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Review Article

Combating Counterfeit Medicines Through Regulatory Initiatives and Emerging Technologies

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Abstract: Access to healthcare is a fundamental human right, and it is the government's responsibility to ensure that its citizens receive reliable medical services backed up by a strong healthcare infrastructure. In recent decades, both the government and healthcare sectors have been seeking an effective solution to the rise of counterfeit pharmaceuticals, which pose a major threat to society. According to the World Health Organization's estimates, approximately 40 percent of medicines developed in low-income countries may be adulterated or denatured. Counterfeit drugs lead to economic loss in the billions worldwide, risks to patient safety, and diversion of funds towards pharmaceutical research and innovation. A decade-long strategy has been introduced by the United States Food and Drug Administration as a response to these concerns, the plan aiming to improve drug traceability throughout the supply chain process. The task of mandating the printing of barcodes and human-readable data on packaging has been designated to the Healthcare Distribution Alliance. Moreover, the FDA is also involved in helping wholesalers and pharmaceutical manufacturers to leverage blockchain technology for secure data transfer and traceability within interoperable digital networks. Preventing counterfeit medicines from making their way into the supply chain remains a major obstacle for governments and regulatory authorities. Likewise, there is an increasing emphasis on implementing stricter guidelines to avert counterfeiters and criminals from infiltrating counterfeit medicines into the market. The healthcare sector requires strong regulatory measures and secure technologies to ensure the shipment of safe, authentic drugs to patients.

Keywords: Pharmaceutical Supply Chain, Drug Traceability, Drug Counterfeit, Pharmaceutical Serialization, Track and Trace System, Enterprise System, Blockchain, IoT

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1. Introduction

Pharmaceutical drug serialization serves as an essential procedure for digitally tracking and tracing pharmaceuticals within the supply chain. This system is governed by the foundational principles of "What, Why, When, and Where," ensuring that all activities regarding drugs are systematically charted digitally for future audits and to maintain traceability within the supply chain. The implementation of digital drug traceability is, however, a complex process. The process entails continuous transfers of ownership between manufacturers and buyers. If strict regulations are not put in place, significant risks can be presented to stakeholders and patients, potentially compromising their safety [1,2]. Any errors or oversights in the manufacturing, the supply chain process, material sourcing, storage conditions, or temperature can alter the natural effect of drugs, posing a risk to public health.

The pharmaceutical industry has always been an active sector for criminals and drug traffickers to thrive in, by producing large quantities of counterfeit medicines and distributing them through illicit networks. The COVID-19 pandemic has worsened the

issue of infiltration of counterfeit medicine, triggering a domino effect by causing an increase in the overall production of counterfeit drugs, low business reliability, a lack of reliable resources, and misuse of technologies [3]. Consequently, the economic impacts of this issue result in major revenue losses for partners of the supply chain. Furthermore, this undermines the profitability of the healthcare sector and weakens its ability to invest in pharmaceutical research and innovation for economic growth [4].

To accurately estimate the scale of the counterfeited drug market, four realistic scenarios have been evaluated. Each scenario is associated with an approximate global market value of counterfeit drugs: $100 billion, $200 billion, $300 billion, and $431 billion, respectively. Blockchain-based applications, in conjunction with advanced manufacturing technologies, are being implemented to enhance digital drug traceability, with ongoing improvements at the forefront of innovation. Essential aspects of traceability, including material traceability in continuous manufacturing systems, are subject to being monitored and investigated [5]. Traceability plays a significant role as a primary differentiator in the present economic landscape of the pharmaceutical industry [6]. It assists with waste reduction, prevents counterfeit development, and minimizes targeted recalls. Consequently, traceability strengthens the supply chain processes by improving adaptability, visibility, synchronization, and security.

