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Pharmaceutical medicine traceability: An overview of global compliance

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Abstract

Every human being has a fundamental right to access to healthcare. It is the duty of the government to provide its citizens with high-quality infrastructure and healthcare services. Government agencies and the healthcare sector have been working to reduce the negative effects that bogus drugs have on people's health for the past few decades. According to the World Health Organization, 4 out of 10 medicines in emerging and underdeveloped nations are either fraudulent or may be contaminated. The international economy suffers from counterfeit drug costs in the billions of dollars, and organizations are forced to spend less on research and development (R&D). The biggest difficulty facing the government and regulatory agencies is preventing the entry of fake medications into the supply chain. The government and regulatory bodies are currently creating strict regulations to forbid criminals and medicine counterfeiters from selling phony drugs in markets. To offer patients with safe and effective medications, the healthcare business needs strict laws and secure systems. The FDA has released a 10-year implementation roadmap for drug traceability in the US. The Healthcare Distribution Alliance (HDA) has additionally specified that the product packaging hierarchy print multiple barcodes and human readable data. The FDA is taking part in a pilot initiative with major prescription medicine producers and wholesalers to deploy blockchain technology in an open-source, interoperable digital network for ensuring the transfer of digital traceability data between licensed business partners.

Keywords: Drug Traceability; Drug Counterfeit; Pharmaceutical Serialization; Regulatory Compliance; Supply chain; Blockchain; Developing Countries

1. Introduction

Pharmaceutical medication serialization is a key idea in the digital tracking and tracing of pharmaceuticals in the supply chain. The what, why, When, and where principle underpins digital drug serialization, which makes sure that any operations involving drugs are digitally recorded for future audit and supply chain traceability. The supply chain for tracking down original drugs is rather complicated. The ownership of the drug's brand between the maker and the buyer is continuously changing during this process. All stakeholders, including patient lives, are at risk since the supply chain lacks strict standards and secure technologies. Any mistake or unfavorable occurrence in the production process, supply chain, material sourcing, optimal storage, or temperature might impact the efficacy of pharmaceuticals, which can harm people's health.

The majority of nations already follow legislation regarding pharmaceutical serialization and processing drug production. Numerous manufacturers are having trouble implementing serialization because their bar-incompatible codes make them non-compliant. Noncompliance and incompatible barcodes have the ability to reduce manufacturing line productivity, necessitate significant human and financial resources for new data management systems, and increase the risk of uncontrolled tracking of returned serialized medications due to inventory issues. medication packaging underwent significant changes as a result of the implementation of the digital medication serialization legislation, including label redesign, alignments, and incorporation of serialization product data, product graphic elements, and

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pharmaceutical barcodes in accordance with HDA recommendations. Correct barcodes must be used in drug packaging by the pharmaceutical sector to prevent supply chain confusion that could lead to the consideration of potential suspect drugs and postpone further market distribution. In order to reduce the danger of illicit and counterfeit pharmaceuticals entering the supply chain, it is urgent for the market to implement serialization regulations. However, doing so will need a sizeable capital commitment to pay for the start-up costs associated with packaging serialized drugs. Manufacturers must invest in digital devices, infrastructure, and equipment such as new packaging lines, barcode printers, optical vision devices, grading and validating systems for barcode labels, and global traceability systems. Incorporating blockchain can also be utilized to create dependable end-to-end digital tracking systems for the supply chain. Assigning GS1 standard barcodes to all tiers of packing units can be quite handy [1].

2. Product Identifier and Barcode requirements

The majority of nations already follow legislation regarding pharmaceutical serialization and processing drug production. Numerous manufacturers are having trouble implementing serialization because their bar-incompatible codes make them non-compliant [2]. Noncompliance and incompatible barcodes have the ability to reduce manufacturing line productivity, necessitate significant human and financial resources for new data management systems, and increase the risk of uncontrolled tracking of returned serialized medications due to inventory issues. medication packaging underwent significant changes as a result of the implementation of the digital medication serialization legislation, including label redesign, alignments, and incorporation of serialization product data, product graphic elements, and pharmaceutical barcodes in accordance with HDA recommendations. The pharmaceutical business must use the proper barcodes on drug packaging to prevent supply chain confusion that could lead to the consideration of potential suspect drugs and further delay. Manufacturers must invest in digital devices, infrastructure, and equipment such as new packaging lines, barcode printers, optical vision devices, grading and validating systems for barcode labels, and global traceability systems [3]. Incorporating blockchain can also be utilized to create dependable end-to-end digital tracking systems for the supply chain. By placing GS1 standard barcodes on all tiers of packaging, it can serve as the product's digital identity, which is very valuable. As part of the GMP procedure, the industry must also educate and train its personnel to validate label data on packages. Any typographical error or missed detail could undermine consumer confidence and put drugs at risk of agency recall.

