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Pharmaceutical Drug Serialization in the Supply Chain

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Abstract: ***Pharmaceutical medication serialization is often a regulatory requirement established by large nations to combat pharmaceutical drug counterfeiting. Since the 19th century, drug fraud has been a serious issue for the healthcare sector. The regulator y and healthcare organizations struggle from time to time to reduce the danger of negative outcomes brought on by fake medications. According to estimates from the World Health Organization (WHO), four out of every ten pharmaceuticals sold in underdeveloped or disadvantaged nations may be tainted. Ultimately, because of stolen, diverted, and counterfeit pharmaceuticals, drug makers lose billions of dollars annually. The regulatory authorities are currently developing severe regulations to prevent criminals from supplying and diverting fake or stolen medicine in the supply chain. To offer patients with safe and authentic medications, the healthcare business needs strict rules and secure traceability technologies. In essence, pharmaceutical drug serialization offers benefits by enhancing the supply chain's drug security by lowering adverse occurrences and investigations. Additionally, tracking and tracing technology is used in pharmaceutical drug serialization to take advantage of the advantages of tracking individual drug packages in the supply chain.***

Keywords: Drug Traceability, Drug Counterfeit, Pharmaceutical Serialization, Supply chain, Blockchain, Track and Trace System, Enterprise System.

I. INTRODUCTION

Counterfeit drugs are typically pharmaceuticals that have been purposefully made fraudulently in order to conceal the authenticity of the drug. Additionally, serialization of pharmaceuticals is a powerful procedural notion that helps to safeguard and authenticate pharmaceuticals across the supply chain. The current digital supply chain revolution is expanding the reach of traditional company while utilizing the advantages of cutting-edge technology. Finally, to address the problems with medicine counterfeiting in the supply chain, the pharmaceutical corporations are implementing stricter technologies and regulatory compliance. Criminals and drug counterfeiters produced large quantities of adulterated pharmaceuticals during the current pandemic and distributed them via their sources of illicit networks and online dark social platforms. Furthermore, because to the COVID-19 supply chain disruption, non-business resilience, and fear of ransomware, the mass fabrication of counterfeit medications has escalated [1]. Basically, four different scenarios with projected worldwide counterfeit medication markets of $100 billion, $200 billion, $300 billion, and $431 billion, respectively, are assessed in order to determine the precise size of the market [2].

II. PREVIOUS ADVERSE EVENTS OF DRUG COUNTERFEITING

By default, Drugs that are counterfeit sometimes include no active substances or fewer active chemicals, as well as adulterants, phony ingredients, wholly inaccurate labeling, and erroneous brand names. The World Health Organization (WHO) estimated in 2003 that subpar and/or counterfeit pharmaceuticals generate about $32 billion in annual revenue for criminals and counterfeiters [3]. A 2012 survey by Outsourcing Pharma revealed that 75% of fake medications sold worldwide had some connection to India, 7% to Egypt, and 6% to China [3]. Over 100 cardiac patients died in 2012 after receiving treatment with fake medication from Pakistan's Punjab Institute of Cardiology [4]. A blood thinner called heparin that was contaminated caused the deaths of about 149 persons in 2007–2008. The FDA conducted more research, which showed that heparin was legitimately imported into the US.

The FDA has removed about 18 million Lipitor tablets off the market in 2015. After an investigation by authorities, it was found that Lipitor and Celebrex were being diverted and smuggled into the United States from countries in South America and were being rebranded to conceal the true source of the medications. Additionally, thieves inserted stolen GSK and Roche medications valued around $8 million into the supply chain. Around 64% of antimalarial medications imported into Nigeria in 2011 were thought to be possibly fake, according to estimates. 70% of all imported meds came from China and India, which is also the primary supplier of fake medications [6]. Later, regulatory agencies' top worry turned to tramadol, an opioid control drug prescription, because it sparked a sizable black market and was associated with a high number of reported overdose deaths [7].