2. Online Counterfeit Medicine Market

The struggle regarding illegal and counterfeit drugs extends beyond national borders, standing as a significant international issue. The vast majority of these counterfeit pharmaceuticals are dispersed in underdeveloped or developing countries, such as South Asia and Africa, where the distribution rates are estimated to be 70%. Nearly one-third of the world's nations lack strict regulatory standards for drugs, therefore presenting themselves as vulnerable targets for illicit manufacturing and distribution networks. Due to the absence of strict regulations and oversight, millions of individuals are exposed to potentially denatured and compromised substances, therefore jeopardizing future business expansion initiatives [7]. The innovation and expansion of e-commerce platforms and the globalization of consumer markets have created new channels for the distribution of fraudulent medications, including pathways such as online shopping and delivery services. Moreover, the anonymity, convenience, affordability, and global accessibility offered by internet-based technologies have vastly contributed to the rapid influx of online pharmacies, whose numbers are estimated to exceed 35,000 websites [8]. However, the majority of these online pharmacies operate without proper authorization, lacking critical safeguards such as the requirement for valid prescriptions, valid licenses or certification, and adherence to local, national, or international pharmaceutical regulations [9].

These illegal and fraudulent online pharmacies stand as potential risks to patient and public safety, as they serve as sourcing and distribution centers for medications that have been tampered with or altered. They operate outside the regulatory setting of the controlled supply chain and operate without any oversight from a certified healthcare professional. Individuals who support unauthorized online pharmacies through being customers play a role in contributing to the reduction of regulatory mechanisms that are implemented to ensure the quality and safety of medications. Consequently, at the same time, they also contribute to the expanding market of counterfeit pharmaceuticals worldwide [10]. Individuals who interact with these fraudulent online pharmacies are also presented with cybersecurity risks, including financial theft, data dredging, and exposure to possible computer viruses and malware. This intensifies the already existent vulnerabilities regarding public health [11]. Consequently, as a result of e-commerce globalization, a "digital" grey market has emerged, operating independently from the authorized supply chain. While this new emergence offers convenience, it also poses considerable risks. Importantly, persistent challenges related to equitable access and

affordability of prescription pharmaceuticals remain significant factors behind the continued presence of this alternative demand and sourcing channel [12].

3. Drug Serialization challenges and concerns

To mitigate the risks associated with counterfeit drugs implanting drug traceability within the supply chain is a necessary regulatory requirement. However, while attempting to meet this mandate, underdeveloped and impoverished nations encounter various hurdles. Challenges include insufficient funding for infrastructure development, a shortage of skilled workforce, restricted access to secure technologies, and the limitations on the capacity of local pharmaceutical manufacturers to implement and invest in drug traceability systems [13,14]. Additionally, smaller manufacturers face additional significant challenges arising from geopolitical and economic disparities, civil conflicts, political instability, persistent distrust in government institutions, and the adverse impacts of climate change and environmental vulnerability [15].

Skilled and reliable human resources are necessary for the implementation and maintenance of serialization systems for drug traceability. Any errors, whether human, technical, or mechanical, can pose risky implications for the public society. India, for example, is a place where the Directorate General of Foreign Trade (DGFT) requires a "dummy or fake serialization number for primary packages directly from the manufacturers, which results in confusion [16]. In order to meet serialization regulations, small manufacturers are required to invest substantially in computer systems, vision systems, barcode grading systems, and effective quality control measures to adhere to national standards. Processes such as identifying and eliminating misprinted drug packages on the production lines frequently require AI-based applications to optimize manufacturing efficiency and minimize manual intervention [17].

The implementation of digital pharmaceutical product traceability provisions necessitates that manufacturers allocate additional facility space for specialized packaging equipment, label grading systems, barcode printers, and vision systems. Such technological setups often require substantial financial investments, which might perhaps surpass the financial resources of some manufacturers [18]. Investments in serialization equipment, labelling software, and digital traceability systems can significantly affect the financial stability of small pharmaceutical manufacturers. Even with significant capital in infrastructure to meet serialization compliance, small manufacturers may find themselves compelled to consider alternative market segments, ultimately resulting in decreased revenue. With the rapid advancement of technology, the pharmaceutical industries are increasingly leveraging various IT platforms to support the planning and execution of clinical trials. Nevertheless, the implementation of such technologies may present additional financial challenges and operational complexities, particularly for small manufacturers.