Figure 1 Temper Evident sealing for drugs security

It is imperative that a barcode have correct encoded information that can be scanned, read, and decoded anywhere. The manufacturer must make sure the appropriate barcode is printed on the product packaging to comply with regulations. The Healthcare Distribution Alliance (HDA) advises encoding all fixed length data items before moving on to variable length ones. Additionally, it should be noted that some data scanning devices have a practical length limit, which can be avoided by encoding GTIN/NDC + unique serial number first. Additionally, the label needs to include the storage temperature, medicine potency, strength, three-part NDC code, manufacturer and distributor information, Global Trade Item number, unique serial number (if the product is serialized), lot number, and expiration date [4]. The GS1-28 Databar Linear barcode must be attached to the logistical item in trade for serialization. For homogenous pallets, GS1-128 barcodes can contain product information such as Pallet level GTIN (DGFT regulation for India). Manufacturer may encrypt extra information, but it must be labeled "Internal Use Only" to avoid complicating and confusing the supply chain and causing an expensive delay in the distribution of medicines.

3. DSCSA Serialization regulation in United States

The first requirement was to track the pharmaceutical product down to the lot level (US DSCSA 2015), as there was no regulatory compliance provision to encode a unique product identity at the level of the medication package [5]. To confirm the product's identity, the manufacturer must identify the lot of the product. The DSCSA announced its 2023 Act enabling supply chain partners to communicate data electronically in an interoperable manner. By establishing

components for ensuring the interoperable, electronic tracing of pharmaceutical items at the package level, these increased security rules, which take effect in 2023, build on what has already been done [6]. The 2023 Act's requirements are complicated, and creating an interoperable technology framework for data transmission is required. On November 27, 2023, the DSCSA 2023 Act will go into effect, as stated in 582(g) of the Federal Food, Drug, and Cosmetic Act (FD&C). The DSCSA 2023 Act's key features have been detailed by Healthcare Distribution Alliance (HDA).

The Drug Supply Chain Security Act (DSCSA) 2023 Act lays out the criteria for creating an interoperable system that enables supply chain partners to track a product's unique identification at the unit level [7]. Stakeholders will be able to collect and use traceability data in this way to design solutions for electronic interoperable verification and tracing that are effective and efficient. Network interoperability, coordination, and supply chain partner participation were all necessary for an interoperable solution. The importance of data governance for the effective implementation of DSCSA 2023 interoperability has been widely acknowledged by the supply chain participants, including FDA [8].

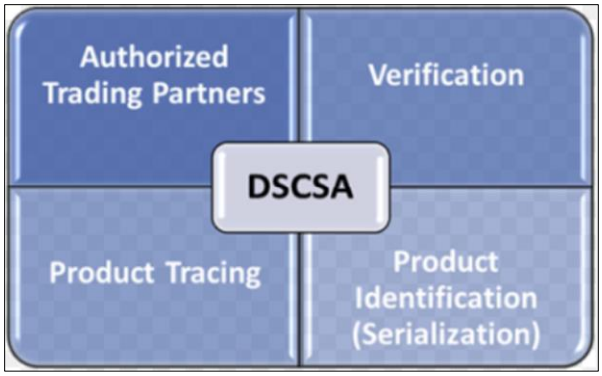

Figure 2 DSCSA 2023 Act: Unit level Traceability

The primary feature of the FDA's Enhanced Drug Distribution Security (EDDS) programme is digital data interchange. According to FDA regulations, trading partners and federal, state, and local authorities are required to monitor the quality of prescription pharmaceuticals and safeguard the supply chain's integrity. The purpose of the DSCSA regulations is to enhance the monitoring of supply chain partners that are engaged in the production, repackaging, wholesale distribution, warehousing, or logistical operations of prescription medications [10]. The establishment of the upgraded system required by section 582(g) of the FD&C Act is facilitated by the gradual implementation of the DSCSA requirements for product tracking, product identity, permitted trading partners, and verification.