III. DSCSA SERIALIZATION REGULATION IN UNITED STATES

In the United States, the majority of the population may be exposed to drugs that are fake or stolen. People who are Hispanic, educated, living in poverty, non-citizens, without health insurance, managing expensive out-of-pocket insurance costs, and buying fake pharmaceuticals from criminal websites or social media platforms [8]. In November 2018, the United States of America became compliant with serialization. Although the serialization requirement was supposed to go into effect in November 2017, compliance was delayed for a year due to the manufacturers', supply chain partners', and wholesalers' lack of preparation. All pharmaceutical prescription drugs must comply with this serialization requirement and have a distinctive product identifier for traceability. The Drug Supply Chain Security Act (DSCSA) has developed a step-by-step implementation plan that will take eight years, from 2015 to 2023. As part of this approach, it has been mandated that each individual medicine packet contain a unique product code and a 2D data matrix for electronic traceability. Further, all supply chain participants, such as the producer, repackagers, wholesalers, and dispensers, are required to electronically upload data for unit level traceability under this serialization legislation. Additionally, it mandates that packaging hierarchy of aggregated data be included in EPCIS file and electronically transferred to the supply chain partner [9] The Drug Supply Chain Security Act (DSCSA) mandates that all supply-chain participants, including wholesalers, distributors, dispensers, and pharmacies, authenticate the product's unique identifier when it is requested by a business partner, regulatory body, or state agency. The DSCSA 2023 Act would ultimately replace the requirement for lot level traceability with unit level traceability, and all supply chain participants will be required to electronically share serialized data using an interoperable technological manner [11]. Additionally, this clause will make it easier for the pharmaceutical industry to adopt and use a robust system. For product traceability, the electronic traceable system should be able to store and handle large volumes of data. Each product packaging should include a 2-dimensional (2D) data matrix barcode with human readable form of data when printing product packaging labels, and in a linear barcode or 2D data matrix barcode when printing labels on a homogenous case, according to the Drug Supply Chain Security Act (DSCSA) section 582(a)(9) of the FD&C Act. [12, 13]

IV. EU-FMD SERIALIZATION REGULATIONS FOR EUROPE

The legislative Directive 2011/62/EU was enacted by the European Union Council in 2011 and a plan to reduce the risk of stolen and counterfeit medicines on the European market was started [14]. In essence, it modified the inaugural European Union Directive on Falsified Medicines (EU-FMD), which replaced Directive 2001/83/EC. Additionally, the parliamentary Delegated requirement 2016/16 was essential in ensuring that the serialization requirement was followed in every European nation [15]. The European Union finally put its serialization legislative regulation into effect on February 9, 2019. Actually, this legislation does not include a traceability requirement for all pharmaceutical products and devices; it only applies to prescribed medications 16]. Pharmacies in European nations are thought to supply about 10 billion packages of prescription medications each year. A consolidated cloud-based system for product tracing was adopted as a result of this law. For improved medication traceability, this law requires the Marketing Authorization Holder (MAH) to transfer unit level unique identifier data to a centralized cloud-based database. The European Union has established a "Book-End" strategy, requiring each supply chain participant to confirm the unique identity embedded on product labels. The European Union's medicine traceability model makes use of patient security, data privacy, a robust system, and the accuracy of transaction data all throughout the supply chain. The central cloud-based data repository for medication traceability is called the European Medicines Verification Organization (EMVO) [17]. Additionally, it connected to the NMVS and transferred data to the NMVS database repository. Every EU nation is required by law to implement a verification system that connects to EMVO for the validation of unique product identifiers. When a medication is dispensed to a final consumer, the NMVS system connected with the country's pharmacies and hospitals changes the status of the medication's unique identity as deactivated.

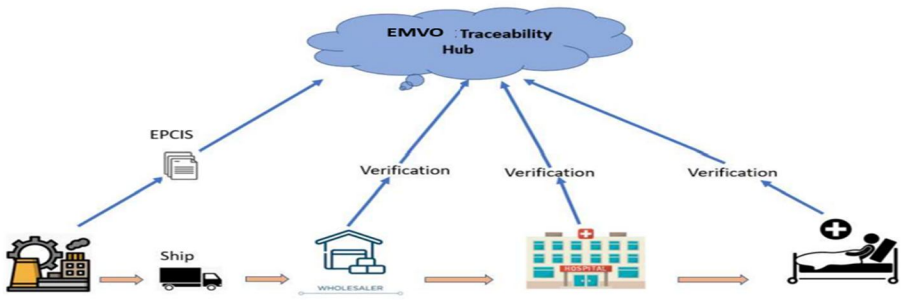

Figure 1. European serialization process flow.

V. OTHER GLOBAL SERIALIZATION EFFORT

Regulatory organizations from throughout the world are currently establishing track and trace systems and embracing serialization compliance. Following that, the 1990-founded International Council of Harmonization (ICH) promoted public health awareness by putting policies into practice. In order to monitor and track fake medications, the World Health Organization launched the Global Monitoring and Surveillance System (GSMS) in 2013 [18]. The idea of implementing serialization traceability in the supply chain is not new. In 2013, Turkey successfully adopted the Pharmaceutical Track and Trace System (PTTS). Each product unit must, by law, be represented with a distinct 2D Data matrix code [19]. There are regulations governing serialization traceability in place in some nations, including China and South Korea. In China, each pharmaceutical drug will have a specific number that the maker will receive from the appropriate regulatory body [20]. Any prescribed medication manufactured or exported in Saudi Arabia is required by the Saudi Food and Drug Administration (SFDA) to have a unique identifier in each prescribed serialized packet in accordance with GS1 standard. GTIN, USN, batch, and lot expiration. For total traceability, it must also keep track of all drug-related activities, such as commission, aggregation, and ship events. All goods manufactured or imported into Bahrain must enter a unique serial number into the NHRA-MVC Traceability Hub. Each stakeholder, including the distributor, dispenser, pharmacy, and hospital, must confirm the product's unique identify before dispensing it to the consumer [21].

