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INSIGHTS

United States Drug Supply Chain Security Act (DSCSA)

Requirements and Implications for the Pharmaceutical Industry

A worldwide effort to require serialization and traceability of individual pharmaceutical products packages or containers is underway.

Until late 2013, there was no federal requirement to implement unique, serialized identification and traceability of pharmaceutical products. Florida and California, among other states, enacted varying laws regarding electronic pedigree and serialized product, which raised notable concern in the pharmaceutical industry regarding conflicting requirements and inefficient and costly solutions. There was a clear preference for a uniform federal standard that would allow a longer period of time to achieve compliance.

Both the House and the Senate were debating bills to establish more stringent, uniform federal requirements for the pharmaceutical industry. Near the end of 2013, the houses agreed to combine the compounding pharmacy bill and the serialization and traceability legislation, H.R. 3204, into a single law. In the United States, the federal law known as the Drug Quality and Security Act, or DQSA, was signed by the President on November 27, 2013.

DQSA Titles

The DQSA consists of two major sections, known as “titles.” Title I is the Compounding Quality Act (CQA); it establishes requirements for compounding pharmacies.

The second section, Title II – Drug Supply Chain Security Act (DSCSA), establishes federal requirements for the serialization and traceability of pharmaceutical products. Under the United States Constitution, and asserted in the law, the DSCSA preempts all overlapping or conflicting state laws. Thus the Florida and California laws are no longer valid. In general, the DSCSA establishes comprehensive requirements that must be addressed over a ten year period (from the enactment date).

DSCSA Requirements

Lot Level Traceability

The first requirement is that all trading partners - manufacturers, repackagers, wholesalers, third party logistics providers (3PLs), and dispensers - must have a means of transmitting lot level product information (TI), together with transaction history (TH) and a transaction statement (TS), to their trading partners. TI,

TH, and TS can be transmitted by either electronic means or on paper until November 27, 2023. From that date forward, only electronic transmission will be permitted. With the exception of dispensers, this information must be provided starting January 1, 2015; dispensers must start by July 1, 2015.

Transaction information (TI) consists of:

- Product name(s), strength and dosage
- National Drug Code (NDC) number
- Container size and number of containers
- Lot number
- Transaction date
- Shipment date (if more than 24 hours after the transaction date)
- Business name and address of the shipping partner transferring ownership
- Business name and address of the receiving partner to whom ownership is being transferred

Transaction History (TH) is a comprehensive set of prior transaction information (TI) from the manufacturer to the current trading partner.

The Transaction Statement (TS) is a legal statement noting that the trading partner issuing the TS is authorized under the DSCSA, they have not knowingly transmitted false information, and they have not knowingly altered the transaction history. Each trading partner must maintain a record of TI, TH, and TS for a minimum of six (6) years starting from the transaction date.

The United States Food and Drug Administration (FDA) is required by the law to issue guidance to the pharmaceutical industry for meeting these requirements by the first anniversary of the enactment date. Practically, such guidance will be issued too late to provide effective help to the pharmaceutical industry. Numerous pharmaceutical companies and trade organizations provided feedback to the FDA, urging them to allow companies flexibility in meeting these lot level traceability requirements by the January and July 2015 deadlines. Judging from the feedback provided, many companies will modify existing ASN transmissions to provide electronic transmissions, and will modify paper packing slips or invoices for trading partners that are currently unable to accommodate electronic transmissions.

There is strong interest in using EPCIS to supplement and, in many cases, replace ASN. Version 2.0 of the EPCIS standard, which would accommodate the DSCSA requirements, will come into effect in the second half of 2014. Therefore version 2.0 will not be fully employed at many companies by the January 2015 deadline. Some companies intend to apply or initiate web portals to replace paper documentation. All the entities who submitted comments to the FDA consider paper documentation inefficient and believe it will be replaced by either electronic or web-based approaches prior to the November 2023 DSCSA deadline.

DSCSA

Serialization by Manufacturers

On and after November 27, 2017, each package and homogeneous case of pharmaceutical product manufactured or sold in the United States and its territories must be identified by a unique product identifier. A record of these product identities must be maintained by the manufacturers for no less than six (6) years.

To meet this requirement, companies can add a two dimensional (2D) barcode to the label of each product. At minimum, each package label will need to be altered to accommodate the barcode. In some cases, significant label redesign will be required to ensure both machine and human legibility. Label colors may also need to be modified to ensure sufficient contrast with the barcode, so they can be electronically scanned with “A” or “B” grade results.

Downstream Serialization Deadlines

The DSCSA establishes a rolling implementation schedule for individual packaging serialization requirements throughout the supply chain. Unit level serialization is required on November 27, though the year varies by the type of downstream trading partner.

2017	2018	2019	2020
Manufacturers	Repackagers	Wholesalers	Dispensers

Aggregation by Manufacturers

The DSCSA does not expressly require aggregation; that is, the assignment of unique bar codes to bundles, cases, and pallets to establish a set of parent/child relationships. The DSCSA uses phrases such as: "…which may include the use of aggregation and inference as necessary (pilot projects)…," "…including those involving the use of aggregation and inference…," or "…enable secure tracing of product at the package level, including allowing for the use of verification, inferences, and aggregation as necessary…," indicating that aggregation is a desirable means of ensuring product traceability. Major wholesalers and 3PLs are requiring manufacturers to provide aggregation, in addition to individual package serialization, in advance of the November 2017 deadline in order to conduct their businesses more efficiently. It is increasingly evident that aggregation, although not a de jure requirement, is effectively a de facto requirement of the DSCSA.