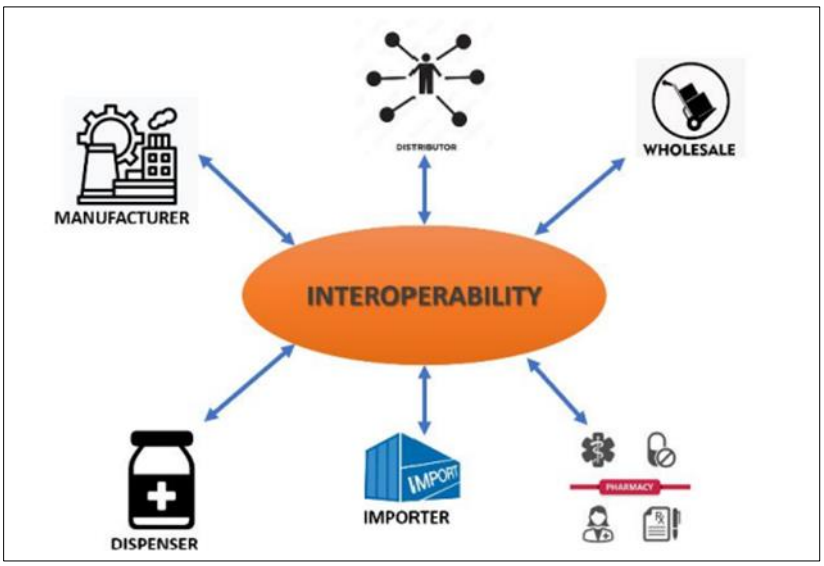

Figure 3 Interoperable Data Exchange Network

Partners in the supply chain must be able to securely and interoperably exchange Transaction Information (TI), Transaction Statements (TS), and Transaction History (TH). The National Drug Code (NDC) number, Lot number, Lot

expiration date, and other serialization information must also be included by the supply chain partner. Verify that the format of your final paper follows this model before submitting it. Make that the title and author blocks, section headings, document margins, column width, column spacing, and other aspects all look good. According to FDA regulations, trading partners should quickly identify dubious product and quarantine it until a full investigation has determined the product is fake [11]. Trading partners should generally use caution and limit their commercial dealings to authorized trading partners. Trading partners should discuss with each other. To help them decide if a drug should be regarded as a suspect product, trading partners should discuss any observations, queries, or concerns they may have regarding the status of a drug.

