



Why Pharmaceutical Drug Traceability in the US Needs a Centralized Cloud-Based Platform

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Author's contribution

The sole author designed, analyzed, interpreted and prepared the manuscript.

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ABSTRACT

Pharmaceutical serialization is a regulatory compliance that assures a unique identifier assigned to every unit of prescribed medicine. This unique identifier is used for product tracking and authentication in the supply chain. Initially, in 2018, the Drug Supply Chain Security Act (DSCSA) implemented pharmaceutical drug serialization regulations to mitigate the risk of counterfeit medicine entering the US market. Under this regulation, the pharmaceutical drug manufacturer is required to print a 2D data matrix barcode encoded with unique identification on each drug unit. Basically, printing a unique identification code on each prescribed drug for authenticity and traceability is not sufficient to eliminate the risk of drug counterfeiting. Subsequently, criminals and drug counterfeiters can still supply illicit or stolen drugs into the supply chain through an illegal source or online trade by imitating the same information in multiple units. After this regulation's enforcement, we observed that the US market lacks a mechanism to authenticate individual drug units with a centralized, secure repository before dispensing them to patients. Since the COVID-19 pandemic, drug counterfeiters and criminals have produced large quantities of contaminated drugs, which they then distribute through their illicit networks and underground social media platforms. Furthermore, COVID-19 supply chain disruptions, non-business resilience, and the fear of

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ransomware have all contributed to a rise in the mass fabrication of counterfeit medications. Ultimately, the United States needs a centralized cloud-based database hub where all authorized trading partners should be connected for medicine authentication. In this process, the manufacturer must update the product's unique identifier in the centrally connected hub database before supplying drugs to the market. Further, the dispenser, pharmacy, or hospital should authenticate the unique identifier of the product using the same database before dispensing it to patients. Finally, this process will ensure that patients are getting authenticated medicine and will mitigate the risk of dispensing counterfeit or illegal drugs.

Keywords: Drug traceability; pharmaceutical serialization; drug counterfeit; supply chain; centralized cloud for pharmaceutical; track and trace system; Blockchain for drug traceability.

1. INTRODUCTION

Since the early 19th century, counterfeit medicines have been a major global challenge for governments, regulatory agencies, and the health industry. In essence, criminals or forgers fraudulently or intentionally produce fake drugs by copying the same labels and packaging to conceal the drug's authenticity. In general, these drugs contain no ingredients or are insufficient and pose a potential threat to the patient's health. Nearly 30 billion US dollars are spent each year on illicit drugs around the world, mostly in low- and middle-income nations [1-3]. Typically, drug serialization is a regulatory compliance designed to ensure the authenticity of the drug by encoding unique key data into barcodes printed on drug packages [4]. Once drugs are suspected in the supply chain, the presence of illegal compounds can be detected using complex analytical methods like HPLC and X-ray fluorescence [5,6]. At first, the serialization of medicines began in 2000 under the name of the "Bollini Law" by the Italian regulatory authority. Under these regulations, each package of medication should have a label containing a barcode encoded with a unique serial number. This concept has been formalized and adopted by the USA and the European Union (EU) countries. In the United States, the Food and Drug Administration (FDA) has mandated serialization compliance in 2018 under the Drug Supply Chain Security Act (DSCSA). In these regulations, each prescribed drug manufacturer must print the 2D data matrix barcoded with a unique product identifier, lot, and expiration date on the individual package of the drug. Currently, drug authenticity can only be confirmed in the United States after it has been suspected in the supply chain due to deceptive or incorrectly printed labels or after it has been discovered by enforcement authorities during an unlawful drug diversion. In this article, we will further compare

the US and European serialization regulations and assess the need for a centralized cloud-based database hub for drug authentication and traceability in the US supply chain.

2. CURRENT PHARMACEUTICAL DRUG TRACEABILITY PROCESS IN US

In 2013, the United States government passed H.R. 3204, the Drug Quality and Security Act (DQSA). Under this law, manufacturers or repackagers are required to affix or imprint a unique product identifier on each package and homogenous case of certain prescribed drugs intended to be distributed in the United States. This law comprises Title II, the Drug Supply Chain Security Act (DSCSA), which outlines a 10-year implementation plan to implement serialization compliance in the entire supply chain for the US market. Subsequently, drug manufacturers are required to exchange transaction information (TI), transaction history (TH), and transaction statement (TS) effective January 1, 2015. The US regulatory authority Drug Quality and Security Act (DQSA) mandated two data carriers, i.e., a 2D data matrix and a 1D linear barcode, for serializing drug packages and pallets. In general, 2D datamatrix barcodes are 2-dimensional square codes that can contain a variety of data as per requirements. In the United States, DSCSA mandated that every prescribed drug manufacturer encode or imprint a unique product identifier, lot number, and expiration date to make a standardized numerical identifier [SNI].

