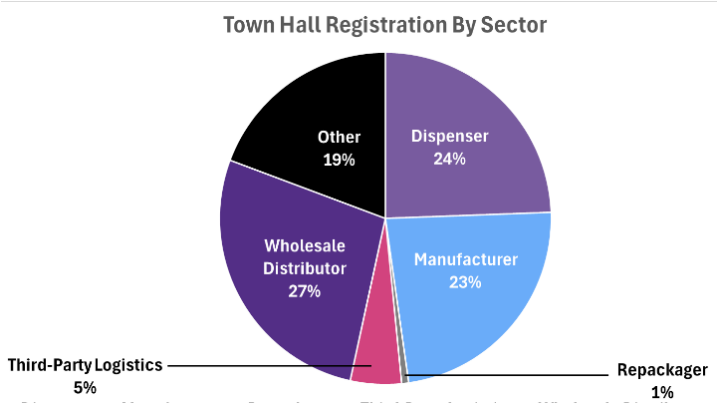
FDA-PDG Town Hall: Progress Toward End of Wholesale Distributor Exemption

SUMMARY

PDG's role in the town hall summarized in this report was primarily facilitation of the exchange of information among industry stakeholders and FDA. This report summarizes the comments and recommendations of *participants* in the town hall. PDG TAKES NO POSITION ON THE COMMENTS OR RECOMMENDATIONS MADE BY THOSE PARTICIPANTS AND SUMMARIZED IN THIS REPORT.

The second of three virtual town halls of 2025, hosted by FDA and the Partnership for DSCSA Governance (PDG), occurred on June 24 and 25, 2025. This town hall was designed to provide a forum for trading partners across the supply chain and other interested parties to share information on continued implementation of the Drug Supply Chain Security Act (DSCSA) and areas of remaining concern, with a **focus on the impacts of the upcoming (August 27, 2025) exemption expiration for wholesale distributors**. By way of background, throughout 2025, the Partnership for DSCSA Governance (PDG) and FDA are hosting three virtual, public town halls, each scheduled two months prior to the expiration of the Drug Supply Chain Security Act (DSCSA) phased exemption periods for trading partners.[1] Each town hall is preceded by a meeting with FDA and PDG membership. The first town hall took place in March 2025, the recording and meeting summary for which is available on the PDG website.

The most recent wholesale distributor town hall provided stakeholders with an opportunity to share information to support all trading partners in achieving **enhanced product tracing and verification collaboratively**. **More than 1,400 individuals registered for the event**, representing the broad diversity of the supply chain and related entities.



[1] In October 2024, FDA published its DSCSA Exemptions from Section 582(g)(1) and Other Requirements of the FD&C Act for Certain Trading Partners, which exempts eligible authorized trading partners from certain DSCSA requirements. These phased exemption periods provide trading partners with additional time as they work towards full DSCSA implementation while maintaining patient access to medicines. The exemption periods follow the FDA-issued stabilization period, which ended on November 27, 2024. The exemption periods expire on different dates based on sector, as follows:

- **Eligible Manufacturers and Repackagers** – May 27, 2025.
- **Eligible Wholesale Distributors** – August 27, 2025.
- **Eligible Dispensers with 26 or more full-time employees** – November 27, 2025.

Collectively, these exemptions are referred to as "the phased exemption periods" in this document.
In addition to the phased exemption periods, **dispensers with 25 or fewer full-time employees** are also exempt until November 27, 2026.

During the town hall, participants repeatedly emphasized the **value of the FDA-implemented phased exemption periods**, including the **substantial progress** made throughout the supply chain since the expiration of the exemption period for manufacturers on May 27, 2025. Participants reported **consistent improvements in data volume, quality, and exchange**, and noted their continued work to improve **exceptions handling knowledge and capabilities**, especially with the increase in data flow. While participants identified remaining potential risks and DSCSA implementation issues in ensuring alignment across organizations, **the wholesale distributors engaged in the town hall expressed confidence in their ability to be ready by the end of their exemption period on August 27, 2025**.

