and may even contain harmful toxins.

A well-known European research project recently released a report claiming that selling counterfeit drugs is considered a more profitable business than selling real drugs (Plotnikov, V., 2018). Additionally, the report projects that the yearly loss of revenue from drug sales is roughly 4.5%, or €10 billion.

Despite significant investments in protective measures by the pharmaceutical industry, counterfeiting remains a formidable challenge. Modern anti-counterfeiting

strategies, relying on advanced technologies and computational power, have only been partially successful, with nearly half of the fake medications evading prevention (Fighting counterfeit pharmaceuticals: New defences for an underestimated - and growing - menace, 2024).

Counterfeit drugs pose a severe threat, especially in low- and middle-income countries, with devastating consequences for patient health, economic burdens, and trust in healthcare systems. The World Health Organisation (WHO) estimates that 10% of medical supplies in these nations are either counterfeit or of low quality (Substandard and falsified medical products, 2018).

Counterfeit medications lead to ineffective treatment, adverse reactions, and, tragically, fatalities. The complexity of the drug supply chain (as shown in Fig 1), coupled with the rise of e-commerce, further exacerbates the problem, enabling the distribution of fake drugs that imitate genuine products, often containing harmful substances.

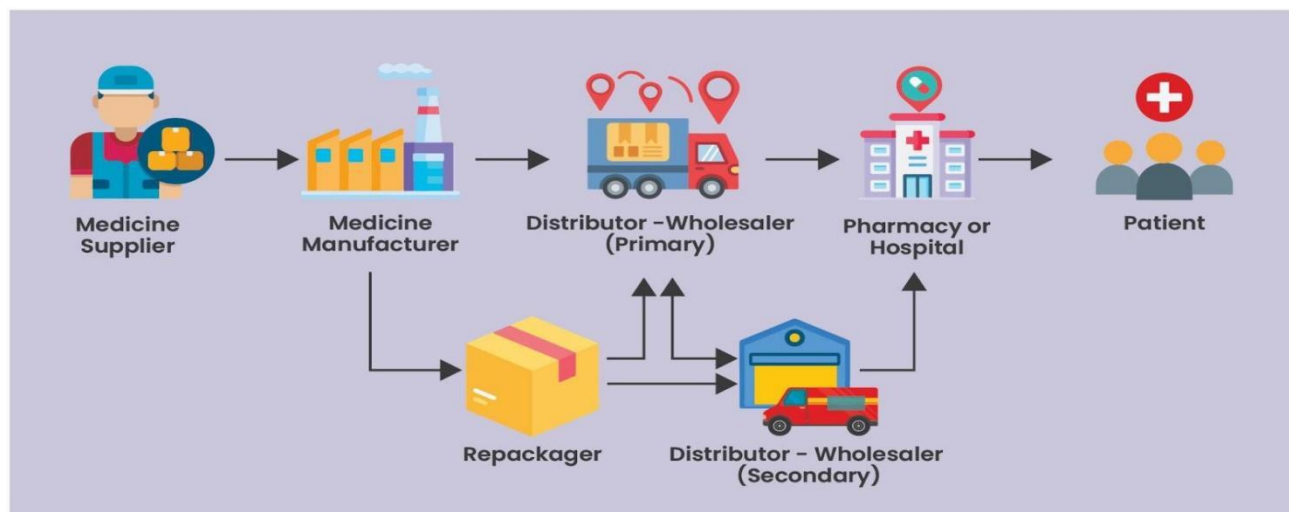


Figure 1: Drug Supply chain

Despite substantial investments in protective measures, the pharmaceutical industry faces challenges in curbing counterfeiting. Modern anti-counterfeiting strategies, while effective to some extent, have not fully addressed the issue, with approximately half of the fake medications bypassing prevention measures (Fighting counterfeit pharmaceuticals: New defences for an underestimated - and growing - menace, 2024).

