Discussion Topics for FDA's DSCSA Public Meeting
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act
Meeting # 2 – December 5-6, 2017

As part of its efforts to help ensure that safe and effective prescription drugs are available to U.S. patients, FDA is working to further secure the pharmaceutical distribution supply chain through implementation of the Drug Supply Chain Security Act (DSCSA). The DSCSA outlines critical steps to build an electronic, interoperable system by 2023 that can trace certain human, finished, prescription drug products as they are distributed within the U.S. The new system will enhance FDA's ability to protect consumers from exposure to drugs that may be counterfeit, diverted, stolen, intentionally adulterated, the subject of a fraudulent transaction, or otherwise harmful. FDA and supply chain stakeholders play important roles in addressing the challenges of improving the security of the pharmaceutical distribution supply chain.

This public meeting is the second in a series of meetings at which FDA and supply chain stakeholders will have the opportunity to discuss issues related to the enhanced prescription drug distribution security provisions of the DSCSA and collaborate on implementation strategies. The discussion topics for this meeting include electronic interoperability, standards for data exchange, data architecture, and aggregation and inference. FDA will continue discussions on these and other relevant topics as future public meetings.

For the purposes only of this public meeting, FDA is providing the following information to help facilitate discussion.

Enhanced Drug Distribution Goals

The DSCSA establishes requirements for the interoperable, electronic tracing of products at the package level that go into effect in November 2023. The 2023 system is expected to provide:

- Electronic exchange of information by trading partners at the package level
- Verification of product identifiers at the package level
- Prompt response to suspect and illegitimate products at the time they are found
- Improved efficiency of recalls
- Transparency and accountability in the pharmaceutical distribution supply chain

Topics for discussion at the public meeting

The following topics will be discussed at the meeting: (1) electronic interoperability, (2) standards for data exchange, (3) data architecture, and (4) aggregation and inference. FDA recommends that stakeholders who are coming to the meeting be prepared to discuss their views, expertise, and experiences with respect to these topics, how the topics relate to their vision for the 2023 system, and what specific requirements, guidance, or other information they need from FDA on each topic. Additional information about each topic is provided below to help prepare participants for the discussions at the public meeting. The information may also be helpful to stakeholders intending to submit comments on these topics to the public docket.

Electronic Interoperability

The DSCSA outlines requirements for enhanced drug distribution security by November 2023 through electronic, interoperable product tracing requirements at the package level. FDA has used *"interoperability"* as a guiding principle for DSCSA implementation and will continue to in its efforts to determine the needs for enhanced drug distribution. For the discussion purposes, FDA has previously proposed the following description for the concept of "interoperability":

> *Interoperability is the ability to exchange information accurately, efficiently, and consistently among trading partners.*

After considering comments received following the August 23, 2017 public meeting, FDA has revised its description for the concept of "interoperability" to:

> *Interoperability is the ability of systems to exchange information accurately, efficiently, and consistently in a usable format.*

There is an assumption that interoperability will be accomplished through electronic means, resulting in "electronic interoperability." The revised description is intended to be broader than the initial description and should allow for flexibility in determining the system and processes needed for enhanced drug distribution. The revised description also incorporates the need for accuracy, efficiency, and consistency, which are essential for any system involving data and the exchange of data. We hope this public meeting, particularly the sessions on standards for data exchange and data architecture, will provide a forum for stakeholders to discuss what FDA and trading partners will need to do and/or develop to achieve *electronic interoperability*.

Standards for Data Exchange

DSCSA currently requires the exchange of data related to product tracing of certain prescription drugs as they are distributed in the U.S. Current product tracing requirements include lot-level information in the transaction information and transaction history. To enable package-level product tracing information that will be required by November 2023, we will discuss with stakeholders the standards needed to accomplish the change from lot-level to package-level product tracing information, including whether the initial standards used for lot-level tracing are applicable to package-level product tracing. If they are not applicable, are there other currently available or emerging standards that could support the secure, interoperable electronic data exchange among the pharmaceutical distribution supply chain and if they comply with a form and format developed by a widely recognized international standards development organization. We will also discuss whether any of the currently available standards could facilitate the creation of a uniform process or methodology for product tracing that ensures the protection of confidential commercial information and trade secrets.

Data Architecture

FDA recognizes the importance of "data architecture" for the 2023 system. FDA's working definition for the concept of "data architecture" is:

> *Data architecture is a set of rules, policies, standards and models that govern and define the type of data collected and how it is used, stored, managed and integrated within and between organizations and respective systems.*

The session about data architecture will include a discussion on how trading partners should provide product tracing information to other trading partners, FDA, and other appropriate Federal

and State officials, and how that information should be maintained and accessed. The data architecture should enable interoperability and ensure:

- The ability to exchange and use data for product tracing and verification
- The ability to maintain the data
- The ability to request and promptly obtain data to fulfill the request
- Appropriate access to the data
- Privacy, security, and integrity of the data and the system

We have heard at previous public meetings and through comments that many stakeholders prefer a distributed data architecture model, so we will be focusing on this model at the meeting. Stakeholders should plan to discuss issues related to the use of a distributed data architecture model for an electronic, interoperable system, including, but not limited to, privacy and security, how communication of data will occur, and how product tracing data will be managed and maintained, and the different data architecture needs for product tracing and verification. We will discuss the issues are surrounding who is responsible for the data and what role(s), if any, third parties might play in managing and maintaining product tracing data managing and maintaining. Stakeholders should also plan to discuss the use of master product data and how it would be managed under a distributed data architecture model. Stakeholders should plan to discuss what standards can be used for data exchange under a distributed data architecture model.

Aggregation and Inference

At previous public meetings and in comments submitted to public dockets for DSCSA-related matters, different sectors of the supply chain have provided differing views on the activities related to aggregation and inference. We recognize that each sector may have a need for aggregation and inference, and may currently use some of these practices as part of their normal operations. Stakeholders should plan to discuss the advantages and disadvantages of the use of aggregation and inference, what procedures are essential for aggregation and/or inference, and when inference would be used in distribution and whether it is essential for every trading partner. FDA would also like to understand how the use of aggregation and inference may change when the DSCSA's enhanced drug distribution security provisions take effect in 2023, and what the challenges may be for implementation.