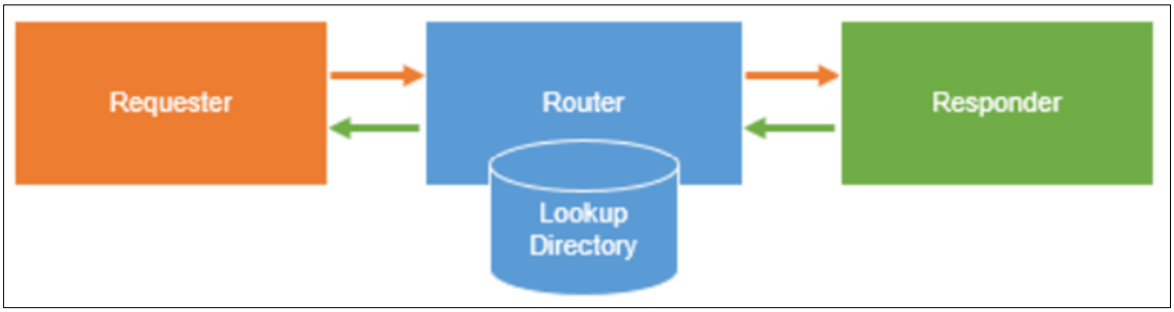

Figure 4 Verification Router Services

4. EU-FMD Serialization Regulations for Europe

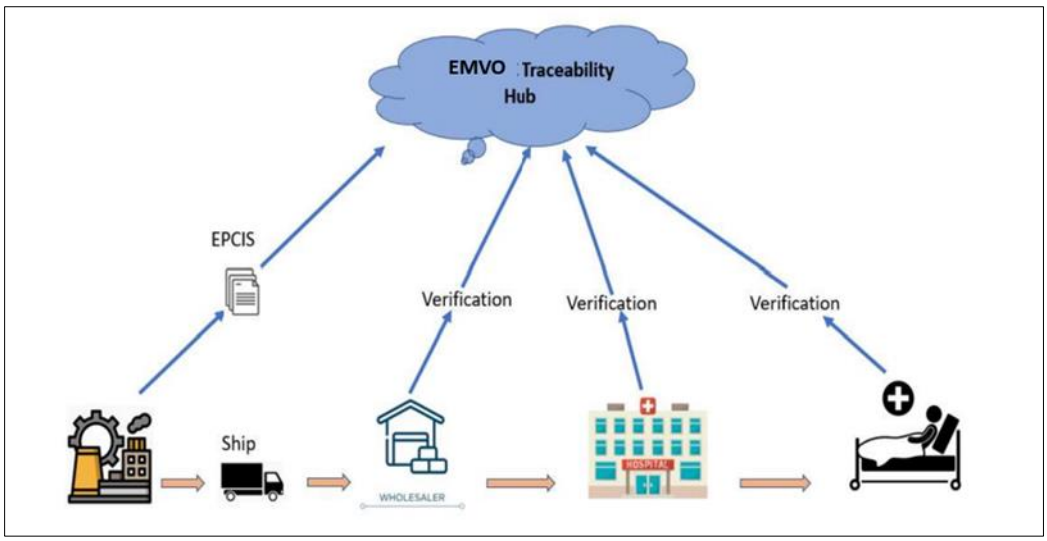

Figure 5 European serialization process flow

False drugs are imitations that pass for real, authorized prescriptions. The European Union's (EU) strict regulatory framework for the licensing, production, and distribution of medications is based on the Directive (2011/62/EU) on counterfeit medicines for human use, which ensures that only authorized pharmacies can sell medications [12]. Pharmaceuticals may only be purchased from licensed retailers, including legitimate online sales. The European Medicines Agency (EMA) and its partners are closely coordinating the implementation of this regulation. In July 2011, the EU's regulatory authorities attempted to improve patient and consumer safety by passing the Falsified Medicines Directive (2011/62/EU) on substandard drugs for human use. On July 21, 2011, the Directive came into force. Member States must start enforcing their laws in January 2013 [13]. Marketing approved holders must insert a unique identifier (a 2-dimension barcode with a tamper-evident chip) on the container of Shipped Products in accordance with Commission Delegated Regulation (EU) 2016/161 [14]. The annexes to the rule contain a list of the pharmaceuticals that fall under this criteria. The data is a part of the new end-to-end system for verifying medicines introduced by the Regulation and will be uploaded by the businesses discovered in the primary EU archive for each medicine's unique identity. Depending on the drug's source, retailers must scan pharmaceuticals at various points throughout the supply chain to verify their legality. Before a drug is given to a patient, it must be checked out of the repository at pharmacies and medical facilities and authenticated as the final stage in the supply chain. The firms identified in the primary EU

archive for each medicine's unique identity will submit the data as part of the new end-to-end system for certifying medicines created by the Regulation. Retailers must scan medications at various stages along the supply chain to confirm their legality, depending on the drug's source. As the last step in the supply chain, a drug must be checked out of the repository at pharmacies and medical facilities and validated before it is administered to a patient.

The Directive mandates that EU member states establish sanctions for drug fraud and incorrect use of active substances and excipients that are efficient, reasonable, and preventative. In a report delivered to the European Parliament and Council in January 2018, the Commission offered a summary of the sanctions in place in each EU member state as well as a qualitative assessment of their effectiveness. External research assisted the Commission in its assessment. Since February 2019, manufacturers must mark prescription pharmaceuticals with the additional safety components in accordance with EU Directive 2011/62, with very few exceptions. We have described the European serialization and pharmaceutical verification procedures in Fig. 5. The European Medicine Verification Organization (EMVO) is in charge of the central EU HUB. Every manufacturer is required to submit unique identity data to the hub, which is then transmitted to national networks, where it acts as a hub for transaction storage. As a result, each member state of the European Union has a National Medicine Verification System (NMVS) that is connected to the Centralized European Hub (EU-Hub). Last but not least, the EMVO platform enables pharmacies and other health-related entities to validate the legitimacy of a pharmaceutical product. In conclusion, if we compare US and European regulation, then the US needs to adopt EU-FMD centralized database to verify drug authenticity in the supply chain [15].

5. Serialization Regulation for Russia

Despite having an earlier date of January 2020, the serialization laws of Russia as down in Federal Law No. 425-FZ were effective in July 2020. All prescription and over-the-counter (OTC) medications allowed for sale in Russia are covered by them [16]. The OTC drug serialization standards are more stringent than those of the FMD and DSCSA. The new rules mandate that, in addition to the GTIN, serial number, batch number, and expiration date that are already required by the FMD or the DSCSA, a crypto code be included on all 2D barcodes. The Russian track and trace digital system, also known as Chestny ZNAK, is controlled by the Center for Research in Perspective Technologies (CRPT), which cannot provide such cryptographic keys. Because they are hard to copy or manufacture, crypto codes are believed to improve security [17].