4. Drug Supply Chain Security Act in United States

In the United States, a significant portion of the population faces the risk of exposure to counterfeit or fraudulent medications. This vulnerability disproportionately affects individuals with limited educational backgrounds, those who live below the poverty line, non-citizens, people without health insurance, those who encounter high out-of-pocket insurance expenses, and those who obtain counterfeit drugs from illicit channels such as the dark web or social media platforms. The implementation of serialization compliance in the United States began in November 2018, subsequent to an initial announcement regarding the implementation of serialization regulations in November 2017. Nevertheless, compliance was postponed by a year due to insufficient readiness among wholesalers, supply chain partners, and manufacturers [19].

All prescribed pharmaceutical medications are required to feature a unique product identifier for enable traceability. The Drug Supply Chain Security Act (DSCSA) has established an eight-year phased implementation plan from 2015 to 2023. As part of this framework, compliance requires the application of a unique product code with a 2D data matrix to each medicine packet for electronic traceability. Furthermore, all supply chain partners, including manufacturers, re-packagers, wholesalers, and dispensers, are required to electronically transmit unit-level traceability. Additionally, the adoption of a packaging hierarchy with aggregated data in Electronic Product Code Information Services (EPCIS) files, along with electronic transmission to supply chain partners, is also mandated [20]. The DSCSA requires that stakeholders in the supply chain, including wholesalers, distributors, dispensers, and pharmacies, verify and authenticate suspected or potentially counterfeit product unique identifiers upon request from trading partners, regulatory authorities, or state agencies. The DSCSA 2023 Act supersedes the lot-level requirements with unit-level traceability, compelling all participants in the supply chain to exchange serialized data electronically through interoperable technologies. This provision intends to assist pharmaceutical companies in implementing and adopting such systems. For the ability to conduct effective product tracking, the electronic traceability platform must possess the ability to store and process substantial volumes of data. In agreement with Section 582(a)(9) of the FD&C Act under the Drug Supply Chain Security Act, each product packaging must possess a two-dimensional (2D) data matrix or linear barcode containing human-readable data at the time of printing product packaging labels on homogenous cases [21]. Transaction information pertaining to medications, referred to as T3 information, must be collected and shared with partners to comply with regulations such as the Drug Supply Chain Security Act (DSCSA). This information includes:

- The proprietary or trademarked name(s) of the product
- Product strength and dosage form
- National Drug Code (NDC) of the product
- Container size
- Quantity of containers required
- Product lot number
- Date of transaction

5. Conclusion

The abundance of counterfeit pharmaceuticals poses a significant risk to public health and compromises patient safety. Over the past decades, the World Health Organization (WHO) has overseen various initiatives aimed at reducing the threats associated with counterfeit medications. Evidence indicates that the majority of illegal and counterfeit pharmaceuticals are circulated mainly within developing or economically disadvantaged nations, constituting up to 70% of the total distribution. In the United States, the Drug Supply Chain Security Act (DSCSA) has created a comprehensive 10-year framework to ensure serialization compliance. The DSCSA 2023 Act provisions require that distributors and manufacturers electronically transfer serialized data via interoperable networks. Furthermore, the FDA is also initiating a pilot program to assess the integration of blockchain technology within these networks to authenticate "Authorized Trading Partners." The DSCSA Act additionally demands the electronic transfer of serialization data among all supply chain partners, assisting with product-level traceability. By adopting secure, advanced technologies and implementing key product identifiers into barcodes, the risk of counterfeiting within the supply chain can be significantly reduced. The increasing acceptance of serialization technologies globally

demonstrates their effectiveness, with numerous countries anticipated to enforce serialization as a regulatory standard for prescription pharmaceuticals in the near future.

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