The DSCSA suggested that logistics units or pallets be affixed with SSCC labels with a 1D linear barcode printed on them. Pallets are made by keeping shipper cases in an arranged manner and then shrink-wrapping them to secure them from damage.

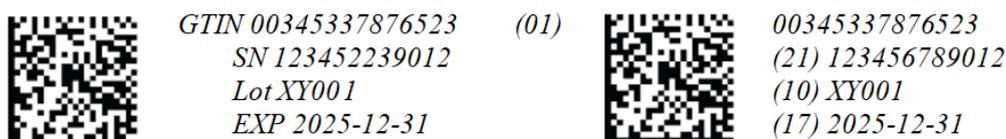


Fig. 1. GS1 2D Datamatrix Barcode required for Pharmaceutical Serialization



Fig. 2. GS1 1D Databar Liner Barcode required for Pharmaceutical Serialization



Fig. 3. 3 Segmented National Drug Code (NDC) Number

The "standard numerical identifier" basically defines a combination of numerical or alphanumeric characters to uniquely identify a product or its packaging hierarchy. The US regulatory body, Healthcare Distribution Alliance (HDA), requires that a unique product identifier be a combination of a Global Trade Item (GTIN) and a unique serial number up to 20 digits. The HDA also recommends that drug manufacturers also follow General Specification 1 (GS1) guidelines and the Health Industry Business Communication Council (HIBCC) standard format approved by the FDA. The DSCSA warns that the Global Trade Item Number (GTIN) must not be interchanged with the National Drug Code (NDC) number and should be printed in human-readable formats, i.e., "4-4-2", "5-3-2", or "5-4-1," separately on the drug packaging label [7].

The DSCSA mandated printing encoded data in 2D barcode, i.e., GTIN, serial numbers, batches, and expiry dates, alongside the barcode in

human-readable form. In some situations, when radio frequency scanners are non-functional and cannot scan the 2D barcode for medicine authentication, manual verification can be carried out by verifying data printed in human-readable form. Subsequently, GS1 also recommends that NDC numbers with a combination of serial numbers will not serve the purpose of unique identification of drugs. Finally, GTINs should be created by incorporating NDC numbers for the US market.

3. EXISTING PROBLEMS OF DRUG TRACEABILITY IN THE US SUPPLY CHAIN

The United States is a major importer of generic and prescribed drugs. In 2018, DSCSA mandated that all prescribed drugs in the US market must be serialized by the drug manufacturers. Drug counterfeiting is still a challenge and ongoing issue in the US market for

regulatory authorities, despite their strong efforts. To mitigate this issue, the FDA and DSCSA have made many efforts to stringently regulate the supply chain by implementing stricter rules and penalties [8,9]. Still, counterfeiters and criminals can supply fake or illegal drugs in the supply chain through smuggling or diversions. Finally, the authenticity of drugs can only be verified once suspected in the supply chain due to misleading or misprinted labels or caught during illegal diversion by enforcement authorities. In this study, we observed the following major issues in the pharmaceutical supply chain in the United States:

3.1 No Medicine Authentication in Supply Chain Distribution

In the United States, manufacturers need to imprint a 2D Datamatrix barcode on the label, encoded with a unique product identifier. Subsequently, manufacturers distribute products to supply chain partners, and hereafter, supply chain partners do not need to verify product authenticity throughout the entire supply chain. Ultimately, there are the highest possibilities that drug counterfeiters or criminals can divert fake drugs through an illegal route to the supply chain in the US market. Serialization compliance for stopping counterfeit drugs in the US market will be more impactful when supply chain partners verify product unique identifiers if they have not been supplied from registered or designated distributors.

3.2 No Online Medicine Verification is Required During Dispensing

Generally, in the United States, patients get prescribed drugs from pharmacies or hospitals. The fact that the dispenser or pharmacy is not required to confirm the product's authenticity during drug dispensing to patients. This could pose a potential risk for patients to medicate with counterfeit or illegitimate drugs and can raise adverse events for their health. Additionally, it is an extreme challenge for the dispenser to determine whether the batch of medications is part of a recall due to contamination in the manufacturing process, dose strength and potency issues, or label misprints.

