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Supply Chain Security Act 2023 : Interoperable Data Exchange for Drug Traceability

Shambhu Sarkar
JHS Pharma, Yardley, Pennsylvania, USA
Corresponding authors Email : Inform.shambhu@gmail.com

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ABSTRACT

The purpose of this paper is to focus on the requirements of the 2023 DSCSA Act. recommended by HDA. Drug Supply Chain Security Act (DSCSA) has outlined the guidelines to develop and enhance drug supply chain security act by 2023. This includes product tracing requirements that went into effect in 2015 for manufacturers, re-packagers, wholesale distributors and dispensers (primarily pharmacies) [1].

As we are approaching to 2023, It will be final phase of 10 yearlong implementation of Drug Supply Chain Security Act (DSCSA) since compliance enacted in 2013. Verification router services (Saleable Return) is another compliance which was scheduled to enforce on 2020 but it is now push back to 2023 due to Covid-19 impact. Under 2023 DSCSA Act, manufacturers need to provide product tracing information in secure and interoperable manner electronically to distributors and wholesaler in supply chain. Wholesaler must transfer product tracing information to dispensers and pharmacy and verify saleable returns receive from supply chain stakeholders. Dispenser/Pharmacy should be able to receive Electronic Product Code Information Services (EPCIS) and product tracing information electronically and to be able to reconcile physical product unique identifier with electronic records. Finally, everyone in supply chain must be connected electronically through interoperable network which will allow regulatory bodies to track and trace the information's.

DSCSA 2023 Act is very impactful regulation which also requires supply chain partners to exchange traceability information's such as Transaction History (TH), Transaction Information (TI), and Transaction Statement (TS) electronically. Electronic product Code Information Services (EPCIS) version 1.2 will have all provisions of TH, TI, TS, and adaptation of EPCIS version 1.2 will fulfill the requirement for all stakeholders in supply chain.

Keywords: Drug Traceability, Pharmaceutical Serialization, Interoperable, Data Exchange, Interoperable Tracing, Technical Infrastructure, Wholesalers, Distributors, Track and Trace System, EPCIS.

I. INTRODUCTION

Digital technology and transformation have been changing the world from its traditional way of doing business. Regulatory bodies and other functional departments are taking advantages of new technologies to implement regulations so it can unitize its maximum potentials. With digital transformation in drug traceability, pharmaceutical manufacturing and distribution companies are taking all measurement to revisit everything they do, from internal systems to customer interactions both online and in person. Digital transformations in pharmaceutical industries have reshaped how companies approach customer service and supply chain operations.

New drug serialization and traceability mechanisms were evaluated at the joint initiative of drug manufacturers, wholesale distributors and community pharmacists. Pharmaceutical industry is further trying to adopt new secure technologies like block chain in interoperable digital communications [2]. The main aim of traceability of pharmaceutical regulation is to ensure patient safety by securing digital traceability in supply chain and expediting investigative and regulatory process within specified period.[3] Initial requirement was to trace the pharmaceutical product at lot level (US DSCSA 2015) as there wasn't any provision in regulatory compliance to encode unique product identifier at medicine package level. Manufacturer needs to identify the lot of product to verify the product's identity.[4] It was clearly observed that world need effective solution to detect counterfeit medicine to improve supply chain visibility and patient safety.[5] Most of young generation use internet for social media platforms, chatting and online shopping including purchasing medications. Most of social media platforms, search engines and other online sites use the algorithmic systems that track all activity and access browsing history. It uses users all data, including visited web pages, time spend on page, watched videos or clips etc. and propose list of similar products. Artificial intelligence-based algorithms application collects all content search by similar users or current users' historical data, suggest a custom-made list and influenced users mind to take decision. Criminals use some unsolicited social media platforms to mislead user to sell fake products by advertising attractive price, fast delivery, and additional gifts. These advertisements are not credible and sometime ended up as phishing or scams. Initially users are unaffected by these advertisements and when they actively search medication, platform will deliver more drug-related ads, pages, and hashtags to a user's feed, further enabling the illicit activity.[6]

Although current serialization process does not guarantee to mitigate complete risk of counterfeit drug in supply chain but it closes the basic gaps and make difficult for illicit drugs to enter in market. [7]

The paper must emphasize concepts and the underlying principles and should provide authentic contribution to knowledge. If your paper does not represent original work, it should have educational value by presenting a fresh perspective or a synthesis of existing knowledge. The purpose of this document is to provide you with some guidelines. You are, however, encouraged to consult additional resources that assist you in writing a professional technical paper.

