

Blockchain Technology for Strengthening the Indian Generic Medicine Supply Chain and Combating Counterfeit Drugs

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Abstract

India is one of the leading distributors of generic medicines globally, but its supply chain faces numerous challenges including substandard medicines, counterfeiting, and inefficient logistics. Blockchain technology offers a promising solution by providing a secure, decentralized, and transparent platform to track and verify the entire drug supply chain from production to delivery. This paper investigates the potential of blockchain to mitigate counterfeit drug circulation, improve trust in Indian generic medicines, and enhance the efficiency of supply chain management. It explores real-world applications, such as NITI Aayog's collaboration with Oracle and other blockchain initiatives globally. The paper concludes that blockchain can restore stakeholder confidence, address counterfeiting challenges, and position India as a leader in global pharmaceutical supply chains while improving public health outcomes through better product traceability. By embracing blockchain, the Indian pharmaceutical industry can revolutionize drug distribution and contribute to a safer global medicine supply chain.

Keywords: Blockchain, Indian generic drugs, counterfeit drugs, anti-counterfeiting, pharmaceutical supply chain

INTRODUCTION

The World Health Organization (WHO) issued a warning in October 2022 that four contaminated cough syrups allegedly produced by an Indian pharmaceutical manufacturer could be the cause of the deaths of 66 children in Gambia [1]. This incident has once again raised serious concerns about counterfeit medicines as well as the quality of Indian generic medicine manufacturers and suppliers. As per the World Health Organization's 2018 factsheet, it is estimated that around 10% of medical products in low- and middle-income countries are either substandard or counterfeit [2]. India is one of

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the world's largest producers of generic medicines, and it is claimed that India and China are responsible for the majority of contaminated, suboptimal, or counterfeit medications distributed globally. The European Commission claimed in a disturbing report that India is responsible for 75% of all cases of poor-quality medicines worldwide [3].

The Drugs and Cosmetics Act (1940) gives government agencies the authority to inspect, seize, and confiscate goods that are found to be "adulterated spurious misbranded" and regulates the importation, production, and distribution of drugs in India. The act was amended in 2008 to

increase the punishment for offenders [4]. Even if the manufacturer's standard is met, it is necessary to ensure that the correct product reaches the stakeholder, and the supply chain is not disrupted.

India has implemented some initiatives to combat counterfeit drugs. In January 2011, the Directorate General of Foreign Trade¹¹ released a public notice regarding the introduction of a track-and-trace system using barcode technology, aligned with GS1 standards (an international standard system), for all drugs and pharmaceutical products exported from India. This notice requires all export pharmaceutical consignments to be marked and coded using GS1 barcode standards at various packaging levels [5]. Using bar codes or QR codes at various levels of the supply chain can help to solve major counterfeit medicine issues. However, these are not foolproof, as counterfeiters can duplicate QR codes, or they can compromise, hack, or make their own versions of the website or application of the QR code service provider [6]. So, there is a need for newer technology that can be more secure and difficult for counterfeiters to compromise. The blockchain technology, which has evolved recently, may have such potential.

THE BLOCKCHAIN TECHNOLOGY

Blockchain, in simple words, is a sophisticated data-storing and sharing technology where data is stored in a chain of blocks and is distributed across a network of computers. This means that instead of having a central database controlled by a single entity, the data is stored on many different computers, with each computer having a copy of the entire database. Each block on a blockchain will be containing a unique digital signature, timestamp, and data of transactions which could be anything from a financial transaction to a piece of digital art. Each data block on the blockchain is connected to the preceding block in a sequential manner, and any attempt to alter or remove it would be immediately detectable by others on the network [7].

Bitcoin, a famous virtual currency that came into existence in 2009, is a classic example of the real-world utility of blockchain technology. Bitcoin transactions are documented in blocks that are verified by computers globally. The validators compete to solve a mathematical problem to guess the solution for decoding the unique signature for the new block. Once a new block is generated, the pending transactions are added to it and projected to the network. Once all the validators authenticate the transactions in the new block it is added to the previous block [8]. Validators are called miners since they use energy in the form of electricity to power their computers to solve the problem. The miner who mines the new block will get new bitcoins as a reward. This rewarding system for being honest and the expensive computational requirement for compromising the network keep the Bitcoin system secure and resistant to attacks.

