Partnership for DSCSA Governance (PDG)

DSCSA Implementation Survey Results

Survey Conducted: May 23, 2024–June 10, 2024; October 14, 2024–October 30, 2024; February 26, 2025–March 12, 2025

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EXECUTIVE SUMMARY

The Drug Supply Chain Security Act (DSCSA) required drug manufacturers, wholesaler distributors, dispensers, and repackagers (collectively, "trading partners") to implement secure, electronic, interoperable systems and process for enhanced product tracing by November 27, 2023. In August 2023, FDA published its Compliance Policy, Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act, which established a one-year stabilization period to afford trading partners the necessary flexibility to maintain patient access to medicines while maturing and stabilizing their interoperable systems and processes.

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.

In addition to the phased exemption periods, dispensers with 25 or fewer full-time employees are also exempt until November 27, 2026.

In effort to better understand trading partner progress toward each of those deadlines and to inform any necessary action, the Partnership for DSCSA Governance (PDG) surveyed trading partners to better understand the industry's progress in achieving interoperable data exchange and traceability during the stabilization period. The survey was issued to trading partners in three iterations:
- May 23, 2024, to June 10, 2024;
- October 14, 2024, to October 30, 2024; and
- February 26, 2025, to March 12, 2025.

This report provides the results of these surveys. Each survey question has been analyzed in two ways and presented in two graphs. The first graph summarizes the results from all three iterations of the survey. Because response rates were variable across the iterations of the survey, the second graph presents the responses of only those organizations who responded to *both* the June 2024 and March 2025 surveys, providing a control group to present trends across consistent respondents.

The information in this report is organized into four sections:
- Respondent Demographics,
- Data Exchange Rates,
- Assessing Data Quality and Accuracy, and
- Implementation of Verification and Tracing.

DSCSA IMPLEMENTATION SURVEY RESULTS

Respondent Demographics

Graph 1 shows the demographics of participants for each survey occurrence.

138 trading partners responded to the June 2024 survey.

- Manufacturers were the most frequent respondents, representing 62 out of 138 respondents (45%). Of the 62 Manufacturers, more than 45% have annual revenue of more than $1 billion.
- Pharmacies represented a total of 42 out of 138 respondents (30%). Pharmacy respondents also represented a diversity of organization sizes.
- Wholesale Distributors had a total of 26 (19%) of respondents. Wholesale distributor respondents also represented a diversity of organization sizes.
- Third-Party Logistics Provider had four (3%) respondents.
- One reverse distributor responded to the survey (1%).

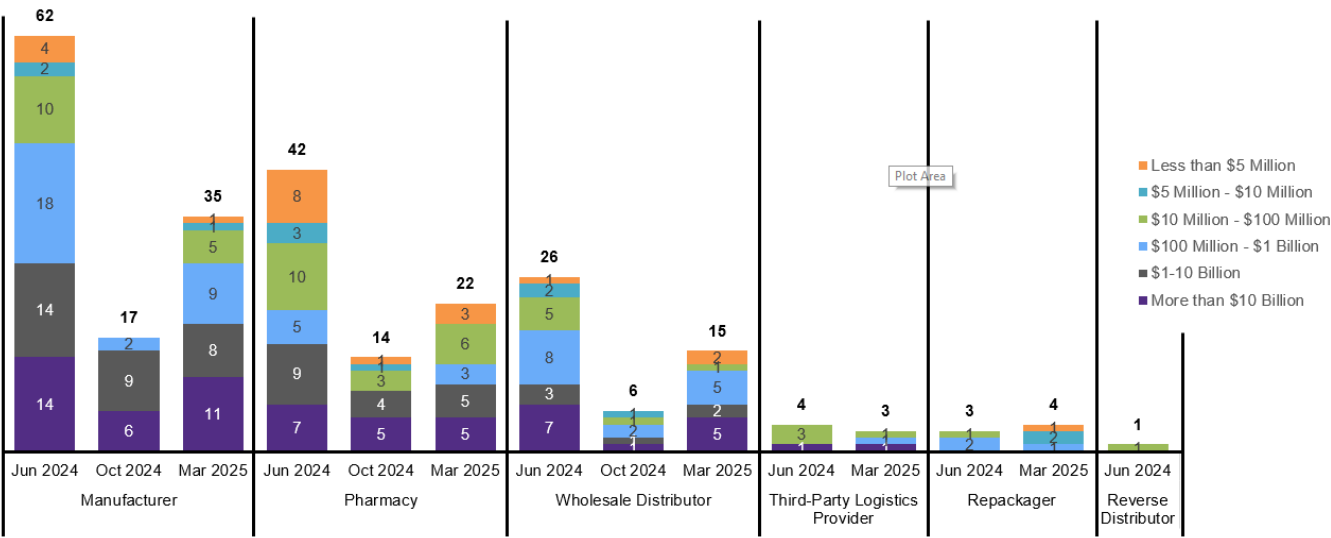37 trading partners responded to the October 2024 survey.