The phased exemption periods implemented by FDA continue to be highly beneficial, especially with respect to allowing wholesale distributors to isolate DSCSA implementation into manageable upstream and downstream segments.

Participants in the town hall emphasized the **value that the phased exemption periods have provided**, and continue to provide, to trading partners across the supply chain. Particularly, wholesale distributors have found the phased exemption periods to be highly beneficial by allowing this sector—which sits in an oftentimes challenging position between other supply chain trading partners—**to first focus on its upstream DSCSA readiness before turning to its downstream readiness**. Prior to the expiration of the exemption period for manufacturers on May 27, 2025, wholesale distributors focused on ensuring data connectivity and receipt of information with upstream trading partners. Since then, wholesale distributors have been able to shift their focus to downstream connectivity and data transfer. Additionally, wholesale distributors reported increased collaboration with their dispenser trading partners to help further their readiness of DSCSA compliance by the November 27, 2025, deadline for eligible dispensers not subject to the small business dispenser exemption issued by FDA.

Manufacturers and dispensers also noted the success of the exemption periods. As trading partners approach the end of the wholesale distributor exemption period on August 27, 2025, the phased exemption periods are allowing trading partners to make **significant strides toward robust and accurate exchange of serialized Transaction Information (TI)**, and trading partners are poised to continue making progress through the November 27, 2025, exemption expiration date for eligible dispensers. The phased exemption periods have helped—and continue to help—trading partners to improve their systems and processes for enhanced drug distribution security, ensure access to medicines, improve the resiliency of the pharmaceutical supply chain, and protect the country's public health.

Substantial progress continues across the supply chain, and trading partners and other interested parties are optimistic in the ability of wholesale distributors to comply with the upcoming expiration of the exemption period for wholesale distributors.

Of note, no stakeholders participating in the town hall expressed a need to extend the exemption period for eligible wholesale distributors. During the meeting, wholesale distributors reported that their **data connections with trading partners to exchange serialized TI have significantly improved, as seen through both inbound and outbound data exchange**. PDG presented survey results confirming this increase in data transmission, with a full survey report available here. Highlights from the report include:

- PDG received 26 wholesale distributor respondents in June 2024 and 31 in June 2025.

- In June 2024, only 4 percent of wholesale distributor respondents reported routinely receiving complete serialized data from at least 80 percent of their suppliers when purchasing product.
    - One year later, 64 percent of wholesale distributor respondents reported receiving complete serialized data from at least 80 percent of their suppliers, with 46 percent of these respondents receiving complete information from at least 95 of their suppliers.
- Similarly, with respect to outbound data in June 2024, only 12 percent of wholesale distributor respondents reported routinely providing complete serialized data to at least 80 percent of customers when selling product.
    - By June 2025, this data point increased to 59 percent, with 44 percent reporting they provide complete serialized data to at least 95 percent of their suppliers.

Additionally, during the town hall, the Healthcare Distribution Alliance reported that the percentage of purchase order lines that could experience disruption due to inaccurate or missing data from upstream trading partners has decreased from roughly 9 percent in February 2025, to 2.5 percent in June 2025. Downstream, the American Society of Health-System Pharmacists (ASHP) reported that dispensers are receiving production Electronic Product Code Information Services (EPCIS) messages with an approximate success rate of 81 percent.

The increase in serialized data exchange has helped to **close gaps in data quality visibility**, and wholesale distributors reported improvements in performing saleable returns verifications and processing saleable returns data. Additionally, **close collaboration among trading partners**, particularly between wholesale distributors and dispensers, has been notable in progressing DSCSA implementation. Distributors described efforts to provide downstream support, such as building customer-facing portals and providing onboarding and technical training for dispensers.

Wholesale distributors are focused on further improving these data points through continued communication and collaboration with trading partners and refinements in their own systems and processes.

There have been consistent improvements in data quality and exchange throughout the supply chain, with continuous enhancements of systems and processes. With greater amounts of data being exchanged, trading partners are working to improve exceptions handling knowledge and to standardize exception handling capabilities.