VI. CHALLENGES IN PHARMACEUTICAL DRUG SERIALIZATION

To reduce the danger of product fraud, pharmaceutical serialization is a very strict and controlled regulatory process. While wealthy nations like the United States and Europe introduced serialization in 2018 and 2019, respectively, China and Turkey began the process back in 2013 [21]. In the end, the serialization procedure required that each product be printed with a 2D barcode that is a unique product identifier. Any supply chain stakeholder can easily verify the authenticity of a product by scanning a 2D barcode with a unique identification printed on the product packaging. Due to their reliance on outdated systems, many manufacturers today are having trouble implementing serialization regulations. Another challenging aspect is the continued data migration from the legacy system to the traceability system. Some manufacturers claimed to have spent around $50 million developing serialization compliance capabilities [22]. Another major obstacle to the implementation of pharmaceutical serialization is the requirement for manufacturers or supply chain participants to produce, record, and communicate serialized event data with clients and regulatory bodies. [23] through the end, data must be shared through a strict and secure network. Any network compromise that causes data to leak gives crooks and counterfeiters more opportunities [24]. Implementing serialization regulatory compliance is an expensive procedure because it requires spending money on packaging hardware, packaging software, printers, RF scanners, and extra labor. Due to low profit, competition, inexperienced labor, and limited infrastructure, many pharmaceutical manufacturing enterprises in developing nations lack the funds to embrace serialization compliance [25]. Additionally, the company needs to purchase extra packaging space for the installation of specialist packaging equipment, a label grading system, and a palletization system. Small pharmaceutical companies typically lack the financial resources to set up huge production facilities [26]. They are more concerned with the production and distribution of branded or generic medications for a particular target market or for the treatment of a certain ailment. Due to inadequate infrastructure, a lack of funding for research and infrastructure improvements, small firms do confront some significant supply chain issues [27]. Existing pharmaceutical facilities struggle to reach international standards because they must make significant expenditures in new production and packaging equipment. The traceability requirements for digital pharmaceutical items necessitate additional room in the manufacturing units for specialist packaging equipment, label grading systems, barcode printers, and vision systems that print the unique identifier on every level of packaging. Manufacturers must make a significant financial commitment in this configuration, which may exceed their financial capacity. A small pharmaceutical manufacturer's financial situation becomes entirely out of balance after investing in serialization equipment, label software, and a digital traceability system.

VII. FUTURE SCOPE OF PHARMACEUTICAL DRUG SERIALIZATION

Only drugs that have been prescribed by a doctor are covered by the serialization regulation. It has frequently been observed that serialization laws lack impact in the absence of strict legislation and rules. It allows counterfeiters and criminals a chance to supply illegal goods into the supply chain. By confirming the validity of the pharmaceuticals, digital drug traceability plays a significant role in reducing the risk of counterfeit drugs. To combat the supply of bogus medications in the legal market, pharmaceutical supply chain stakeholders might implement a safe and trustworthy blockchain technology [28].

Pharmaceutical serialization is a difficult regulatory process since it must guarantee drug security and supply chain traceability [29].

Wholesalers, distributors, and dispensers are required by this law provide electronically unit level aggregate data in an interoperable way [30]. The DSCSA is now analyzing how block-chain technology might improve the security and traceability of the medication supply chain. In this pilot initiative, the DSCSA hoped to provide the pharmaceutical sector permission to give real-time, authentic information to patients. The patients can check the information by scanning the barcode from the drug packaging using web- and mobile-based applications. Patients will be able to access real-time drug information and verify the legitimacy of the products thanks to this approach. Additionally, it will guarantee the supply chain's security, safety, and openness of product information [31]. Additionally, this technical development will enable all supply chain participants to gather helpful traceability data for strict solution building for electronic serialized data transmission in an interoperable manner.