Blockchain Technology

Blockchain, a decentralised distributed ledger system, can help solve product traceability issues in an efficient and trustworthy manner. The technology known as blockchain, which gives rise to cryptocurrencies, finds

application in a wide range of sectors involving transaction processing, such as banking, energy, supply chain management, trading commodities, and healthcare. To combat the issue of counterfeit drugs, blockchain technology may provide a reliable, secure, and permanent solution for drug provenance and traceability. A distributed shared data platform that ensures data security, transparency, immutability, and permission-only access can be established by utilising blockchain technology to store and share transaction data among various supply chain participants. As a result, it provides a proactive approach to tracking, detecting, and managing counterfeit goods in pharmaceutical supply chains.

In the context of medication security, blockchain, a collection of blocks takes on a new significance. Every transaction in the pharmaceutical supply chain is tracked and documented in the blockchain, from manufacturing to shipping, registration, and sale. This ensures Counterfeiting is addressed by the characteristics of blockchain, such as distributed networks, cryptographic verification, and immutability. The blockchain tracking system facilitates immediate chain participation, making it easy to identify fraudulent activities within the supply chain. In addition to preserving the integrity of the supply chain, this transparency gives patients and chemists the

pharmaceutical legitimacy, improves testing, keeps the temperature under control, and establishes an open tracking system for drug validity.

Functioning of Blockchain

ability to independently confirm the data, boosting patient confidence in the drugs ([Blockchain: A new security check for medicines: Merck KGaA, Darmstadt, Germany, 2020](#)). To stop the counterfeiting of medications, workflow based on blockchain technology used nowadays has been shown in Figure 2.

