CHAPTER: 06

BLOCKCHAIN-BASED SOLUTION FOR TACKLING COUNTERFEIT DRUGS IN INDIA

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INTRODUCTION

The global issue of counterfeit drugs is a growing concern, affecting every country and posing a significant threat, especially to lower-income and lower-middle-income countries. While there isn't a universally agreed-upon definition of counterfeit medicines, the World Health Organization's widely accepted definition from 1992 characterizes them as intentionally and fraudulently mislabeled concerning identity and/or source. Counterfeit products can vary, including those with correct ingredients, incorrect ingredients, no active ingredients, insufficient active ingredients, or fake packaging. Recent WHO estimates indicate that approximately 1 in 10 medicinal products circulating in low- and middle-income countries is either substandard or falsified. The increased accessibility of drugs through various channels has significantly multiplied the potential risks of exposure to counterfeit products. Furthermore, counterfeiters have become more sophisticated in manufacturing and distributing fake drugs, making them harder to detect. These illicit practices pose severe public health concerns, lead to substantial financial losses, and tarnish the reputation of pharmaceutical companies, pharmacies, and healthcare practitioners, ultimately eroding public trust in the healthcare system [1].

One of the primary challenges confronting pharmaceutical industries today revolves around ensuring the traceability and security of their supply chain, encompassing the journey from raw materials through manufacturing to the end consumer. Despite previous attempts to address this issue using tracking solutions like barcodes or radio-frequency identification (RFID) tags, the persistence of counterfeiting is attributed to the absence of real-time data and inefficient integration of data from diverse suppliers [5].

In India, the prevalence of fake medicines is a significant worry, with approximately 3% of drugs being deemed substandard or counterfeit, according to the National Drug Survey 2014-2016 conducted by the National Institute of Biologics under the Ministry of Health & Family Welfare. In response to these challenges, the introduction of 'Blockchain-based solutions' to the pharmaceutical industry is

proposed—a decentralized and distributed ledger that records data for individual transactions on a common blockchain overseen by a government regulator. This approach to monitoring and tracking offers real-time visibility into any tampering or falsification activities, allowing for immediate recording and rectification [2].

RESEARCH QUESTION

How were blockchain-based solutions utilized to address the issue of counterfeit drugs in India?

RESEARCH OBJECTIVES

1. To examine the present state of the pharmaceutical market on both a global and national scale.
2. To explore counterfeit drugs and their consequences within the drug supply chain.
3. To gain insights into the viewpoints of key stakeholders' manufacturers, retailers, and pharmacists regarding blockchain technology.
4. To analyze the increasing influence of blockchain-based solutions in the pharmaceutical sector.
5. To provide recommendations for the development of a strategic path forward.

RESEARCH METHODOLOGY

The research design employed for this study is a comprehensive literature review focusing primarily on the Indian Pharmaceutical market, with an additional exploration of the global pharmaceutical market to provide a holistic perspective. The data collection process involved a systematic search across diverse sources, including published studies, thought leadership papers, journals, analyst commentary, blogs, and news articles.

This approach aimed to compile and assimilate online material, offering an in-depth understanding of several key aspects. These include

the challenges and implications posed by counterfeit drugs to the broader pharmaceutical market, a thorough examination of the current global and national pharmaceutical landscape, a detailed analysis of the pharmaceutical supply chain network and the roles of various stakeholders, insights from previous 'track and track studies' conducted in India, and a critical analysis of Blockchain solutions with their growing applications in different pharmaceutical sectors. The inclusion criteria encompassed any information evaluating or discussing the issue of substandard or counterfeit medicines in India, alongside the introduction of blockchain-based solutions to address this problem.

RESULTS & DISCUSSION

The growth of the Indian pharmaceutical industry emphasizes the critical importance of an efficient drug distribution process to ensure widespread availability, extending even to rural areas. The supply chain in India is highly fragmented, witnessing the emergence of pharmacy chains like Wellness Forever, Med-plus, Front Line, Apollo, Frank Ross, and Roshan, alongside the increasing prominence of online pharmacies such as 1 MG, Pharm Easy, Med-plus, Net Meds, Myra, and Med-life [3,4].

The complex supply chain presents entry points for counterfeit products, posing a significant risk during the various stages of distribution. Counterfeit drugs, characterized by deliberate mislabeling, present a severe threat to public health, potentially containing incorrect or no active ingredients, incorrect quantities, forged packaging, and manipulated expiry dates. Counterfeit drugs, particularly those for serious conditions like AIDS or cancer, are lucrative markets for criminals, jeopardizing the reputation of pharmaceutical brands.

Initiatives like the proposed 'trace and track' mechanism and the Drug Authentication and Verification Application (DAVA) aim to address these challenges but fall short in ensuring complete visibility and traceability. The integration of Blockchain technology emerges as a transformative solution, providing a decentralized and secure ledger for real-time tracking and traceability throughout the pharmaceutical supply chain. Despite the technology's potential, challenges such as

resistance to adoption, limited knowledge, high implementation costs, regulatory gaps, talent acquisition, and security concerns impede its widespread incorporation in the healthcare sector [6-8].

CONCLUSION

Establishing and ensuring the implementation of standardized and effective collaboration mechanisms among diverse stakeholders, including health authorities, law enforcement, customs, the judiciary, manufacturers, wholesalers, retailers, health professionals, and consumers, is imperative.

Comprehensive training programs for all involved stakeholders are essential to enable them to verify and report counterfeit drugs accurately. The initiative should be widely promoted and advertised to encourage the active participation of all stakeholders. Health practitioners should take a proactive role in educating the public about the detrimental consequences of using counterfeit drugs and create incentives for the timely reporting of such cases.

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