- Manufacturers accounted for 17 respondents (46%), and the majority of manufacturers have an annual revenue over $1 billion (88%).
- 14 pharmacies responded to the October 2024 survey, making up 38% of participants.
- Wholesale distributors made up 16% of participants with six respondents.
- No third-party logistics provider, repackagers, or reverse distributors responded to the October 2024 survey.

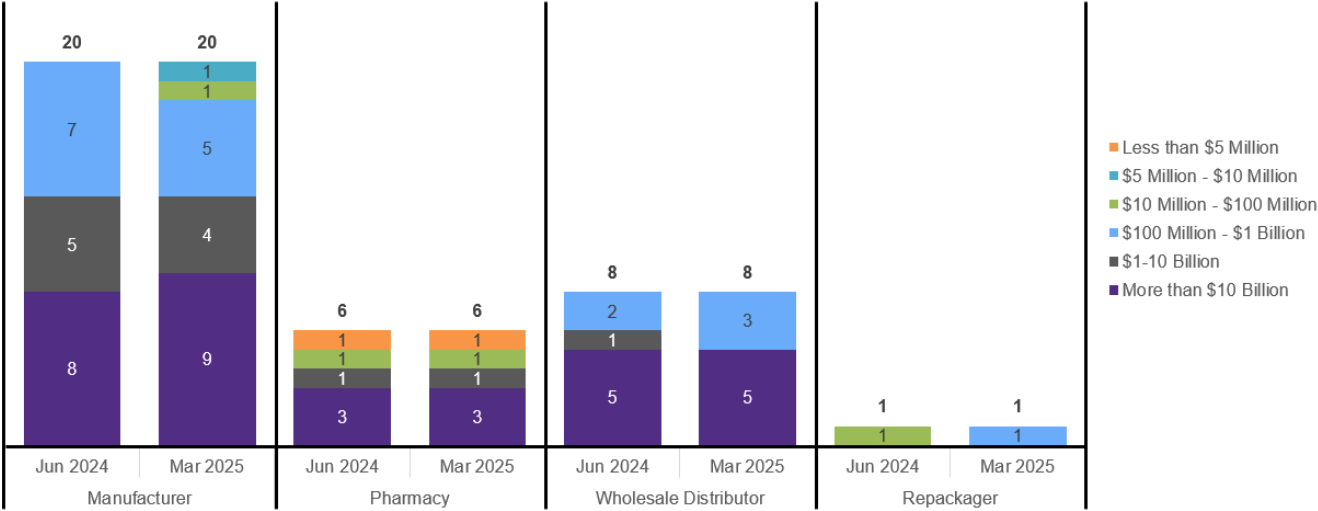79 trading partners responded to the March 2025 survey.

- Manufacturers again accounted for the most respondents with 35 respondents (44%). The majority (54%) of manufacturers have an annual revenue of more than $1 billion.
- 22 pharmacies responded to the survey (28%), with a diversity of business sizes.
- 15 wholesale distributors responded to the March 2025 survey (19%). Nearly half (47%) have an annual revenue of more than $1 billion.
- Four repackagers responded to this survey (5%).
- Three third-party logistics providers responded to this survey (4%).
- No reverse distributors responded to the March 2025 survey.

Graph 2, below, reflects only those organizations who responded to _both_ the June 2024 and March 2025 surveys. This control group represents approximately one-quarter of the total June 2024 respondents and approximately one-half of the March 2025 respondents. Across the sectors, the control group skews more heavily toward manufacturers and wholesale distributors with light response rates among pharmacies.

Graph 1 (All Respondents)

Number of Respondents by Sector and Size
June 2024 N= 138   October 2024 N = 37   March 2025 N= 79

Legend:
- Less than $5 Million
- $5 Million - $10 Million
- $10 Million - $100 Million
- $100 Million - $1 Billion
- $1-10 Billion
- More than $10 Billion

Graph 2 (Control Group)

Number of Respondents by Sector and Size
May 2024 N= 35   March 2025 N= 35

Legend:
- Less than $5 Million
- $5 Million - $10 Million
- $10 Million - $100 Million
- $100 Million - $1 Billion
- $1-10 Billion
- More than $10 Billion

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THE FOLLOWING QUESTIONS QUANTIFY THE FREQUENCY OF DATA EXCHANGE OCCURRING AMONG TRADING PARTNERS.

When Purchasing Product: For approximately what percent of your suppliers are you routinely receiving complete serialized data (i.e., transaction information)?

The graphs below provide insight into the percentage of suppliers from whom repackages, wholesale distributors, and pharmacies are routinely receiving complete serialized data from their suppliers.

Graph 3 shows a marked increase in data receipt by wholesalers (most often from manufacturers) from June 2024 to March 2025. In June 2024 only one wholesale distributor reported receiving complete serialized data from 80% or more of its suppliers. In March 2025, 12 of 15 wholesale distributors reported receiving complete serialized data from 80% or more of their suppliers. Trends were more difficult to identify among pharmacies given the low response rates.