3.3 No Electronic Data Exchange between the Supply Chain Partners or with Centerlized Database Hub

In the United States, DSCSA does not require the supply chain parties to exchange serialization

data electronically. Nor is there a central database where supply chain partners can authenticate the unique product identifiers originally used by the manufacturer during packaging. This increases the vulnerability of the entire supply chain and provides an opportunity for counterfeiters and criminals to supply fake drugs to the market through illegal sources.

4. COMPARASION BETWEEN US PHARMACEUTICAL TRACEABILITY PROCESS AND EUROPEAN MODEL

Since 2013, the Drug Quality and Security Act (DQSA) has enforced the drug counterfeit law in the US. The DQSA has mandated that all supply chain partners implement a stringent electronic system that would allow them to track and trace all products unique identifiers in the US market. The Drug Supply Chain Security Act (DSCSA), which describes methods to establish interoperable electronic product tracing at the package level to identify and trace specific prescription pharmaceuticals as they are delivered in the U.S., is being put into effect by the FDA [10]. Additionally, the FDA conducts an electronic review of each imported shipment of a product subject to FDA regulation. The FDA has requirements that every imported medicine must adhere to in terms of quality, safety, and efficacy. The FDA also verifies drugs, registration, listing, drug applications, drug labeling, and other related regulations under Current Good Manufacturing Practices (cGMPs). Similarly, since 2018, there has been legislation on counterfeit drugs where US regulatory authority, the Drug Quality and Security Act (DQSA), has mandated that every drug manufacturer encode two data carriers, i.e., a 2D data matrix and a 1D linear barcode, for serializing drug packages and pallets. The US regulation does not require wholesalers or dispensers to authenticate medicine units before dispensing them to patients or hospitals.

The European Medicines Agency (EMA) and the European Commission are part of a vast network that unites some 50 regulatory agencies from 31 nations. The European system of drug regulation continuously assesses the safety of all medications that are sold on the EU market. All medications, excluding those on the whitelist, must be authenticated and identified in accordance with EU Directive 2011/62. A mandatory logo was added by implementing Regulation 699/2014, which regulates websites that distribute medications online [11-13].

Table 1. Serialization and drug traceability comparisons between the US and Europe

Drug traceability functions	United States	European Union
Print the 2D data matrix with the unique product identifier on the packing labels.	The DSCSA has mandated printing GTIN, Lot No., Expiry Date, and Serial Numbers in 2D Datamatrix barcodes on product packages.	European Union EU Directive 2016/161 requires the printing of GTIN, Lot No., Expiry Date, and Serial Number. Some countries in Europe, e.g., Portugal, additionally require the imprinting of an NHRN number.
Uploading product unique identifiers into a centralized cloud-based database for drug verification in the supply chain	Drug traceability regulations in the United States do not have a centralized cloud-based database hub where supply chain participants can upload the unique serial number of the drug for verification in the supply chain.	The European Union has implemented a centralized database hub, the European Medicine Verification System (EMVS), where all drug brand owners must upload their product unique identifier (GTIN + serial number) in its database before supplying or distributing medicine in the market.
Medicine verification by all distributors and wholesalers in the supply chain	In the United States, distributors and wholesalers are not required to verify the authenticity of the drug following receipt from supply chain partners.	The European Union has mandated that all designated distributors and wholesalers need to verify products unique identifiers with EU-Hub.
Medicine verification by dispensers	Another fundamental problem in the U.S. in dealing with counterfeit drugs is that pharmacies or distributors are not required to verify the drug's authenticity at the time of drug distribution to patients.	Distributors or pharmacies are responsible for verifying the authenticity of drugs through the National Drug Verification System when dispensing drugs to patients.
Verification of salable returns	In accordance with the DSCSA, wholesalers and distributors are required to verify the unique identification of the returned product with the brand owner prior to reselling the returned drug on the market.	The designated distributors and wholesalers are responsible for verifying the authenticity of drugs throughout the supply chain with the National Drug Verification System.
Serial number prediction for counterfeiting.	The DSCSA does not recommend using any particular process to make the prediction of serial numbers difficult for counterfeiters. The manufacturers can use sequential serial numbers, which are easy to predict.	The EU's Falsified Medicinal Products Directive (FMD) requires the manufacturer to use 1/10,000 randomized serial numbers. This randomized requirement makes it harder for counterfeiters to predict serial numbers.