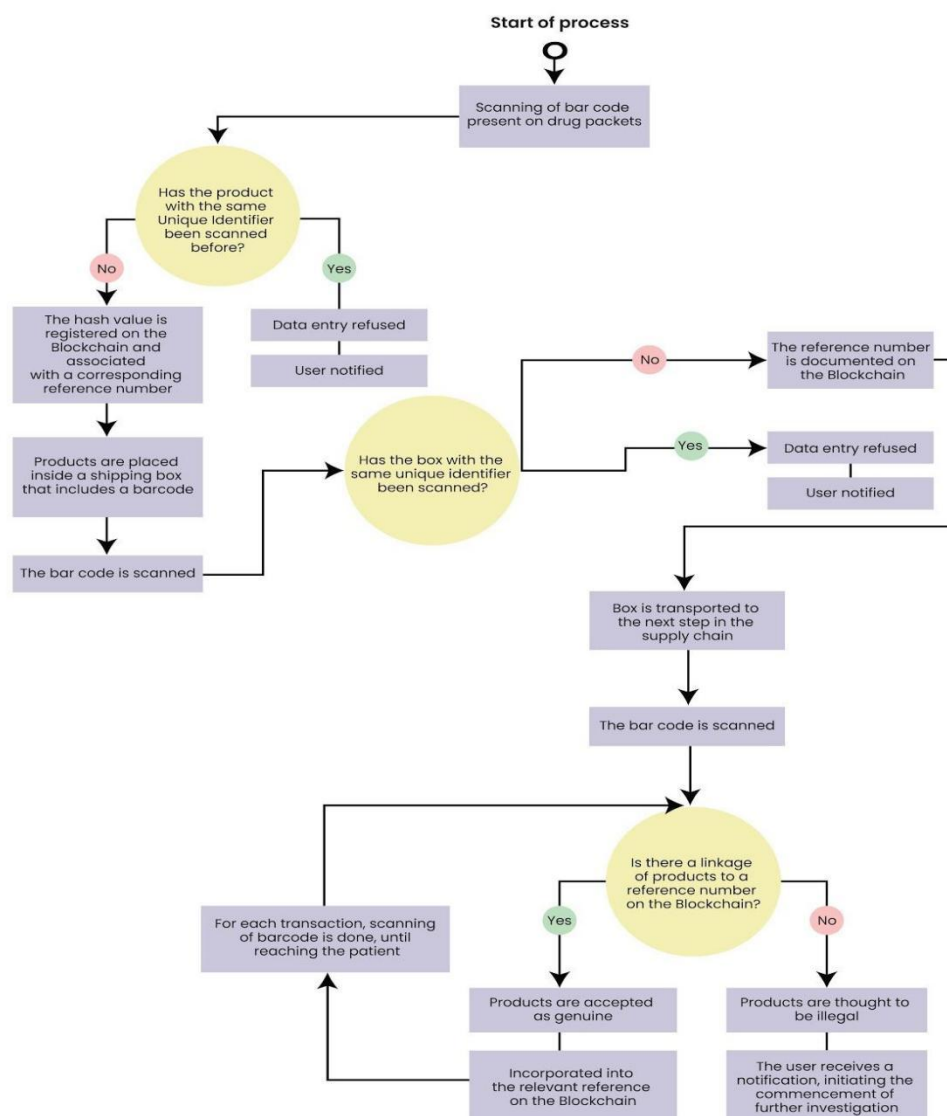


Figure 2: Workflow with blockchain technology

Blockchain technology could be integrated with existing technologies such as radio frequency identification (RFID), near field communication (NFC), quick response

code (QR), and e-pedigree to create more interoperable and well-integrated anti-counterfeiting solutions (Archa et al., 2017). It is evident from several recent pilot

projects involving significant stakeholders as indicated in Table 1 that blockchain-based solutions are gaining

traction in the pharmaceutical sector (Center for Drug Evaluation and Research. DSCSA Pilot Project Program).

Table 1: Drug traceability pilots based on blockchain.

(Center for Drug Evaluation and Research. DSCSA Pilot Project Program).

Serial Number	Product and pilot participants	Platform	Type of solution
1	LedgerDomain—University of California Los Angeles Health	Hyperledger	A blockchain-based method for identifying counterfeit goods
2	TraceLink—more than 22 participants, comprising distributors, wholesalers, and manufacturers	Hyperledger	Digital recalls and blockchain network solutions that are compatible
3	IBM, KPMG, Merck, Walmart	Hyperledger	Blockchain-based tracking and tracing method
4	MediLedger—Amerisource Bergen, McKesson, and drug manufacturers Genentech, Pfizer, Gilead	Permissioned Enterprise Ethereum	Product verification using blockchain technology for salable returns
5	SAP Multichain— McKesson, Novo Nordisk, Merck, Amerisource Bergen, GSK, Amgen, Boehringer Ingelheim	Multichain	Tracking salable returns and verifying counterfeits using blockchain technology
6	IDLogiq	Private platform	Authenticated intelligent medication management based on blockchain technology

Developments in Blockchain

The success of initiatives like the Merck Group and other blockchain implementations in the pharmaceutical industry highlights positive outcomes and improvements in patient safety.

The Indian government recently ordered that, on the labels of their primary packaging or secondary packaging, manufacturers of 300 drug formulation products listed in Schedule H2 of Rule 96 of the Drugs and Cosmetics Act print or affix a barcode or quick response code that stores data or information readable with a software application to facilitate authentication. Information such as the batch number, the date of manufacture and expiration, the brand name, the manufacturing licence number, the name and address of the manufacturer, and the unique product identification code must all be included in the data or information ([300 drug formulations to have mandatory](#)

[barcodes on packages soon to curb sales of Spurious Medicines, 2022](#)).

Limitations and Challenges

Stakeholder agreement

All parties involved in the pharmaceutical supply chain use a distributed ledger called a blockchain network, where anyone with access to the platform's sensitive private data can store their primary business data. Potential stakeholders may be hesitant to join such networks, especially when multiple businesses are competing in the same supply chain, out of concern that they will lose their competitive advantage ([Zhang et al., 2018](#)).

