Partnership for DSCSA Governance (PDG) and FDA Frequently Asked Questions (FAQs) from the 2024 Joint Public Meeting

The following questions represent some of the most frequently asked questions during the PDG-FDA Joint Public Meeting: DSCSA Stabilization Period Midway Checkpoint. Meeting organizers were not able to answer every question submitted during the Joint Public Meeting due to time constraints, but all questions were tracked and shared with appropriate meeting representatives.

The answers in this document are provided for informational purposes only by PDG and do not constitute legal advice. Action on the basis of these answers should involve consultation with professional legal counsel.

1. Is the pedigree provision of the Prescription Drug Marketing Act (PDMA) still in effect?

No. As of January 1, 2015, the "pedigree" provision of the Federal Food, Drug and Cosmetic (FD&C) Act (added by the PDMA of 1987) that required certain wholesale distributors to provide to the person who received the drug "…a statement…identifying each prior sale, purchase or trade of such drug…" no longer exists and is no longer in effect. The DSCSA removed the drug pedigree language and replaced it with new language in section 503(e) of the FD&C Act, which pertains to new licensing requirements and uniform national standards for wholesale distribution of prescription drugs. DSCSA also added product tracing requirements in section 582 of the FD&C Act to provide and capture product tracing information associated with each transaction for most human prescription drugs in finished form. *See FDA Drug Supply Chain Security Act Product Tracing Requirements: Frequently Asked Questions*.

2. What information do trading partners need to submit to be granted a WEE? And how does a trading partner submit a WEE to the FDA?

The FDA has released a guidance document on WEEs titled "Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act" (August 2023) that answers this question, and many other potential inquiries trading partners may have about the WEE application process. In summation, trading partners need to submit the following information:

- A detailed statement describing the reason(s) justifying the request.
- Pertinent and applicable supporting documentation.
- Any special circumstances of a product and/or transaction.

The FDA has also noted the following information is useful to include in WEE applications:

- Steps that have been completed to implement the section 582 requirements for which the waiver or exemption is being sought.
- Explanation detailing why additional time is needed.
- Steps that will be taken to fully implement requirements.
- Number of full-time employees employed by the trading partner seeking the waiver or exemption.

- Identity of the manufacturer who holds the approved application(s) for the product(s) involved, if a co-licensed partner or affiliate submits a waiver or exemption request.

The FDA has also provided additional recommendations that are specific to WEE requests for trading partners who do not expect to be in compliance on November 27, 2024 at this link.

3. When the FDA grants a WEE, is this information available publicly?

No, to protect supply chain safety, the FDA will not be releasing a public list of WEEs granted to trading partners. Instead, trading partners will need to leverage their relationships with their upstream and downstream partners to verify which products have been granted a WEE. For more information on this, please visit the FDA's webpage on WEEs linked here.

4. Does PDG have educational materials on how to learn more about how to comply with the DSCSA?

Yes, PDG has several resources:

- A series of videos explains the DSCSA at a high level, and a webinar series explains the PDG Blueprint.
- The PDG Blueprint captures and organizes the various industry requirements for interoperability and helps trading partners implement the DSCSA at a technical level. The Blueprint itself can be found on PDG website here.
- PDG also supports an educational resource that explains the basics of the DSCSA for dispensers at https://dscsa.pharmacy.

5. Has the FDA considered a phased approach to enforcing the DSCSA in each sector?

The FDA's most recent announcement established that Small Dispensers will receive enforcement discretion through November 2026 and the stabilization period will end for all other trading partners in November 27th, 2024.

6. Who is eligible for the small dispenser enforcement discretion?

According to FDA's announcement of the Small Dispenser Exemption, For the purpose of the small dispenser exemption, a dispenser is considered a "small dispenser" if the corporate entity that owns the dispenser has a total of 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians. The FDA believes this definition best incorporates small pharmacy operations and those who are most in need of additional time to comply with the requirements of the DSCSA.

If a dispenser meets the FDA definition of a Small Dispenser as defined in the draft guidance document, that small dispenser is automatically exempt and does not need to apply for a Wavier, Exemption, or Exception from the FDA.

7. Are there resources available to help trading partners handle exceptions?

The Healthcare Distribution Alliance (HDA) has put together guidelines prepared by technical experts of the HDA Exceptions Handling Work Group. As the supply chain moves toward stabilization, the mandatory interoperable exchange of serialized data adds significant complexity to sector operations

and there will be instances where there is a mismatch between data and product. The guidelines focus on the interactions between manufacturers and distributors while providing a series of scenarios and best practices.