DSCSA announced its 2023 Act for data exchange electronically in interoperable manner between supply chain partners. This enhanced security provisions will be effective in 2023 build upon what has been accomplished to date by defining elements for achieving the interoperable, electronic tracing of pharmaceutical products at the package level [8]. Requirements under 2023 Act is complex and requires developing technical architecture for data exchange interoperable manner. DSCSA 2023 Act will enforce

on November 27, 2023, are set out in §582(g) of Federal Food, Drug and Cosmetic Act (FD&C). Healthcare Distribution Alliance (HDA) has outlined following essential attributes of this DSCSA 2023 Act. [9]

- Authorized trading partners in supply chain must exchange transaction information (TI) and a transaction statement (TS) in a secure, interoperable, electronic manner § 582(g)(1)(A). A secure interoperable network will be established among authorized trading partners for data exchange electronically.
- With all products uniquely serialized, labelled as per DSCSA (§ 582(g)(1)(B)) and identified, unless excluded, authorized trading partners provide and maintain serialized product data in all DSCSA-covered transactions, resulting in "one up, one down" unit-level traceability. It means authorized trading partners in supply chain must receive serialized unit level data from preceding business partner and he must exchange same data with subsequent business partner for ownership transfer.
- Each trading partner holds, owns, and controls its own transaction data and, in response to appropriate requests, can promptly respond with that data and/or facilitate the gathering of that data.
- Robust systems for the identification, investigation, and handling of suspect and illegitimate products. Authorized trading partner must response to data verification request within 24 hours of request being made.
- Robust systems for verifying product identifiers in suspect and illegitimate product investigations and for the resale of returned products.
- A system that uses aggregation and inference to enhance efficiency.
- Business processes in place to address and reconcile transaction data errors.

Recently Healthcare distribution Alliance has conducted conference where multiple stakeholders and participants described their preparation and readiness for the DSCSA 2023 compliance.

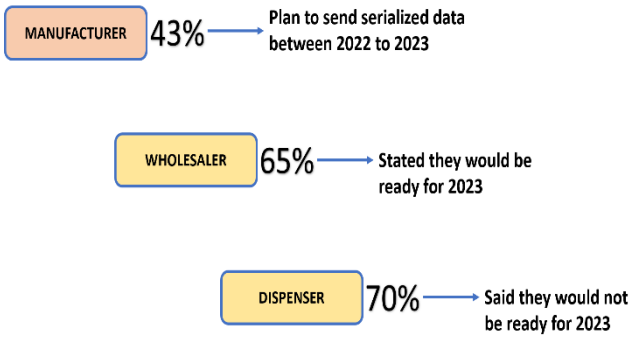

Figure 1 : DSCSA 2023 Act Readiness and Preparation by Stakeholders. (Source: Inmar Intelligence)

II. UNIT LEVEL TRACEABILITY OF UNIQUE IDENTIFIER

The Drug Supply Chain Security Act (DSCSA) 2023 Act outlines requirements to develop interoperable system which allow supply chain partner to trace unique identifier of unit level product. This will allow stakeholders to gather and use traceability data for effective and efficient solution building for electronic interoperable verification and tracing. Interoperable solution required cooperation between supply chain partners, coordination, and interoperability in networks. The Supply chain partners including FDA, have broadly recognized that data governance is critical to the successful implementation of DSCSA 2023 interoperability.