Interoperability

The widespread use of business platforms and software by numerous organisations to offer effective integration strategies is known as interoperability. It provides a way for users of various software packages and platforms to communicate and carry out important business transactions without difficulty. Furthermore, several blockchain systems that are included in the hyper ledger family are addressing interoperability, ensuring optimal scalability, and providing flexibility to enable internal and external business organisation communication (Dagher et al., 2018). Furthermore, several blockchain systems that are included in the Hyperledger family are addressing interoperability, ensuring optimal scalability, and providing flexibility to enable internal and external business organisation communication.

Implementation cost

Since most of the existing solutions are still in the development stage, designing the perfect blockchain application is a challenging task. The issues with privacy, scalability, and interoperability also significantly worsen this problem. Implementation and energy costs are two of the largest problems that most businesses, including the pharmaceutical supply chain, are facing. High implementation and maintenance costs are a result of the current platforms' centralised and inefficient transaction execution as well as legacy software systems. For example, Hyperledger Fabric can process over 3500 transactions per second while using a lot less power than Ethereum because it uses a different consensus mechanism.

Attacks, vulnerabilities and privacy concerns

One of the main advantages and selling points of blockchain technology is its resilience to various types of attacks, including cyberattacks. A recent cybersecurity study lists several security risks, such as man-in-the-middle attacks and malicious actors, that could have an impact on the blockchain network and expose its vulnerabilities (McAfee Labs Threats Report, 2018). These blockchain implementations have bugs and vulnerabilities because they are still in the early stages of development. In the future, phishing scams, technological flaws, implementation exploits, and malware brought on by a lack of policies and procedures will all pose serious challenges that must be overcome. The significance of moral data governance and anonymization strategies is emphasised in addressing possible privacy concerns within the blockchain network.

Lack of standardized regulations

Drug regulatory organisations are in charge of pharmaceutical product quality control, post-market surveillance, efficacy, safety, and monitoring. They frequently supervise the production, delivery, and storage of pharmaceutical goods to promptly identify and appropriately penalise illicit production and trade in counterfeit medications. Because it is more difficult for regulatory bodies to define the legal parameters and context for blockchain technology, regulatory bodies play a more significant and complex role in blockchain-based solutions. When a new transaction is conducted in the network, for instance, these authorities might find it difficult to accurately define the jurisdiction and correct the parties' legal obligations. Another challenge in blockchain networks is handling the requirements of upcoming legislation such as the FDA Drug Supply Chain Security Act, sterilisation, and General Data Protection Regulation. As a result, blockchain technology is still incompatible with the laws and supply chain guidelines that apply to the pharmaceutical industry.

Future Directions

Promising research areas, including integrating blockchain with Artificial Intelligence and the Internet of Things, hold the potential to further enhance drug traceability and personalize medication regimens.

Blockchain's ability to bridge data gaps in clinical trials and facilitate secure information sharing among healthcare providers contributes to improved medical research and drug development.

The evidence and impact of blockchain in reducing counterfeit drug circulation and improving traceability, as supported by research findings and case studies, underscore its potential to revolutionize drug security.

However, challenges such as technical hurdles, regulatory considerations, and privacy concerns must be addressed for widespread adoption. Ongoing research, coupled with advancements in computing power, is expected to refine and secure blockchain technology in the pharmaceutical sector.

As exemplified by the Government of India's mandate for drug manufacturers to implement barcodes or quick response codes, blockchain is gaining recognition as a transformative force in ensuring drug authenticity.