The trend for wholesale distributors is consistent across Graph 3 and Graph 4 (all respondents and the control group), with both graphs indicating an increase in the number of suppliers providing complete serialized data. Findings among pharmacies are also consistent, with both graphs indicating an increase in the amount of complete serialized data being provided by manufacturers, but less instructive due to response rates.
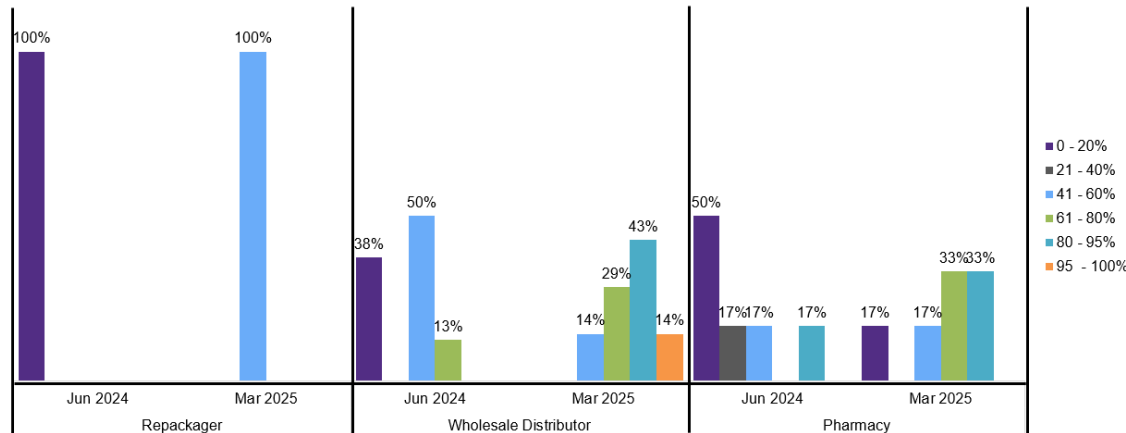
Graph 3 (All Respondents)

When Purchasing Product: From approximately what percent of your suppliers are you routinely receiving complete serialized data (i.e., transaction information)?
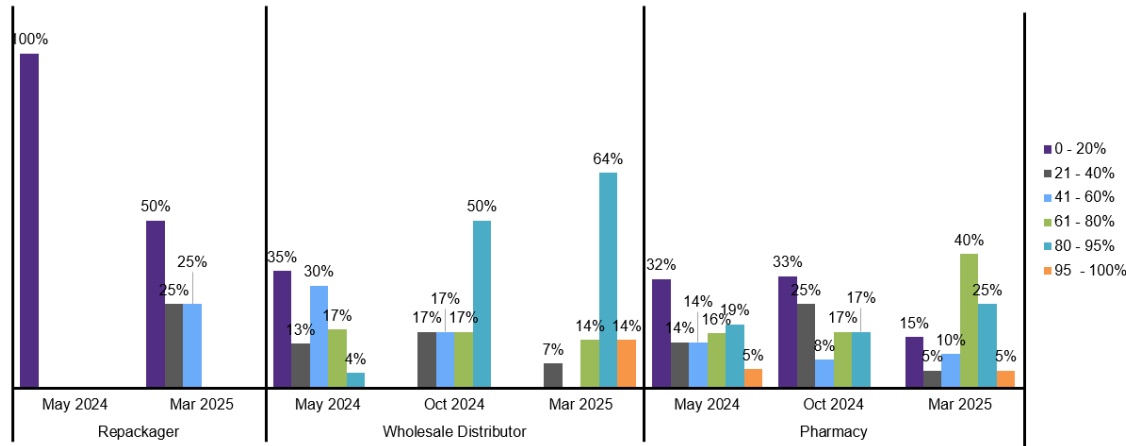
Graph 4 (Control Group)

When Purchasing Product: From approximately what percent of your suppliers are you routinely receiving complete serialized data (i.e., transaction information)?

When Purchasing Product: For approximately what percent of product you purchase are you routinely receiving complete serialized data (i.e., transaction information)?
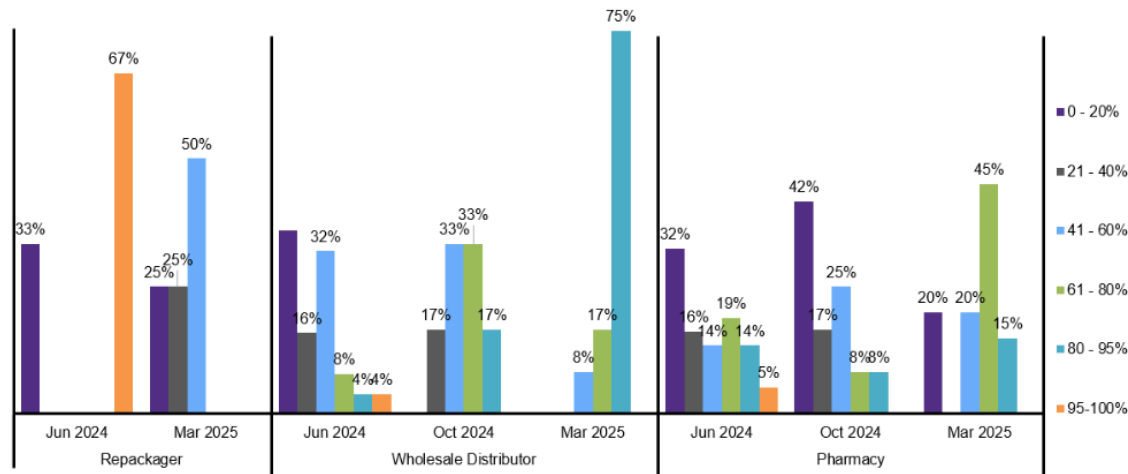
Graphs 5 and 6 shed light on the percent of *product* (as opposed to suppliers) for which trading partners were routinely receiving complete serialized data.