Trading partners reported meaningful improvements in the amount of data transacted and in data quality. As noted above, inbound data volumes and quality are progressing significantly, while outbound data is also steadily improving. This increased data flow is also accompanied by a **heightened focus on data quality**, with trading partners working to address discrepancies and integrate exceptions handling processes within their organizations. As the volume of exchanged data increases, the incidence of exceptions increases, with **troubleshooting of exceptions at the forefront of DSCSA implementation**. This is an anticipated and natural hurdle as data exchange increases, and it is **an indicator that DSCSA implementation is progressing**. **The increase in exceptions handling has prompted a growing emphasis among trading partners to develop "muscle memory" for exception handling**—ensuring systems, processes, and personnel across organizations are prepared to quickly identify and resolve data-related issues. Today, while data exception occurrences are novel and subsequent resolution processes are

prolonged—oftentimes ranging from two to seven days—there has been **continued improvement in response efficiency**.

There remains **opportunity for technical solution development to help trading partners enhance their data exceptions handling capabilities**. Key areas for improvement include enhancing systems for managing master data updates and to allow for partial receiving of product in the event of exceptions or errors. Further, trading partners should communicate regarding embedded elements in barcodes that may go beyond the product identifier components (National Drug Code, lot number, expiration date, and serial number), as these added components can make it difficult for smaller downstream organizations to process inbound data.

Overall, wholesale distributors and other trading partners have undertaken **continuous improvement efforts** since the expiration of the manufacturer exemption period on May 27, 2025. Trading partners reported ongoing enhancements in their processes to analyze data quality and efficiently address the root causes of errors. Wholesale distributors were optimistic about their ability to reach a maximum achievable level of accuracy and sustain their continuous improvement efforts.

Participants identified remaining potential risks, including data connectivity with manufacturers, repackagers, and dispensers as well as quarantined product, including those in shortage.

As DSCSA implementation moves closer to full compliance, town hall attendees identified several remaining *potential* risks that could impact data quality and operations. These potential risks are not necessarily signs of unpreparedness. Rather, they reflect the **significant complexity of implementing final system connections and operational coordination** both internally and between trading partners. Potential risks noted during the town hall include:

- **Establishing remaining connections:** While town hall attendees reported significant strides in data connectivity, as described above, attendees also reported that the remaining connections left to be established are likely those that are the most complex and resource intensive. In many cases, they involve coordination with smaller or resource-limited trading partners, where technical capabilities and staffing vary. As these remaining entities integrate into DSCSA systems, mismatches and coordination issues may occur.
- **Visibility across trading partners:** Wholesale distributors reported that their visibility into downstream trading partners is sometimes restricted due to limitations when working with third-party solution providers used by dispensers. Wholesale distributors have visibility to their interaction with a dispenser's third-party solution provider, but the interactions between the solution provider and the individual dispenser is not visible and harder to discern. This lack of visibility can hinder data exception resolution and reconciliation efforts.
- **Quarantined product:** As exemptions expire and full compliance becomes mandatory, product quarantining may serve as a risk mitigation strategy for trading partners when data discrepancies are found or when serialized data is missing in a transaction. Manufacturer participants in the town hall shared that they are quarantining product accompanied by data associated with data quality concerns. Additionally, some wholesale distributor participants noted that, following the May 27, 2025, manufacturer exemption expiration date, they began quarantining product received without transaction data or with data exceptions. Additional

distributors plan to begin quarantining product after their August 27, 2025, expiration date. Wholesale distributors further reported that, currently, the volume of quarantined product varies day-to-day, with the unpredictable volume impacting distribution centers. However, the overall impact on product availability thus far has been minimal. A likely increase in quarantined product after the August deadline may pose potential supply chain challenges if data quality issues arise or response times lag.