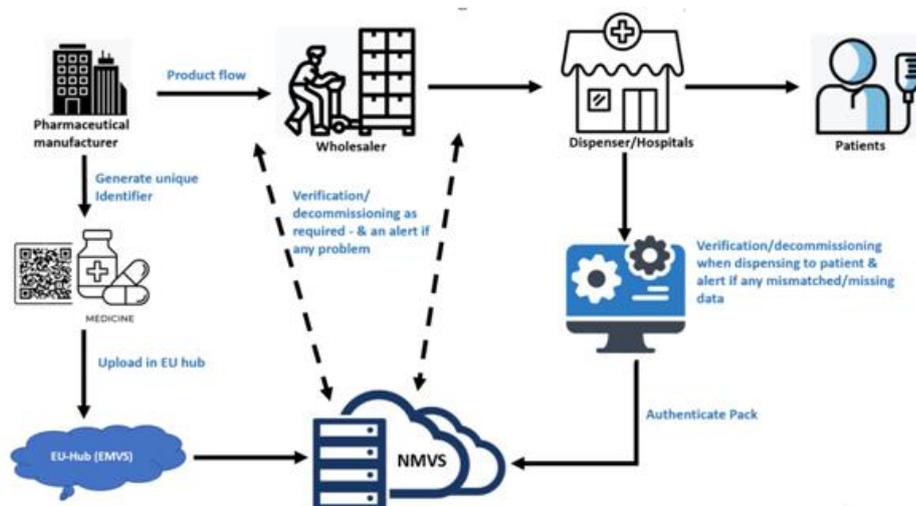


Fig. 4. European Medicine Verification process in the supply chain

With very few exceptions, since February 2019, it has now been required that manufacturers mark prescription medications with the additional safety components based on EU Directive 2011/62. In Fig. 4, we have explained the European serialization and medicine verification processes. The EU has a centralized EU HUB that is regulated by EMVO (European Medicine Verification Organization). It serves as a hub for transaction storage, where every manufacturer must upload unique identifier information to the hub, which is then distributed to national networks. Subsequently, every country in the European Union has its own National Medicine Verification System (NMVS), which is integrated with the Centralized European Hub (EU-Hub). Finally, pharmacies and other health-related organizations can confirm the legitimacy of a pharmaceutical product using the EMVO platform [14-16].

Despite the fact that both the US and the EU have laws against drug fraud, the processes used for drug tracing are significantly different. In Table 1, we have compared the serialization and drug traceability requirements between the US and Europe.

5. DSCSA EFFORTS TO IMPROVE DRUG TRACEABILITY IN THE US SUPPLY CHAIN

In the United States, most people have the potential to expose counterfeit or stolen drugs. In general, the majority of this population, which is Hispanic, low-educated, in poverty status, non-

citizens, and without medical insurance, pays high out-of-pocket insurance costs and purchases counterfeit drugs through a clandestine website or social media platform. The Food and Drug Administration (FDA) has been playing a crucial role by ensuring the quality and integrity of drugs for the American people. The Drug Supply Chain Security Act (DSCSA) added Section 582 to the FD&C Act, which identifies product traceability, product identifier, authorized trading partner, and verification requirements for manufacturers, wholesalers, and distributors to help track a product across the pharmaceutical distribution supply chain. [17]. Finally, DSCSA has developed a phased implementation plan over eight years, from 2015 to 2023. As part of this strategy, it has regulated compulsory compliance for the implementation of imprinting a 2D data matrix barcode on individual drug packages for electronic traceability. The DSCSA also regulates those stakeholders in the supply chain, including wholesalers, distributors, and pharmacies, who must verify the unique identifier of the suspected or potentially counterfeit product requested by the business partner, regulator, or government agent. The DSCSA announced its 2023 Act, which enables supply chain partners to communicate data electronically in an interoperable manner. The requirements of the 2023 Act are complicated and require the development of technical architectures for interoperable data exchange. The DSCSA is also improving its drug traceability processes by implementing the following regulations:

5.1 Unit Level Traceability of Medicine by Electronic Data Exchange

The DSCSA announced its 2023 Unit Level Traceability Act, enabling supply chain partners to interchange data electronically in an interoperable manner. By specifying this regulation act for establishing interoperable electronic tracing of pharmaceutical items at the package level, these increased security rules, which will take effect in 2023. The 2023 Act's requirements are complicated, and creating an interoperable technology framework is a requirement for data transmission. Following are the DSCSA 2023 Act's key features that have been detailed by the Healthcare Distribution Alliance (HDA) [18].