Wholesale distributors and pharmacies both experienced an increase in the amount of complete serialized data they received when purchasing product in June 2024 versus March 2025. In June 2024, only one out of 26 wholesale distributors reported receiving complete serialized data for 80% or more of purchased product, but in March 2025, three out of four reported receiving complete serialized data for 80% or more of purchased product. Pharmacy rates also improved; 33% of pharmacies reported receiving complete serialized data for more than 60% of purchased product in June 2024, compared to six out of ten reporting receiving complete serialized data for more than 60% of purchased product in March 2025.

The control group (Graph 6) showed comparable improvements in the wholesale distributor and pharmacy sectors.
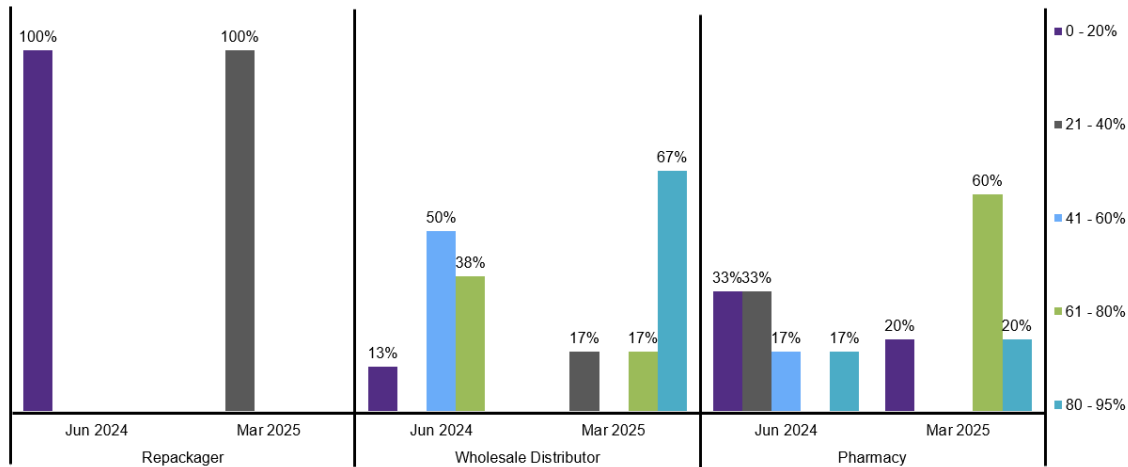
Graph 5 (All Respondents)

When Purchasing Product: For approximately what percent of product you purchase are you routinely receiving complete serialized data (i.e., transaction information)?

Legend: 0 – 20%, 21 – 40%, 41 – 60%, 61 – 80%, 80 – 95%, 95-100%

Repackager — Jun 2024: 33%; Mar 2025: 25%, 25%, 50%, 67%
Wholesale Distributor — Jun 2024: 16%, 32%, 8%, 4%, 4%; Oct 2024: 17%, 33%, 33%, 17%; Mar 2025: 8%, 17%, 75%
Pharmacy — Jun 2024: 32%, 6%, 14%, 19%, 14%, 5%; Oct 2024: 42%, 17%, 25%, 8%, 8%; Mar 2025: 20%, 20%, 45%, 15%

Graph 6 (Control Group)

When Purchasing Product: For approximately what percent of product you purchase are you routinely receiving complete serialized data (i.e., transaction information)?

Legend: 0 – 20%, 21 – 40%, 41 – 60%, 61 – 80%, 80 – 95%

Repackager — Jun 2024: 100%; Mar 2025: 100%
Wholesale Distributor — Jun 2024: 13%, 50%, 38%; Mar 2025: 17%, 17%, 67%
Pharmacy — Jun 2024: 33%, 33%, 17%; Mar 2025: 17%, 20%, 60%, 20%

When Selling Product: To approximately what percent of your customers are you routinely providing complete serialized data (i.e., transaction information)?

This question, and the following question, seek to understand the rate of *outbound* data being provided by the seller of product in a transaction. Graphs 7 and 8 represent the percentage of *customers* to whom manufacturers, repackagers, and wholesale distributors routinely provide complete serialized data.

