The Drug Supply Chain Security Act (DSCSA) Compliance in Supply Chain

Rahul Bhanot

INTRODUCTION

The pharmaceutical industry supply chain is a highly regulated and complicated system designed to safeguard drug quality, verify authenticity, and maintain steady availability. Amid rising concerns about contaminated and counterfeit drugs, in 2013, the United States implemented the Drug Supply Chain Security Act (DSCSA) as part of the Drug Quality and Security Act (DQSA). It was fully implemented in November 2024, and it marks a crucial milestone for the pharmaceutical industry.

The Drug Supply Chain Security Act (DSCSA) outlines steps to achieve an interoperable and electronic way to identify and trace certain prescription drugs at the package level as they move through the supply chain. This helps prevent harmful drugs from entering the U.S. drug supply chain, detects harmful drugs if they do enter the supply chain, and enables rapid response to remove harmful drugs from the supply chain to protect patients.
The article explores DSCSA in detail, highlighting its objectives, implementation timelines, challenges, and technology required for its compliance in the Pharmaceutical supply chain.

Objectives of the DSCSA

The core aim of DSCSA is to boost the FDA's effectiveness to protect consumers and ensure that the drugs provided are effective, safe, and non-contaminated. It was implemented to prevent drug counterfeiting by making a system of tracing and tracking prescribed medications. Other specific goals include:

- Improved traceability: As prescription drugs move in the supply chain from manufacturer to distributor, a national system has been put in place for their tracking and tracing.
- Strengthened verification: The system has been made so that any trading partner can check the drug's originality at any point in the supply chain with the help of the serial number.
- Reduced costs and streamlined recalls: Provides quick and accurate recalls, and efforts have been made to minimise drug recalls, which have reduced health care costs.
- Secured data sharing: DSCSA promotes confidential sharing of data among trading partners.
- Protect Patient Safety: The act aims to ensure that safe and original prescribed medications are made available to patients to protect them from counterfeit drugs.

Implementation Timeline

The DSCSA Timeline involves several important dates, with the major milestone being the stabilization period from November 2023 to November 2024. Other compliance dates are as follows:

- November 27, 2013: DSCSA was signed into law.
- January 1, 2015: Manufacturers, wholesalers, and repackagers were required to provide transaction information.
- July 1, 2015: Dispensers (primarily pharmacies) had to begin receiving transaction information from their trading partners.
- November 27, 2017: Serialization of drug packages for manufacturers with a unique product identifier (such as a barcode).
- November 27, 2018: Serialization for repackagers.
- November 27, 2019: Wholesaler and repackager requirements were introduced. They had to verify the product identifiers before distributing drugs and also keep transaction information (TI), transaction history (TH), and transaction statements (TS) for each product.
- 2020-2023: Product verification requirements and enhanced wholesaler obligations.

- November 27, 2024: End of stabilization period. By this time, all pharmaceutical supply chains should be compliant with DSCSA requirements.

Challenges in Achieving Compliance

Implementing the law came with several technical, operational, and financial challenges. Major difficulties include:

- Data Management: Maintaining and sharing serialised data at this large scale requires extensive IT infrastructure, ensuring accuracy and integrity are maintained across multiple systems.
- System Interoperability and Data Consistency: As trading partners use different IT platforms, a harmonized ecosystem should be built. It is important to share accurate, real-time information across such platforms.
- Training and Shift Management: Transition to the electronics system needs employee training on requirements and procedures. Efficient coordination and communication are needed among trading partners and resolve issues within the system.
- Implementation cost: Small distributors and independent pharmacies may face issues in adapting the technology and upgrading their systems. Hospitals need to integrate their existing system with the new DSCSA-compliant systems.
- Verification of drugs: checking the drugs for their authenticity is a time-consuming process; it might require collaboration with other partners and regulatory agencies.

Impact of DSCSA on the Pharmaceutical Supply Chain

DSCSA compliance has broad impacts. Some are listed as follows:

- Enhanced security and transparency: Serialization of drugs enhances traceability, creating a digital footprint of drugs. It makes the detection of fraud, theft, and counterfeiting easier.
- Accelerated and Accurate Recalls: Strengthened product traceability has enabled manufacturers and the people involved in the supply chain to quickly isolate the affected product and to timely recall the product. It diminishes public health risk and operational disturbance.
- Improved communication and teamwork: Manufacturers, distributors, dispensers, and technology providers are now equipped with more effective tools to coordinate and collaborate seamlessly.
- Enhanced Patient Well-being: As safe and authentic drugs reach patients, DSCSA improves public health.

Technological Requirements for DSCSA Compliance

The following technology is needed to support DSCSA compliance:

- A system for product serialization and a unique identifier is needed. Every drug will be provided a unique serial number and National Drug Code (NDC) for tracking and verification of products throughout the supply chain.
- An interoperable electronic system and verification system for data sharing.
- Software for tracking and tracing product movement.
- Access control measures are used to determine who is authorised to access and modify data.
- Secured cloud storage to store transaction data.
- Data management systems are needed to handle a large volume of data.

CONCLUSION

DSCSA plays a pivotal role in drug safety and transparency. It ensures pharmaceutical supply chain integrity and public health safety. It creates a road map to a trustworthy and transparent system so that only legitimate products reach markets. The law ensures that organisations that meet compliance requirements will see themselves as leaders in the pharmaceutical industry. A patient-centric drug supply chain is well worth the effort.

REFERENCES

[1] https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa
[2] https://www.tracelink.com/dscsa-timeline-what-you-need-know