VIII. CONCLUSION

The healthcare sector is crucial to maintaining human existence. By offering safe and genuine medications, it offers patients life-saving care and therapy. The purpose of the healthcare sector and its professionals is to guarantee that every patient receives the proper care. Clinical studies, investigational reports, marketing plans, defining GMP processes, and developing SOPs are just a few of the stages that the drug invention life cycle goes through before receiving regulatory authority ultimate clearance. Every patient is guaranteed to receive genuine and secure medications thanks to pharmaceutical drug serialization. Since serialization regulatory compliance has been established in the US, Europe, and other parts of the world, medicine authenticity has significantly improved. Adverse incidents have dramatically decreased in number. Regrettably, the serialization of pharmaceutical drugs is a time-consuming and expensive operation. Due to their perhaps limited financial resources, small pharma makers face considerable obstacles in implementing new compliance measures. Other problems including underdeveloped infrastructure, unreliable technology, geopolitics, corruption, a lack of political will, and social and economic inequality in society make it difficult for the pharmaceutical industry to enforce regulations. Most government agencies and regulatory bodies have recently increased their vigilance against the use of illegal and counterfeit pharmaceuticals. They are fighting counterfeiting with a number of measures and strict rules. The block-chain based traceable technology used in the drug serialization process will make it nearly hard for counterfeiters and criminals to distribute illegal drugs into the supply chain.

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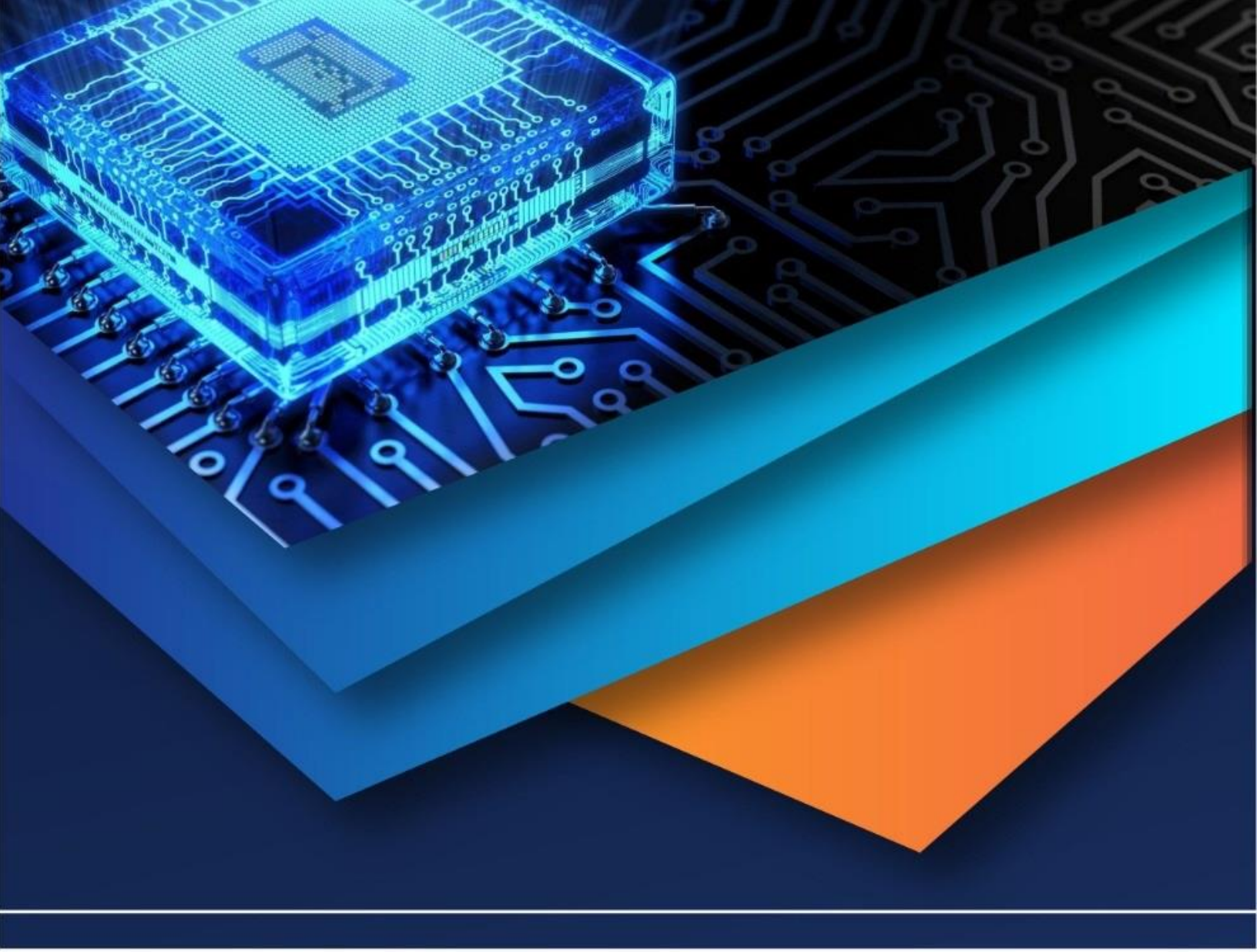

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