Manufacturer responses to this question present an unclear picture of progress. Manufacturer respondents indicated they were providing complete serialized data to a *larger* percentage of their customers in June 2024 than in March 2025 (among both all respondents and the control group). However, this seems at odds with other survey responses. As noted above, wholesalers (the primary customers of manufacturers) have noted a marked increase in the percentage of suppliers (primarily manufacturers) from which they were routinely receiving complete serialized data, and in subsequent survey questions below, manufacturers indicate a significant increase in the volume of product for which they were routinely providing serialized data.

Across both all respondents and the control group, wholesale distributor respondents indicated a significant increase in the percent of customers to whom they were routinely providing complete serialized data. Among the control group, no wholesale distributor reported providing complete serialized data to 80% or more of their customers in June 2024, but half of the wholesale distributor respondents reporting providing complete serialized data to 80% or more of their customers in March 2025.
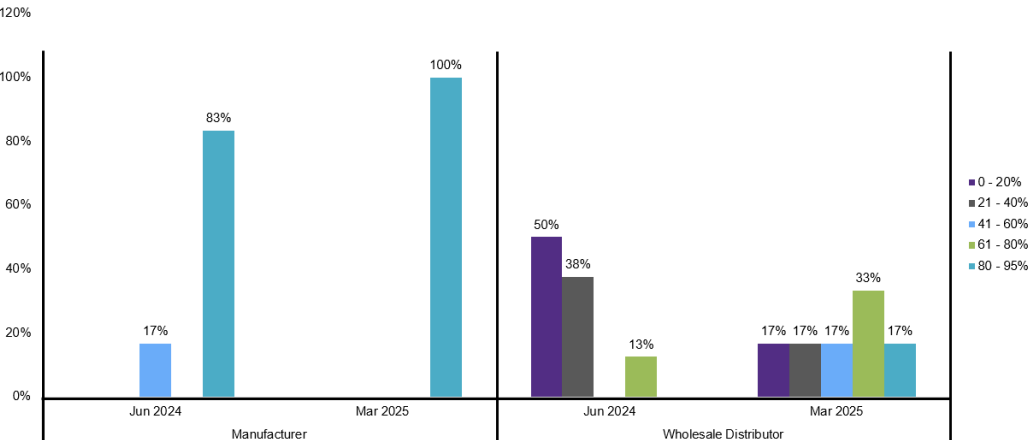
Graph 7 (All Respondents)

When Selling Product: To approximately what percent of your customers are you routinely providing complete serialized data (i.e., transaction information)?
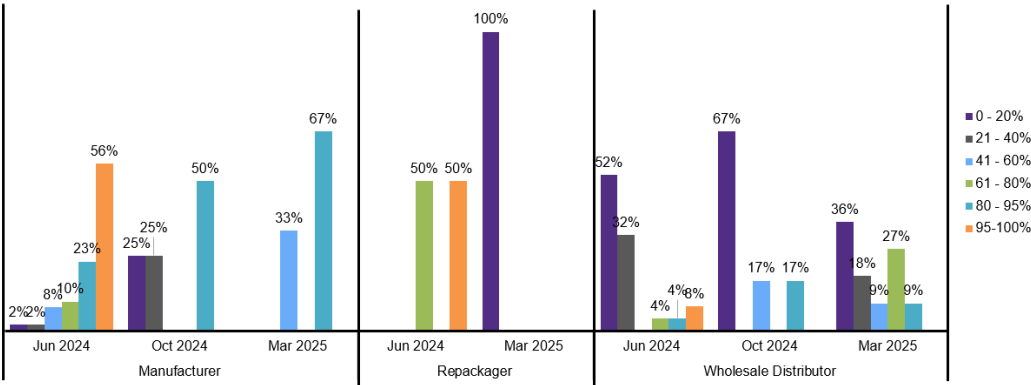
Graph 8 (Control Group)

When Selling Product: To approximately what percent of your customers are you routinely providing complete serialized data (i.e., transaction information)?
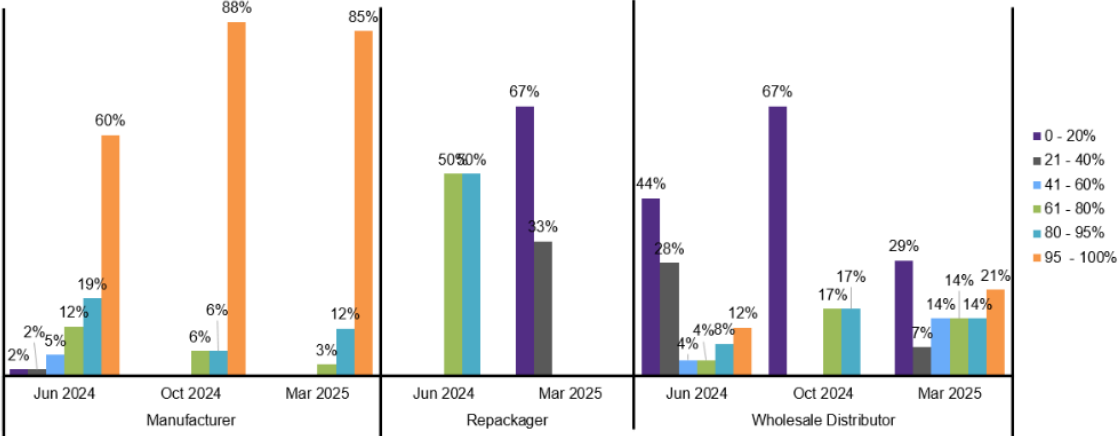
When Selling Product: For approximately what percent of product you sell are you routinely providing complete serialized data (i.e., transaction information)?