Figure 2 : DSCSA 2023 Act: Unit level Traceability

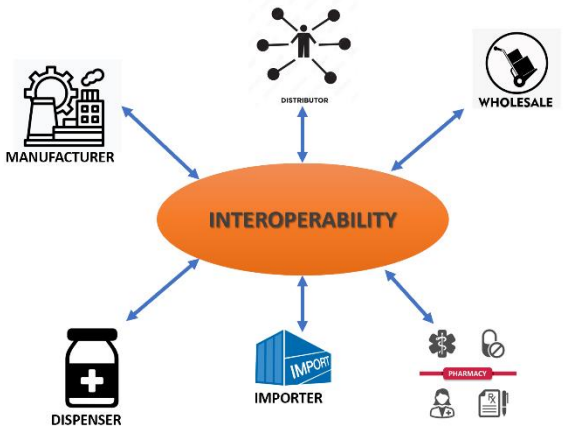

Figure 3 : DSCSA 2023 Act: Interoperable Data Exchange

III. INTEROPERABLE DATA EXCHANGE

Digital data interoperability is main attribute of FDA's Enhanced Drug Distribution Security (EDDS) project. As per FDA guidelines, Trading partners, along with Federal and State authorities must ensure the quality of prescription drugs and protecting the integrity of the pharmaceutical distribution supply chain. The DSCSA requirements are to improve the oversight of trading partners in the supply chain that are involved in the manufacturing, re-packager, wholesale distribution, warehousing, or logistical activities, or dispensing of prescription drugs. The gradual implementation of the DSCSA requirements for product tracing, product identification, authorized trading partners, and verification facilitates the development of the enhanced system as required under section 582(g) of the FD&C Act. [10]. Supply chain partners must be able to exchange Transaction Information (TI) Transaction Statement (TS) and Transaction History (TH) in secure electronically, interoperable manner. Supply chain partner must also include the product identifier (GTIN) of packaging level, Lot number, Lot expiration date, National Drug Code (NDC) number and other serialization attributes.

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IV. INTEROPERABLE DATA VERIFICATION OF SUSPECTED PRODUCT

DSCSA 2023 Act defines that all trading partners in supply chain including dispenser and pharmacy must be able to verify suspected or illegitimate product identifier based on request made by trading partner, regulatory agency, or any state agency. DSCSA 2023 compliance recommend having traceability at unit level instead of lot level so healthcare industry must adopt a robust system which should have highest levels of scalable solution. System should be able to store mass volume of serialized data and can retrieve information easily whenever requested by supply chain partners.

FDA recommendations that trading partner should expeditiously identify suspect product and keep it into quarantine until complete investigation is done concluded product is illegitimate. In general, trading partners should exercise due diligence and shall only conduct business with authorized trading partners.[11] Trading partners should discuss with each other any

observations, questions, or concerns they have related to the status of a drug as a suspect product to aid them in determining whether the drug should be considered a suspect product. [12]

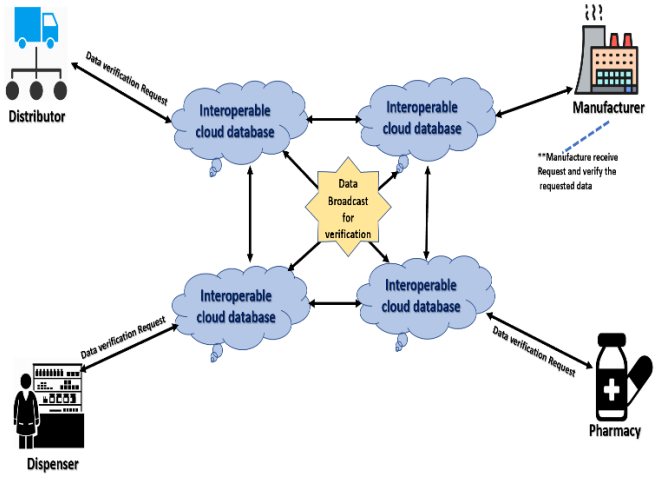

Figure 4 : DSCSA 2023 Act: Interoperable Data Verification

V. INTEROPERABLE DIGITAL DATA TRACING

FDA has defined the guidance of data tracing in section 582(a)(2), FDA recommends establishing the standard procedure of documentation which must used by all stakeholders in supply chain to transmit product tracing information digitally [13]

