Recognizing Traceability Milestones During the Stabilization Period:

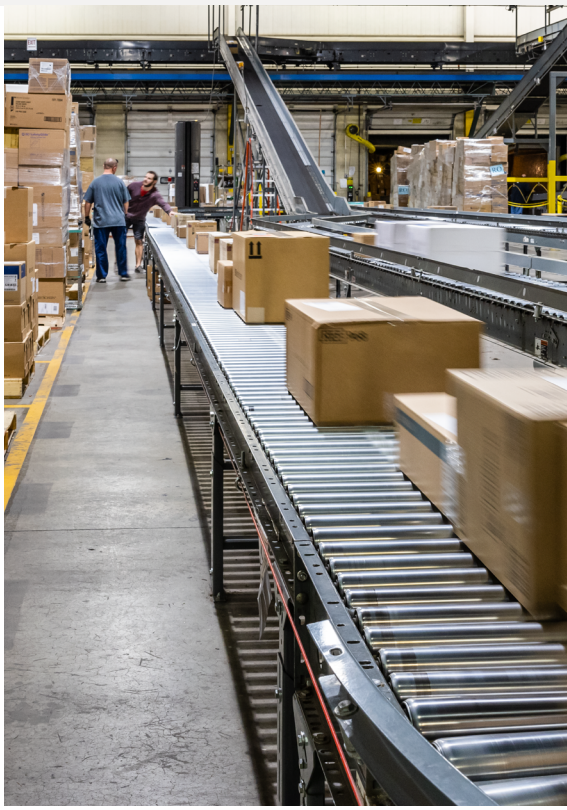
HDA Urges FDA To Recognize a Phased Approach

In 2013, Congress enacted the Drug Supply Chain Security Act (DSCSA), which mandated that all trading partners in the U.S. prescription drug supply chain meet the final requirements of the law no later than November 27, 2023. By that date, manufacturers, wholesale distributors and dispensers must interoperably and electronically exchange data that identify each prescription drug package purchased and sold. Given the complexities of these requirements, FDA issued a "stabilization period" until November 27, 2024, for trading partners to build capacity and stabilize processes.

Meeting a Complex Requirement

The package-level data exchange requirement is interdependent among supply chain segments and is effective for all trading partners at the same time. Accordingly, the ability of wholesale distributors and dispensers to lawfully purchase and resell medicines depends on a manufacturer providing package-level data first.

Though these requirements have been known since 2013, the interdependent requirements led to various states of compliance and uneven readiness across the supply chain for the 2023 compliance deadline. By announcing a stabilization period, FDA is offering an opportunity for trading partners to build capacity and stabilize the complex processes to ultimately exchange accurate package-level data in compliance with the DSCSA.



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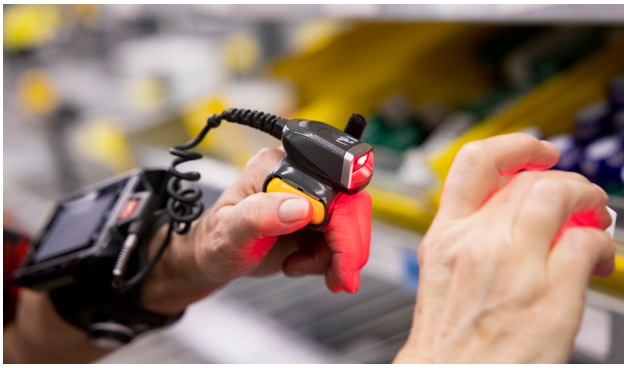
The Importance of Phases Under the Stabilization Period



HDA supports FDA's one-year stabilization period as a useful tool that moves the supply chain to full DSCSA compliance. Yet, it is important to recognize that uneven readiness under the stabilization period still exists, given the single compliance date of November 27, 2024.

Specifically, if manufacturers cannot interoperably exchange accurate package-level data on that date, the DSCSA would prohibit wholesale distributors and dispensers from lawfully purchasing and reselling the prescription drugs needed for patient care. This situation could exacerbate existing drug shortages.

To address uneven readiness, HDA urges FDA to allow for the final DSCSA requirements to be met in three phases with identified milestones within the one-year stabilization period. **If adopted by FDA**, this stepwise approach would recognize certain milestones and give clear direction to trading partners, with full implementation phased in by sector during the stabilization period in a way that is reflective of the natural flow of product and data throughout the supply chain. Trading partners would be able to continue current business practices to ensure medicines can make their way to patients safely and securely, while also continuing the push to package-level tracing and the enhanced supply chain security Congress envisioned.

HDA'S RECOMMENDED PHASES

1 APRIL 1, 2024

By April 1, 2024, FDA generally expects that manufacturers and repackagers will be compliant with Section 582(g)(1)(A) and (B) requirements for all products they transact with other trading partners. Manufacturers and repackagers would be expected to provide accurate and complete aggregated serialized data by this date.

2 JULY 1, 2024

By July 1, 2024, FDA generally expects wholesale distributors will be compliant with Section 582(g)(1)(A) and (B) requirements for all products transacted by wholesale distributors to other trading partners.

3 SEPTEMBER 1, 2024

By September 1, 2024, FDA generally expects dispensers to be compliant with Section 582(g)(1)(A) and (B).

This phased approach during the stabilization period permits an orderly implementation of the 2023 DSCSA requirements without jeopardizing patient safety or disrupting the supply of needed medicines.

For more information about the distribution industry's approach to pharmaceutical traceability and DSCSA implementation visit: www.hda.org/pharmaceutical-traceability

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