This question highlights the rate of data exchange as a percentage of *product* sold (as opposed to percentage of *customers*). Responses indicated a notable increase in outbound data exchange among both manufacturers and wholesalers.

Among manufacturer respondents, there was a significant increase from June 2024 to March 2025 in number of manufacturers who indicated they are providing complete serialized outbound data for at least 95% of their product. Among the control group, as of March 2025, only one manufacturer indicated they were not routinely providing completely serialized data for at least 95% of their product.

Wholesalers also showed significant increase in outbound data across both all respondents and the control group. As of June 2024, a significant majority of wholesalers indicated they provided complete serialized data for less than 40% of their product. By March 2025, a significant minority reported providing complete serialized data outbound for less than 40% of their product, with 43% of the control group indicating they provided complete serialized outbound data for at least 80% of their product.

Graph 9 (All Respondents)

When Selling Product: For approximately what percent of product you sell are you routinely providing complete serialized data (i.e., transaction information)?

Graph 10 (Control Group)

When Selling Product: For approximately what percent of product you sell are you routinely providing complete serialized data (i.e., transaction information)?
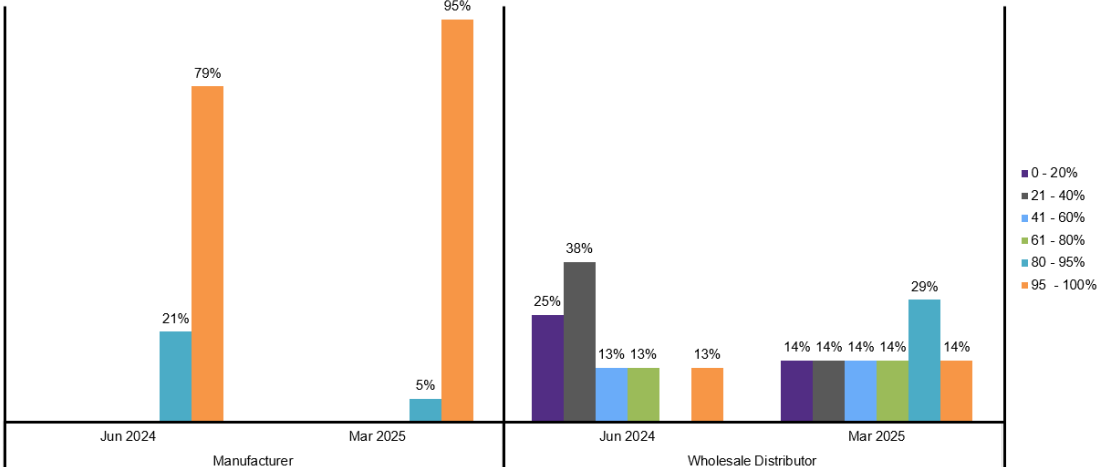
THE FOLLOWING QUESTIONS ASSESS TRADING PARTNERS' ADOPTION OF SYSTEMS AND PROCESSES TO ACTIVELY ASSESS THE QUALITY AND ACCURACY OF DATA.

When Purchasing Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you receive?
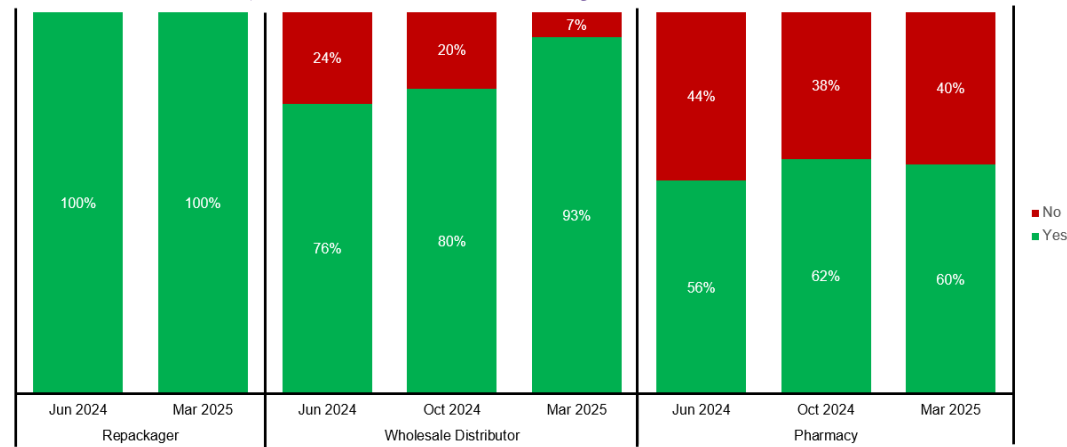
Graphs 11 and 12 represent the extent to which trading partners are actively assessing the quality and accuracy of serialized data they *receive*. This is critical because continued improvement of data accuracy and reliability is necessary to stabilization.