DSCSA requires trading partners to exchange drug product tracing information when they take ownership of drugs, resulting in a tracing record that FDA and others can use to investigate suspect and illegitimate drugs. Under this act, wholesale distributors must have systems in place that will enable them to verify the product identifier, including the standardized numerical identifier, on each sealed homogeneous case of saleable returned product, or, if such product is not in a sealed homogeneous case, on each package of saleable returned product. A saleable returned product may not be further distributed by wholesaler/distributor until the product identifier is verified. The product should be managed as suspect product and keep as quarantine stock if the product identifier is not successfully verified. [14].

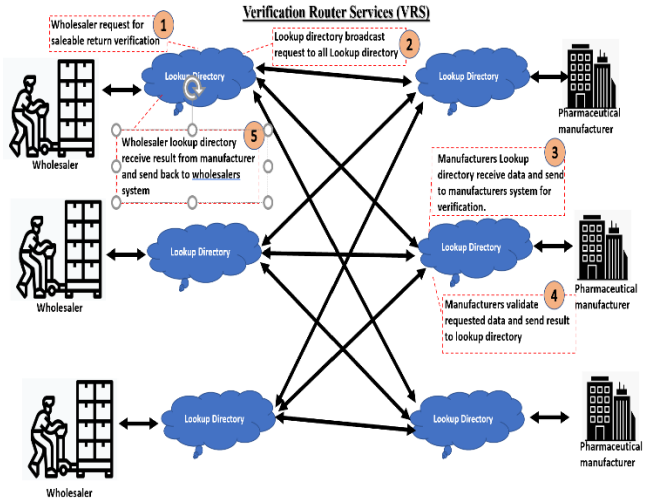

Figure 5 : DSCSA 2023 Act: Interoperable Data Tracing

VI. CONCLUSION

DSCSA has been started its journey on 2013 for drug traceability and since then it is gradually implementing its compliance for over eight years now. DSCSA 2023 Act implementation is biggest change for pharmaceutical industry. It will change every step of how we do business. On November 27, 2023, "the interoperable, electronic tracing of product at the package level requirements shall go into effect" as required by the FDA. DSCSA 2023 Act for product traceability involve much more complexity even with impeccable data and robust system. Every organization must be able to understand, access, record, update, and share it forward and backward with all stakeholders through the supply chain. In addition to standardized product identification and barcodes, all activities must be recorded in supply chain for complete traceability and product authenticity. This record of transaction data detailing the movement of products through the supply chain can be created and shared with the use of GS1's Electronic Product Code Information Services (EPCIS), as recommended in the FDA draft guidance.

HDA also recommend not to use multiple Same barcodes into package labelling Combining the SSCC and GTIN—which puts two serial numbers on the same unit of packaging on the same homogeneous case—can lead to aggregation errors. Nonconformance with Healthcare Distribution Alliance barcode guidelines can decrease supply chain efficiency, resulting in increased costs, product delays, and potential drug shortages. [15]

Stakeholders in pharmaceutical industries are urging FDA to clarify this recommendation in the final guidance since EPCIS meets DSCSA's standards requirements and many believe that without it, full DSCSA implementation will be further delayed as stakeholders wait for clarification. DSCSA has clearly stated that it does not have any intention to further delay DSCSA 2023 Act. It means all stakeholders in supply chain including dispenser must comply with regulation on or before November 27, 2023. Recently DSCSA released its guidelines to help the pharmaceutical industry to setup electronic system as per DSCSA 2023 Act. These guidelines "defines baseline business requirements that frame the general systems and processes for implementation of the main components of the DSCSA: secure, electronic, interoperable systems and processes for the exchange of serialized transaction information (TI) and transaction statements (TS), secure, electronic, interoperable systems and processes for product-identifier verification, and secure, electronic, interoperable systems and processes for tracing."
The Unit level traceability act 2023 will be a milestone for increasing transparency and visibility in supply chain and mitigate the risk of getting counterfeit or illicit drugs to consumers [16].

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