GS1 has also published a guideline titled "Diagrams and XML examples for serialized exceptions processing."

8. Are there resources for handling suspect or illegitimate product and the 3911 process?

The FDA has released three guidance documents on suspect and illegitimate products and the 3911 process since 2021. These guidance documents provide further explanation of what a suspect or illegitimate product is, specific examples of processes that may be used to identify them, and an explanation of the comprehensive systems and processes that trading partners must have in place.

- Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification. (June 2021)
- Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act. (March 2023)
- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs. (December 2023)

The FDA also has a webpage explaining the form 3911 process when a trading partner has determined suspect product is illegitimate.

9. What is the expectation when trading commercial medicinal products to support Clinical Trial Supply?

An industry Q&A produced by the Pharmaceutical Distribution Security Alliance (PDSA) provides one perspective on this issue. Stakeholders are encouraged to review Q&A 11 in its 2023 Q&A.

10. Do EMS services and first responders have to comply with the DSCSA? What about dispensers and other trading partners who transact with them? How should they handle those interactions?

In the guidance "Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act — Compliance Policy Guidance for Industry" FDA noted they understood that some first responders might not meet the definition of "authorized" dispensers under section 581(2) of the FD&C Act because they do not have a valid license under state law. Nevertheless, they may be authorized, in accordance with applicable law, to administer certain products without a license, such as pursuant to proscribed standards of practice and medical treatment protocols. FDA also recognizes that first responders may lack the resources to comply with certain requirements under section 582(d) of the FD&C Act, including receipt, capture and maintenance of product tracing information and verification. In the guidance the FDA also state that transactions between dispensers and first responders may present challenges. The listed challenges are "exchange of product tracing information," "conducting businesses with authorized trading partners," and "having a verification system in place." Due to these challenges, The FDA has indicated it will not enforce the DSCSA against certain trading partners and first responders until further notice.

11. How long do companies need to keep serialized transaction data to comply with the DSCSA?

The DSCSA Requires all trading partners to retain records of serialized transaction data for at least six years for the purpose of potential future suspect product investigations. FDCA 582(b)1(A)(ii), FDCA 582(c)(1)(A)(v), and FDCA(e)(1)(A)(iii).

12. Do veterinarians or veterinary clinics have any obligations under product tracing or other obligations under DSCSA when they use human prescription drugs in animals?

No. If a veterinarian or a veterinary clinic uses human prescription drugs only in animals in accordance with section 512(a)(5) of the FD&C Act, the veterinarian or veterinary clinic is excluded from the definition of dispenser under section 581(3)(B) of the FD&C Act. *See FDA Drug Supply Chain Security Act Product Tracing Requirements: Frequently Asked Questions.*

13. How should trading partners handle drop shipments to dispensers to be compliant with the DSCSA?

Industry Q&A documents produced by the Pharmaceutical Distribution Security Alliance (PDSA) provides one perspective on this issue. Stakeholders are encouraged to review Q&A 13 in the 2014 Q&A and Q&A 8 in the 2023 Q&A.

For more information, please refer to the FDA Draft Guidance "Standardization of Data and Documentation Practices for Product Tracing Guidance for Industry."

The PDG Blueprint also provides detailed data flow process maps for drop shipments in Chapter 3.

14. Did the DSCSA restrict "borrow and loan" activities?

An industry Q&A produced by the Pharmaceutical Distribution Security Alliance (PDSA) provides one perspective on this issue. Stakeholders are encouraged to review Q&As 8 and 9 in the 2020 Q&A.

15. What are FDA's expectations for the use of unit-level scanning when relying on aggregation and inference?

Stakeholders are encouraged to review Sections V.B. and C. in the FDA guidance document "Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act" (January 2024).

16. How can dispenser-generated requests for verification be accomplished when the dispenser has no direct relationship with the manufacturer?

One way to accomplish this is to use the Verification Router Service (VRS). The VRS is an industry-developed solution that allows companies to verify products in compliance with the 2019 DSCSA requirement for serialized saleable returns even if a trading partners have no direct business relationship with each other (like dispensers requesting verification from manufacturers). It enables

verification of product identifiers for suspect or illegitimate product investigations, exception processing, status checks and saleable returns.

For more information please review Chapter 4 of the PDG Blueprint and HDA's documentation on the VRS.