6. Challenges in Pharmaceutical Drug Serialization.

Another significant obstacle to digitally identifying and tracing pharmaceutical supplies in poorer nations is the evolution of technology [18]. Some wealthy nations, like the US and Europe, have recently enacted serialization regulations that mandate that each individual medicine unit bear a unique identity printed with a 2D barcode. This distinctive identity is a crucial tool for validating drugs and identifying their manufacturing chains. Special packaging machinery, tamper-proof seals, and global traceability software were necessary for printing the unique identifier and storing its vital data in the repository [19]. Massive investments and developed infrastructure were needed for the whole serialization of pharmaceuticals for digital traceability setup. Because there is no technical system integration for digitally verifying the authenticity of medications, counterfeit makers or criminals can readily reproduce the product's unique identity and supply it to marketplaces [20]. These counterfeiters and criminals are mainly affecting the most vulnerable population in the world by exploiting their social and economic conditions [21]. Pilot programs with the participation of all stakeholders are typically not a priority in developing nations [22]. The majority of policies in developing nations are implemented carelessly. Before enforcing compliance, the government and regulatory agencies must consider the influence on the capacities of the present market, evaluation and due diligence, the availability of fundamental infrastructure and technologies, and the complexity of established processes [23]. The public's health is seriously threatened by drug fraud. To stop drug trafficking and counterfeiting, all supply chain participants must work together. It took skilled resources to implement and maintain the serialization system for drug tracking [24]. Packaging lines, Barcode readers, scanners, label grading systems, site-level serialization systems, and systems that can handle drug traceability on a worldwide scale are all used in the serialization and drug traceability processes [25]. Any human, mechanical, or technological error has the potential to negatively impact human life [26]. Developing nations can use some best practices to reduce drug fraud until they have in place a reliable system for tracking down drugs [27]. To inform individuals on where to buy drugs, they can advertise awareness campaigns, audio-visual commercials, seminars, and door-to-door campaigns [28]. The government may also set up a government-funded pharmacy and conduct regression analysis on private drug suppliers [29]. Healthcare professionals and patients alike should be cautious about the source of medications in a decent healthcare system. They should assess the response, inform others about how to check the legitimacy of the drug they have purchased, and report any questionable substances. The adoption of effective medicine tracking technologies must be promoted by the government and pharmaceutical

companies, and consumers must be made aware of such tactics. Regressive monitoring strategies must be carried out by regulatory bodies [30].

7. Future Roadmap for Pharmaceutical drugs Traceability

New secure, transparent, and decentralized medication tracing technology must be created to address the problem of fake medicines [31]. Various approaches and techniques, such as those based on mobile technology, serial numbers and QR codes, RFID tags, potent computational techniques (machine learning), and serialization solutions that validate medications at the point of sale, have been proposed and put into use up to this point. Blockchain has developed into a cutting-edge technology that provides a transparent and irreversible system without the requirement for a third party with permission [32]. It is a collection of immutable, timestamped blocks linked together by cryptographic hashes. A special code or a reference to the data that was added to a prior block is contained in each new block that has been put at the end of the chain. The main uses of blockchain technology are to increase product safety and guarantee precise pharmaceutical product traceability [33]. Supply chain and logistics solutions using blockchain technology have lately become very popular because they offer an unchangeable and transparent mechanism to record transactions between parties who are not trustworthy [34, 35, 36, 37]. Blockchain enables us to become more dependable, responsible, and transparent while also supporting in the establishment of a distributed shared data platform [38]. It also helps us to fully understand the scope of the fake drug problem. For many applications in the pharmaceutical supply chain, blockchain technology provides a decentralized, scalable alternative, doing away with the requirement for reliable centralized systems [39]. We can make sure that genuine drugs are delivered to a valid stakeholder at every transfer point and that verified and authenticated transactions continue to be accessible in Medledger by using blockchain technology [40, 41]. This technology creates an impermeable decentralized drug tracing system, lowers barriers in the drug supply chain, and promotes collaboration across pharmaceutical stakeholders with varying levels of trust [42].

8. Conclusion

Drug fraud is a major problem that endangers the public's health and poses a serious risk to patient life. The World Health Organization (WHO) has made several efforts to reduce the risk of fake medicines for a number of years. According to estimates, developing or underdeveloped nations like South Asia and Africa supply the majority of fake and illegal pharmaceuticals; this percentage can reach 70%. A 10-year plan was created under the Drug Supply Chain Security Act (DSCSA) to implement serialization compliance in the United States. Manufacturers, distributors, and wholesalers are required by the DSCSA 2023 Act to transport serialized data digitally across an interoperable network. In a pilot project, the FDA is also implementing blockchain technology to verify "Authorized Trading Partners" in an open network. The DSCSA 2023 Act also requires that all supply chain partners exchange serialization data electronically for unit-level traceability. Reduce the danger of supply chain counterfeiting by implementing safe, strict, and creative technologies and encoding product attributes in barcodes. The adoption of serialization by more nations is a clear indication of its success, and soon most nations will make serialization of prescribed medications a regulatory requirement.

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