Across both all respondents and the control group, wholesale distributors showed an increase in the assessment of data, with 76% of all respondents reporting they actively assess data quality and accuracy in June 2024 and 93% reporting doing so in March 2025. Among the control group, that increase was from 63% in June 2024 to 88% in March 2025.

Pharmacies did not show notable change in their practices in this regard, generally showing a flat rate of assessing inbound data quality and accuracy across both all respondents and the control group.
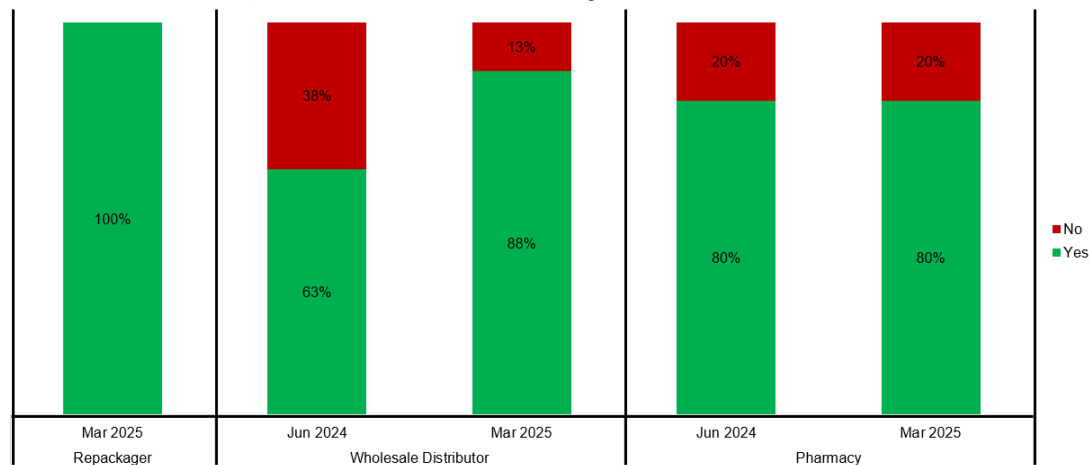
Graph 11 (All Respondents)

When Purchasing Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you receive?

Graph 12 (Control Group)

When Purchasing Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you receive?

When Selling Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you provide?
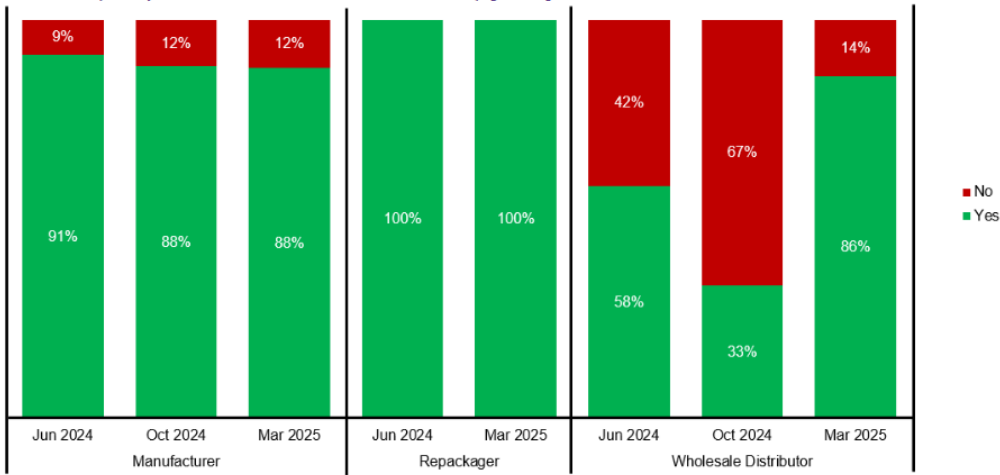
Graphs 13 and 14 represent the extent to which trading partners are actively assessing the quality and accuracy of serialized data they *provide* (i.e., outbound data).

Responding manufacturers reported a consistent, but high, rate of assessing data quality and accuracy across the iterations of the survey.