Different types of blockchain networks exist now, but in general, they are of two types depending on the method of block validation. Proof of work (POW) is the first-generation method used in Bitcoin for validation of blocks of cryptocurrency transactions by using energy. Since energy consumption is a problem of POW, a second-generation method, i.e., proof of stake (POS) is widely used nowadays in most of the blockchain networks. In POS, the participants exchange the virtual coin of the network for the opportunity to verify blocks and subsequently become validators, i.e., they stake their coins as collateral. To create new blocks, validators are chosen at random. The validator subsequently disseminates the new block, along with the new transactions, to the network. The block and its transactions are then validated by other validators in the network, and it is added to the blockchain. The block's validator is rewarded with newly minted virtual currencies and transaction fees. To compromise a blockchain network an attacker should overpower more than half of the validators in the network. It is extremely difficult and expensive, as it requires an immense amount of computational power and resources or a large number of virtual coins of the network [9].

BLOCKCHAIN IN SUPPLY CHAIN

Smart contracts are computer programs that can be programmed onto a blockchain network to automatically carry out the conditions of a contract. Such a smart contract can be used to automatically generate and maintain a ledger for track and trace of the pharmaceutical supply chain.

Packaging at each level of the supply chain can be coded by a unique identity system which will have details of sender virtual address and other product details. Once the recipient scans the package using a provided application, smart contract will execute the transaction to the virtual address of recipient. This will be projected as a transaction to the blockchain network, and it will be added to the block after validation and secured against any changes. By doing this, it is possible to maintain a single ledger in the network that is always open to anyone and contains all distribution-related information from beginning to end [10]. Traditional pharmaceutical supply chain faces a range of challenges, including a lack of transparency, difficulty in tracking products, a lack of trust, etc. The transparency, immutability, and security of blockchain technology that can provide a decentralized distributed ledger system can help to overcome such weaknesses in the pharma supply chain [11].

The FDA pilot program, successfully concluded in 2020, demonstrated how blockchain technology could be leveraged to meet the requirements of the Drug Supply Chain Security Act (DSCSA) for verifying, tracking, and tracing prescription medications and vaccines distributed in the United States. This initiative involved collaboration among International Business Machines Corporation (IBM), Klynveld Peat Marwick Goerdeler (KPMG), Merck & Co., Inc., and Walmart Inc. To track the human papillomavirus vaccine Gardasil in Hong Kong, Singapore-based Zuellig collaborated with the pharmaceutical company Merck. To stop medical professionals from giving patients outdated COVID-19 vaccines, Zuellig Pharma is also tracking vaccinations using eZTracker. The creation of a blockchain solution to identify fake COVID-19 vaccines was put out to tender by UNICEF. It enables the scanning and verification of COVID-19 vaccines so that their serial numbers can be compared to a list of products secured by blockchain [12].

In 2018, to address the increasing issue of counterfeit medications in India, NITI Aayog, the government's leading policy institute, partnered with global cloud provider Oracle, Apollo Hospitals, and pharmaceutical manufacturer Strides Pharma Sciences to pilot a blockchain-based supply chain for genuine medicines [13].

Blockchain technology has been successfully applied to supply chains in various industries, demonstrating its versatility and potential to enhance transparency, security, and efficiency. IBM's Food Trust, in collaboration with Walmart and other major retailers, uses blockchain to trace the origin of food products like leafy greens, reducing food fraud, contamination, and improving recall efficiency [14]. Carrefour, a European retail giant, uses blockchain to trace the origin of poultry, milk, and other goods, giving consumers real-time access to product journey information [15]. Car manufacturer, BMW uses blockchain to trace the sourcing and production of raw materials like cobalt, ensuring they come from ethical sources and are not counterfeit [16]. These examples highlight how blockchain is being adopted across multiple industries to increase trust, improve traceability, and enhance efficiency by creating a tamper-proof, transparent supply chain.

LIMITATIONS AND CHALLENGES OF BLOCKCHAIN TECHNOLOGY

The implementation of blockchain technology in the pharmaceutical supply chain presents several limitations and challenges, notwithstanding its advantages. Scalability is a big issue since the validation process, which puts security first, restricts the network's capacity to handle high transaction volumes. Networks with numerous validators, for instance, guarantee security but frequently slow down transaction processing. Moreover, the complexity of the regulations presents a significant obstacle because the lack of precise guidelines from the authorities makes it more difficult to implement them completely. Furthermore, substantial investments in infrastructure and expertise are required due to the technical intricacies of incorporating blockchain into existing systems. These elements might limit the technology's potential impact in the short term and slow down its implementation.

CONCLUSION

Indian generic drug manufacturers are accused of supplying substandard medicines. The introduction of blockchain technology in the pharmaceutical supply chain of Indian generic drug

exporters can strengthen the industry. Blockchain technology can offer a more transparent and secure solution for medicine supply chain. Building trust and steering clear of rumors about Indian generics are two important benefits of its implementation. Blockchain might contribute to the industry's efforts to win back the confidence of customers, regulators, and stakeholders. Despite the limitations and challenges in implementing blockchain technology in the drug supply chain, it can be a practical step toward a bright future for the Indian generics sector.

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