- Each trading partner has full ownership, control, and access to its own transaction data, which it can instantly provide upon request or assist in collecting.
- Stringent systems for product assessment, identification, and handling of questionable and illegal drugs. Data verification requests must get a response from an authorized trading partner within 24 hours of the request being issued.
- Robust procedures for the resale of returned goods as well as for the verification of product identifiers in investigations into questionable and fraudulent products.
- A system that boosts efficiency through aggregation and inference.

- Errors in transaction data are addressed and reconciled via business processes.

A conference recently held by the Healthcare Distribution Alliance featured presentations from many stakeholders and attendees on their readiness and preparation for DSCSA 2023 compliance. Fig. 5 illustrates the readiness of all stakeholders in the pharmaceutical supply chain. The survey has shown that 70% of dispensers will not be ready for the 2023 unit-level traceability regulation.

As part of the Drug Supply Chain Security Act (DSCSA) 2023, unit-level traceability and aggregation must be developed by supply chain partners. Fig. 6 explains how stakeholders will be able to gather and use traceability data to build electronic interoperable verification and tracking solutions in an effective and efficient manner. In order to achieve interoperability in networks, supply chain partners must cooperate, coordinate, and act as one. DSCSA 2023 interoperability will be successful if data governance is effectively implemented by supply chain partners, including the FDA.

Interoperability of digital data is a key characteristic of the FDA's Enhanced Drug Distribution Security (EDDS) initiative. Trading partners in the supply chain that manufacture, repackage, wholesale distribute, warehouse, or dispense prescription drugs are required to exchange product serialization data electronically in an interoperable manner as per the DSCSA requirements [19-21].



Fig. 5. Stakeholders' readiness for DSCSA 2023 compliance
(Source: Inmar Intelligence)

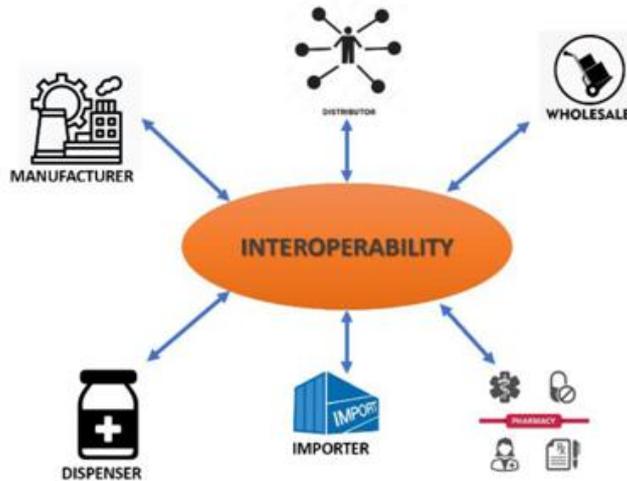


Fig. 6. Interoperable network for salable return verification in the United States

5.2 Verification Router Services (VRS) for Verifying Salable Returns

The drug supply chain security act (dscsa) pilot project program has been established by the u.s. Food and drug administration (fda) in order to carry out the provisions of section 582(j) of the fd&c act. This program is designed to help the fda and other participants in the pharmaceutical distribution supply chain create an interoperable electronic system by the year 2023. The pilot program will study the existing problems in the supply chain by using a unique product identifier for product tracing, enhancing the supply chain's technical capabilities, identifying the system characteristics required to implement the dscsa regulation, and any other problems that may be found during exploration [22]. The dscsa declared the final deadline for verification of

router service compliance to be november 27, 2023. Ultimately, from this date on, the supply chain trading partners will be required to provide transaction data along with serialized products upon a change of ownership. Fig. 7 illustrates an overview of an interoperable verification router service (vrs) that may help prevent the supply chain from becoming infiltrated by counterfeit drugs and reduce the diversion of drugs distributed domestically. Under the vrs regulation, wholesalers and distributors must provide documented evidence, like a valid distribution license, etc., to prove that they are authorized to distribute prescription drugs. The vrs provider will also ensure that the look-up directory (ld) is integrated and available for other manufacturers to verify product identifiers [23,24].

