PDSA
Pharmaceutical Distribution Security Alliance

Drug Supply Chain Security Act of 2013 (DSCSA) Requirements for Manufacturers & Repackagers

The Drug Supply Chain Security Act (DSCSA) established national uniform requirements for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers to achieve interoperable electronic tracing of certain prescription drugs at the package level in the United States. All DSCSA requirements are effective beginning November 27, 2023.

Up until November 27, 2023, shared data must include the **Transaction information (TI).** TI consists of the proprietary name of the product, the strength and dose form of the product, the National Drug Code (NDC) number of the product in the proper format, the container size, the number of containers, the lot number of the product, the date of the transaction, the data of the shipment, the business name and address of the seller, and the business name and address of the buyer.

Under the DSCSA, Manufacturers and Repackagers must comply with the following requirements:

- Affix or imprint on each package and homogenous case a product identifier (PI) that includes in a human-readable and machine-readable format the standardized numerical identifier, lot number, and expiration date of the product.
- Must use a secure, interoperable, and electronic system for the exchange of TI data in the GS1 US EPCIS standard format, supply customers with TI for each transaction, provide the TI to a federal or state official upon request, and maintain TI for each transaction for at least six years.
- Have in place systems and processes to enable verification, tracing, quarantine, and investigation of suspect and illegitimate product, and notify FDA and all immediate trading partners if a product is determined to be illegitimate.
- Must have a current Drug Establishment registration with FDA to be “authorized” under the DSCSA.

Penalties for Non-compliance (21 USC §§ 333(b(1) & (3))

- Failure to comply with DSCSA requirements may be penalized by up to 10 years in prison, a fine up to $250,000, or both.
- Failure to report according to the DSCSA requirements may be penalized by a fine of up to $100,000.

Enhanced Drug Distribution Security (EDDS) Requirements

The EDDS requirements, which build on the DSCSA’s product tracing, product identifier, authorized trading partner and verification requirements, become enforceable on November 27, 2023. These requirements include the following aspects:

EDDS Requirements base upon FDA draft guidance, Enhanced Drug Distribution Security at the Package Level Under the DSCSA, https://www.fda.gov/media/149704/download.

Enhanced Drug Distribution Security (EDDS) Requirements, Continued

- Certain System Attributes
  - A secure, interoperable, and electronic system for the exchange of TI information at the package level for each package,
  - A process for verification of product at the package level,
  - Data architecture that allows for the prompt gathering of information and response to state and federal regulators in the event of a recall or for investigation of suspect or illegitimate product,
  - A process to associate returned packages with applicable TI/TS to determine salability.
- Security Architecture
  - Systems should include appropriate data security standards, security protocols, and security applications to protect data, protect the system itself, protect confidential commercial information, and prevent falsification, malicious attacks, and breaches.
- Enhanced Product Tracing
  - The product's TI must incorporate a product identifier (PI), which includes the National Drug Code (NDC) and serial number, lot number, and expiration date. Industry has aligned and FDA has endorsed the use of the GS1 US GTIN data format standard to meet this requirement.
  - Trading partners should ensure that the TI actually reflects the product that they are purchasing or selling.
- Enhanced Verification
  - Trading partners will need to establish an automated process that, upon receiving a verification request, may provide the following:
    - Verification of the product at the package level,
    - How the request is made (i.e., reading the 2D data matrix barcode to initiate the request), and
    - How the response to the request is managed and communicated back to the requester.
- Identification and Resolution of Clerical Errors and Other Discrepancies
  - If a trading partner identifies a error or discrepancy in the TI that is not indicative of a suspect product, the trading partner should resolve the error or discrepancy in three days.

Additional Resources

- FDA Guidance Documents & Policies: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies
- PDSA Q&A on DSCSA: https://pdsaonline.org/wp-content/uploads/2022/10/PDSA-DSCSA-2023-QA-Document.pdf
- GS1 US DSCSA Implementation Guideline: https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/healthcare/guideline-toolkit/Applying-the-GS1-Lightweight-Messaging-Standard-for-DSCSA-Verification-of-Product-Identifiers.pdf
- PDG Blueprint for 2023 Interoperability: https://dscsagovernance.org/blueprint/