- **Technical inconsistencies in data standards:** Downstream trading partners, including wholesale distributors and dispensers, reported challenges with EPCIS data, such as mismatches between product barcodes and serialized data or deviations from the GS1 implementation guidelines. Attendees reported that they are aware of these potential inconsistencies and are taking steps to address them on a case-by-case basis.
- **Barcode quality:** Town hall participants noted the importance of maintaining barcode quality as product moves downstream. Barcode quality issues have the potential to complicate data reconciliation efforts.
- **Alignment of timing between product and EPCIS messages:** Wholesale distributors reported that, in some cases, especially when there is close proximity of shipping locations, products have arrived at distribution centers ahead of their corresponding EPCIS messages. Trading partners noted the importance of synchronization between the movement of physical product and the transmission of serialized data.
- **FDA-approved waivers, exceptions, and exemptions:** Trading partners, especially wholesale distributors, noted that approved waivers, exceptions, and exemptions requests may be challenging to implement. These stakeholders noted the operational strain created by running dual systems to comply with both lot-level and package-level traceability. Some distributors planned to decommission older systems by August 27, 2025, with the intent to fully shift resources toward serialized data exchange or other planned organizational activities. However, granted WEE requests could lead to a need to maintain both systems longer than initially anticipated, which is technically difficult and increases operational costs for wholesale distributors.

  Distributors recommended FDA:
  - Consider challenges with dual systems;
  - Narrow the applicability of the granted requests; and
  - Time-bind approvals.

While each of these potential risks *could* negatively impact product access, supply chain security, and public health, **wholesale distributors and their trading partners are actively working to minimize actual impacts** in advance of the August 27, 2025, expiration date and are optimistic in their ability to collaborate with trading partners.

Overall, entities throughout the supply chain continue to collaborate to resolve remaining DSCSA implementation issues to ensure alignment across organizations.

As the pharmaceutical supply chain advances toward full DSCSA implementation, **collaboration among trading partners to resolve outstanding challenges** and ensure compliance across all sectors remains

strong. While significant progress has been made in data connectivity, data exchange, and standardization of organizational processes, as described above, **certain complex scenarios still pose barriers to implementation, highlighting the need for continued collaboration:**

- **Drop shipments:** Drop shipments present an ongoing complexity under the DSCSA, given divergence between the flow of serialized product data and the physical movement of product. Though product is sold through a wholesale distributor, it is shipped directly from a manufacturer to a dispenser. Wholesale distributors reported this lack of direct contact with the product has led to challenges in data exchange timing and ensuring that serialized data is correctly captured, validated, and transmitted. This raises the need for increased clarity and communication between trading partners when effectuating drop-ship arrangements.
- **340B drug pricing program:** Trading partners highlighted 340B transactions as another area presenting unique challenges, particularly regarding distinguishing and managing 340B inventory within DSCSA-compliant systems. Trading partners also noted that managing serialized data for 340B-designated products can be difficult, especially when 340B products flow through different distribution pathways. Further, operational nuances of 340B transactions increase the risk of data inconsistencies.
- **National Drug Code (NDC):** Trading partners highlighted the future challenges associated with the expected transition from the 10-digit NDC format to a 12-digit format, as proposed by FDA. Trading partners' systems have been built to support the 10-digit format, and a change will require widespread system updates, label changes, and data alignment. Without a timely shift to the 12-digit format, the pharmaceutical supply chain could face challenges.

Ultimately, the town hall highlighted **optimism as wholesale distributors progress to the end of their exemption expiration on August 27, 2025**. The town hall highlighted areas of improvement and remaining potential risks to the supply chain. **All trading partners remain committed to working together to address remaining challenges and achieve full DSCSA compliance**.

About PDG

PDG is an independent, balanced, sector-neutral, nonprofit industry governance body that supports the secure, electronic, interoperable tracing, and verification of prescription drugs in the U.S. supply chain, as required by the Drug Supply Chain Security Act (DSCSA). Through our public-private partnership with FDA, we collaborate to develop, advance, and sustain an effective and efficient model for interoperability.

PDG membership includes leading authorized manufacturers, repackagers, wholesalers, third-party logistics providers, and dispensers (hospitals and retail and independent pharmacies), as well as leading industry trade associations and technical experts. Together, these members are working to establish a comprehensive vision for industry's implementation of secure, electronic systems and processes for drug traceability in the United States.

For additional information, visit www.DSCSAgovernance.org.