Integration of blockchain technology offers a promising future for the pharmaceutical sector, providing a secure and accessible platform. Success stories like PharmaCrypt and Gcoin blockchain further illustrate the potential of blockchain in the industry (Tseng et al., 2018)

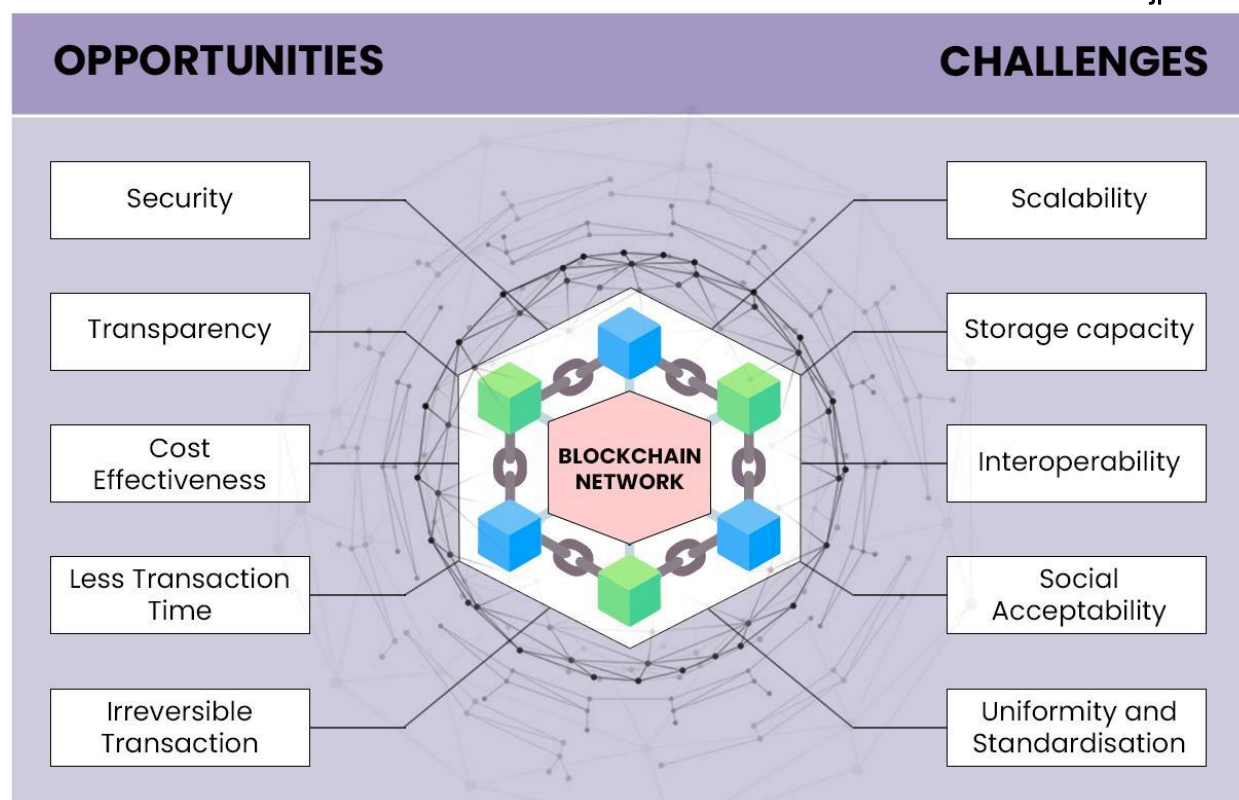


Figure 3: Opportunities and challenges related to blockchain technology.

Opportunities and challenges associated with blockchain technology in combating drug counterfeiting are shown in Fig 3. As research progresses and computing power advances, pharmaceutical companies embracing these cutting-edge technologies can gain a competitive advantage, contributing to safer and more secure medical drugs.

Conclusion

In summary, thousands of lives are lost each year due to counterfeit medications, and the pharmaceutical industry's current protective measures have only partially stemmed the tide. Blockchain technology emerges as a beacon of hope, offering a secure, transparent, and traceable solution to combat drug counterfeiting.

Blockchain's unique features, including immutability and cryptographic verification, address the vulnerabilities of existing anti-counterfeiting measures. The transparency it provides in the pharmaceutical supply chain not only ensures drug authenticity but also empowers stakeholders to actively participate in maintaining the integrity of the supply chain.

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Competing interests

The authors declare that they have no competing interests.

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