By comparison, the South Korean law requires serialization as of January 1, 2015; aggregation is permitted but not, at least yet, required. The laws in effect for Argentina and Turkey require aggregation and the Brazilian law, which goes into effect in December 2016, will require aggregation. The European Union's Falsified Medicines Directive (FMD), which is expected to take effect in the first half of 2018, will require serialization but not aggregation.

Suspect and Illegitimate Products

The DSCSA definitions of 'suspect product' and 'illegitimate product' are outlined below.

Suspect Product

The term 'suspect product' means a product for which there is reason to believe that such product—

(A) is potentially counterfeit, diverted, or stolen;

(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(C) is potentially the subject of a fraudulent transaction; or

(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Illegitimate Product

The term 'illegitimate product' means a product for which credible evidence shows that the product—

(A) is counterfeit, diverted, or stolen;

(B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(C) is the subject of a fraudulent transaction; or

(D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans."

The difference between the definitions is essentially a legal definition. Irrespective of whether a product is "suspect" or "illegitimate," the DSCSA places trading partners under obligation to quarantine such product and promptly investigate the TI, TH, and TS to determine whether the product is genuine or illegitimate. From November 27, 2017 onward, the investigation must include validation of the unique package serialized numerical identifier. Investigation records must be maintained for no less than six (6) years.

Trading partners are also required, under the law, to assist each other in conducting investigations and may be required, from time to time, to retain samples of suspect or illegitimate products under investigation for further analysis by federal authorities or others. Manufacturers and their TI, TH, and TS records are regarded under the law as essential to rapid and effective investigations.

With one exception, the DSCSA does not prescribe precise and detailed procedures for conducting and documenting investigations. As expressed in various articles and seminars, the industry prefers to allow pharmaceutical manufacturers and trading partners to discharge these responsibilities in accordance with their own internal quality control procedures. FDA guidance on this topic is not expected before 2016, but the FDA has not indicated any opposition to this approach.

The DSCSA requires that a product determined to be illegitimate during an investigation be reported to the FDA within 24 hours. Discussion is currently in progress as to how to interpret the 24 hour requirement. The pharmaceutical industry generally takes the position that the 24 hour period begins with investigation

completion. This interpretation would allow time to conduct an investigation, which – depending on numerous and varying circumstances – could require hours or days to perform. The FDA has not yet provided guidance in this regard, but there is currently no reason to believe that the organization would object to this interpretation.

Similarly, the DSCSA requires a trading partner to respond to a request to verify suspect or illegitimate product within 24 hours. The FDA has not yet issued guidance on this requirement. The DSCSA does not mandate, but strongly suggests that these requirements could be satisfied "…by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity."

The FDA issued draft guidelines on June 11, 2014, which are currently being reviewed by the pharmaceutical industry. While there are no major surprises in the draft guidance, one clarification emerged that "any products in the trading partners' possession or control" are subject to the DSCSA, including suspect or illegitimate products that may be identified in foreign countries.

DSCSA Major Provisions

The DSCSA's major provisions are outlined below for reference convenience:

Title II – Drug Supply Chain Security Act

- Sec. 201 – Short Title
- Sec. 202 – Pharmaceutical Distribution Supply Chain
- Subchapter H – Pharmaceutical Distribution Supply Chain
  - Sec. 581 – Definitions
  - Sec. 582 – Requirements
    - (a) In general
    - (b) Manufacturer Requirements
    - (c) Wholesale Distributor Requirements
    - (d) Dispenser Requirements
    - (e) Repackager Requirements
    - (f) Drop Shipments
- Sec. 203 – Enhanced Drug Distribution Security
  - Sec. 582, as added by section 202, is amended by adding at the end the following:
    - (g) Enhanced Drug Distribution Security
    - (h) Guidance Documents
    - (i) Public Meetings
    - (j) Pilot Projects
    - (k) Sunset
- Sec. 204 – National Standards for Prescription Drug Wholesale Distributors
  - (a) Amendments
    - (1) In General
    - (2) Wholesale Distribution
    - (3) Third-Party Logistics Providers
    - (4) Affiliate
    - (5) Standards
  - Sec. 583 – National Standards for Prescription Drug Wholesale Distributors
    - (a) In General
    - (b) Content
    - (c) Inspections
    - (d) Prohibited Persons
    - (e) Requirements
    - (f) Authorized Distributors of Record
    - (g) Effective Date
- Sec. 205 – National Standards for Third-Party Logistics Providers: Uniform National Policy
  - Sec. 584 – National Standards for Third-Party Logistics Providers
    - (a) Requirements
    - (b) Reporting
    - (c) Costs
    - (d) Regulations
    - (e) Validity
  - Sec. 585 – Uniform National Policy
    - (a) Product Tracing and Other Requirements
    - (b) Wholesale Distributor and Third-Party Logistics Provider Standards
    - (c) Exception
- Sec. 206 – Penalties
  - (a) Prohibited Act
  - (b) Misbranding
- Sec. 207 – Conforming Amendment
  - (a) General
  - (b) Effective Date
- Sec. 208 – Savings Clause

FDA Guidance

According to the introductory section of the June 2014 suspect and illegitimate products guidance,

"FDA's guidance documents, in general, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited."

The DCSA establishes the following deadlines by which the FDA is required to issue guidance:

- Suspect and illegitimate product: August 15, 2014
- Standards established under the DSCSA: November 27, 2014
- Process to acquire a waiver from requirements: November 27, 2015
- Exemption for non-serialized product in the supply chain at effective date: November 27, 2015
- Establish standards for licensing of wholesalers and third party logistics providers: November 27, 2015

Responsible, consensus actions in response to the DSCSA will likely be acceptable to the FDA.

About the Author

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