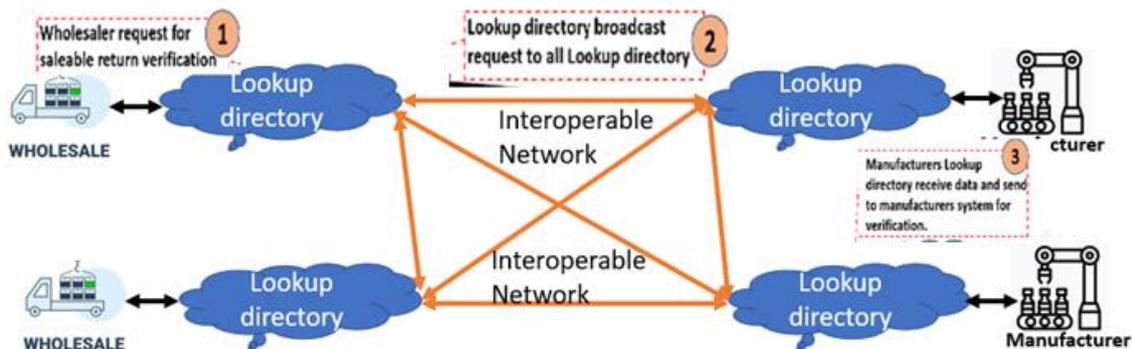


Fig. 7. Verification Router Service for salable return verification in the United States

6. BENEFITS OF ADOPTING CLOUD BASED DRUG TRACEABILITY FOR US MARKET

The supply chain reliability of transaction data, patient safety, data confidentiality, and robust systems are all incorporated into cloud-based drug traceability models. The United States should embrace the European Medicines Verification Organization's (EMVO) central cloud-based data repository for medication traceability's serialization verification process. The purposeful cloud-based verification system for the United States should be connected with all supply chain stakeholders for drug verification and authentication.

Currently, the United States does not have a centralized cloud-based database hub where supply chain stakeholders can upload the unique serial numbers of the drugs for verification in the supply chain. The cloud-based database hub will help the US minimize the risk of entering counterfeit drugs into the supply chain by mandating the requirement of submitting product unique identifiers along with batch and expiration dates. In the supply chain process, the wholesalers and distributors should be responsible for verifying the authenticity of drugs throughout the supply chain with the cloud-based database hub. In the final verification step, dispensers and pharmacies that are connected to a cloud-based database hub must authenticate the unique product identifier along with the lot number and expiration date with the database before dispensing medicines to consumers. The final medicine verification step with the cloud-based database hub by pharmacies and dispensers will mitigate the risk of counterfeit drugs in the supply chain and ensure patients are getting Guinean medicines. Under the cloud-based data hub process for medicine verification, each trading partner has full ownership, control, and access to its own transaction data, which it can instantly authenticate with the cloud-based hub upon request from supply chain stakeholders [25-27]. In this cloud-based database hub project, DSCSA can allow authorized trade partners and patients to access authentic information directly from a secure database on a real-time basis. On the other hand, patients can validate information by scanning barcodes on drug packaging using secure web- and mobile-based applications [28]. In the initial stage, a strategic plan for the Drug Supply Chain Security Act's (DSCSA) eight-year, gradual implementation between 2015 and 2023 has been developed. Subsequently, in November

2018, the United States of America achieved serialization compliance. Currently, the digital supply chain transformation is expanding the reach of conventional businesses while utilizing the advantages of cutting-edge technology. Finally, to combat concerns with medicine counterfeiting in the US, the regulatory agencies should implement stricter technology and regulatory compliance. Still, drug counterfeiting continues to be a problem for regulatory authorities in the US market, despite the DSCSA's aggressive efforts. When it comes to prescribing and dispensing activities, there is an urgent need for a common database and a uniform regulation that can keep errors in check [29].

7. CONCLUSIONS AND DISCUSSION

This study attempts to investigate briefly how it may have a greater impact in the supply chain to stop counterfeit drugs when dispensers and pharmacies validate the product's unique identification with a cloud-based database hub if they haven't received their medications from registered or designated wholesalers or distributors. The study's findings and conclusion show that the present state of serialization regulation in the US is not sufficiently stringent in the supply chain to combat drug counterfeiting. Ultimately, the United States needs a centralized cloud-based database hub where all authorized trading partners should be connected for medicine authentication. In this process, the manufacturer must update the product's unique identifier in the centrally connected hub database before supplying drugs to the market. Subsequently, the dispenser, pharmacy, or hospital should authenticate the unique identifier of the product using the same database before dispensing it to patients. Currently, the pharmaceutical industry has constantly demanded innovative solutions to manage drug counterfeiting efficiently. Further in our study, we observed that blockchain-based cloud databases will be more prominent due to their larger benefit in terms of data security in a stringent network. Subsequently, more studies and pilot projects need to be carried out to assess the feasibility of adopting a blockchain-enabled cloud database for drug authentication by supply chain stakeholders.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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