

## Summary

### Public Meeting Series: Enhanced Drug Distribution Security under the Drug Supply Chain Security Act (DSCSA)

August 23, 2017, December 5-6, 2017 and February 28, 2018

The U.S. Food and Drug Administration (FDA) held two public meetings in 2017 and one public meeting in 2018 regarding the enhanced drug distribution security provisions of the DSCSA. Attendees included members of the drug distribution supply chain and other interested stakeholders such as solution providers and representatives from other government agencies.

The purpose of these meetings was to give stakeholders an opportunity to provide input on strategies and issues related to the implementation of the enhanced drug distribution security provisions of the DSCSA. Discussion topics included, but were not limited to, electronic interoperability, enhanced drug distribution security needs, data architecture, aggregation/inference, and standards for data exchange. During each of the three meetings, FDA heard the issues and concerns raised by outside speakers and attendees, and group discussions examined different perspectives on the topics, including those that applied to a particular sector of the supply chain.

FDA plans to have additional public meetings in the future to continue the discussion regarding these important issues. The information gathered from the meetings and the public comments submitted to the docket will further inform FDA's implementation of the enhanced drug distribution security provisions of the DSCSA.

#### **Following is a summary of each of the three meetings in the series:**

##### **August 23, 2017**

FDA's goal at the first meeting of the series was to obtain information and input from attendees about issues related to the vision for 2023 and the enhanced drug distribution security needs related to tracing prescription drugs at the package level. FDA first provided its vision for 2023 followed by representatives of trading partners in the drug distribution supply chain, who each provided their vision for 2023. Following the speaker presentations, a breakout session was held where the attendees were divided into groups to address specific related questions. Issues raised by stakeholders and discussed at the meeting included roles of supply chain members and FDA when the 2023 systems and processes are in place, opportunities for interoperability, and improving supply chain efficiency and security.

The second half of the meeting addressed the enhanced drug distribution security needs starting with a presentation from FDA followed by a breakout session. Topics addressed by attendees in the breakout session included how to improve the efficiency of the supply chain; what we need to do to increase the security of the drug distribution supply chain; and what needs to be done to ensure the security of the 2023 system. Issues raised by stakeholders included exchange of data, communications and notification; improving efforts regarding the verification of products; data security and authorized access to appropriate data.

**December 5-6, 2017**

The second meeting of the series was a two-day meeting that featured several expert speakers who were invited to present on such topics as standards for data exchange; aggregation/inference, blockchain and verification. Breakout sessions and group discussions were held on each topic. The last breakout session focused on four specific supply chain scenario exercises for attendees to consider and discuss how the scenarios may be handled particularly once products are serialized and under enhanced drug distribution security in 2023. The scenarios that were discussed include: investigating suspect or illegitimate product and responding to verification requests, errors in product tracing information, saleable returns, communications when product has been stolen.

Attendees discussed such issues as the responsibilities of members of the supply chain and the benefits of the enhanced drug distribution security in 2023, including being able to quickly learn exactly where the product came from.

**February 28, 2018**

The third meeting began with a continuation of the discussion about enhanced drug distribution security needs. FDA presented a revised list of enhanced drug distribution security needs that was first addressed at the August 2017 public meeting.

A breakout session by supply chain sector was held on issues related to verification using the product identifier. These sessions included questions that were tailored for the specific sector of the supply chain. Examples of concerns raised during this session included how a manufacturer can determine if the entity requesting verification is legitimate; how verification will be handled when an entity goes out of business but their product is still in the supply chain; and the need to educate more dispensers on verification requirements.

The second half of the meeting focused on the identification and prioritization of topics for which the development of “guardrails” would be appropriate to assist stakeholders with implementation of enhanced drug distribution requirements. Stakeholders expressed a need for further clarification from FDA on a variety of topics. Examples of these topics that were considered priorities by stakeholders included:

- Inference/Aggregation
- Verification
- Governance
- Standards
- Master data
- Data architecture

**Next Steps for FDA:**

- FDA will consider the input provided by stakeholders during the three meetings and comments that were submitted to the public docket in the development of any relevant policy or interpretation that may be issued in a guidance document or regulation for enhanced product tracing and verification.
- FDA will continue to work with drug supply chain stakeholders to implement and operationalize the enhanced drug distribution security system in 2023.
- FDA will continue to update the DSCSA web page with the latest relevant information including guidance documents, regulations, future public meetings, etc.