Taking the October 2024 survey as an outlier due to the low number of respondents, the surveys also indicate a significant increase in wholesalers assessing the quality and accuracy of outbound data. Among the control group, only half of the wholesaler respondents assessed the quality and accuracy of outbound data in June 2024, and 71% of respondents in March 2025.
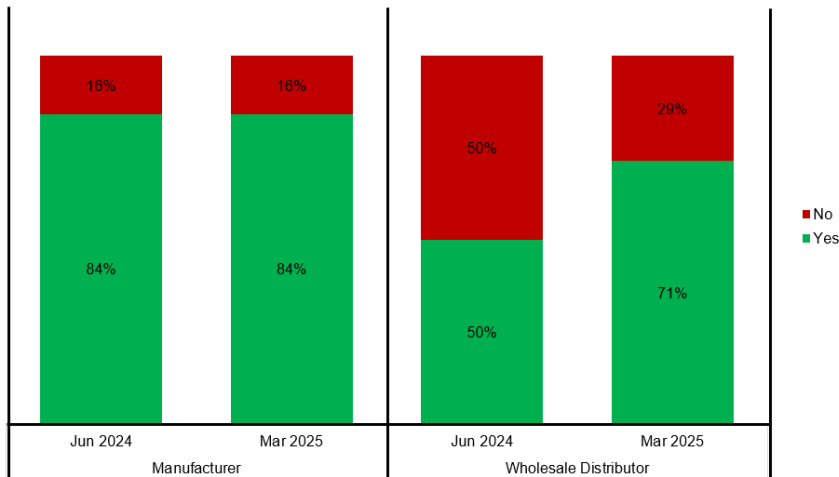
Graph 13 (All Respondents)

Graph 14 (Control Group)

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THE FOLLOWING QUESTIONS ASSESS TRADING PARTNERS' ADOPTION OF SYSTEMS AND PROCESSES TO VERIFY PRODUCT IDENTIFIERS AND TRACE PRODUCT.
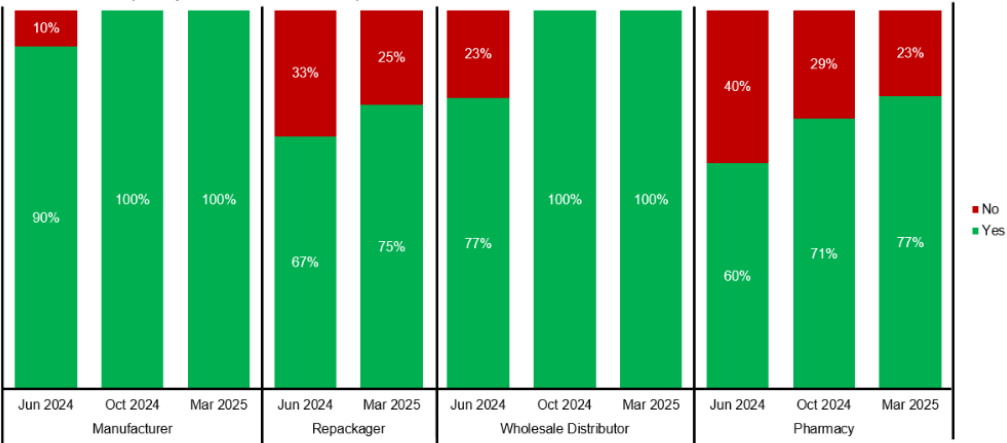
Do you have interoperable electronic systems and processes to verify product identifiers (i.e., serial number)?

The DSCSA requires trading partners to implement electronic interoperable systems and processes for verification of product at the package level, including the serial number. This question highlights the progress of manufacturers, repackagers, wholesale distributors, and pharmacies in implementing such systems and processes.
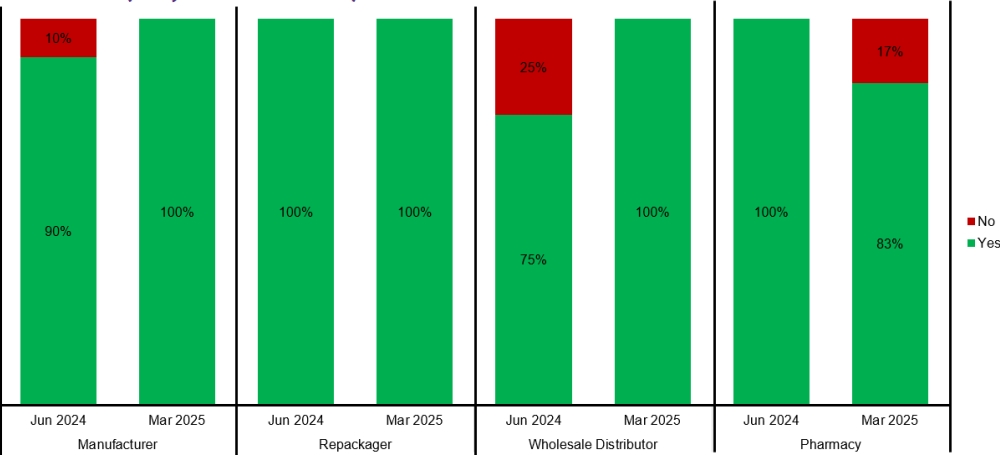
Positively, all manufacturer and wholesale distributor respondents—all respondents and the control group—reported having implemented electronic interoperable systems and processes for verification as of March 2025.

Among all dispenser respondents there appears to have been an increase in implementation of verification systems and processes; however, the data is anomalous within dispensers in the control group, suggesting a decline in such systems and processes among dispensers.

Graph 15 (All Respondents)

Do you have interoperable electronic systems and processes to verify product identifiers (i.e., serial number)?

Graph 16 (Control Group)

Do you have interoperable electronic systems and processes to verify product identifiers (i.e., serial number)?
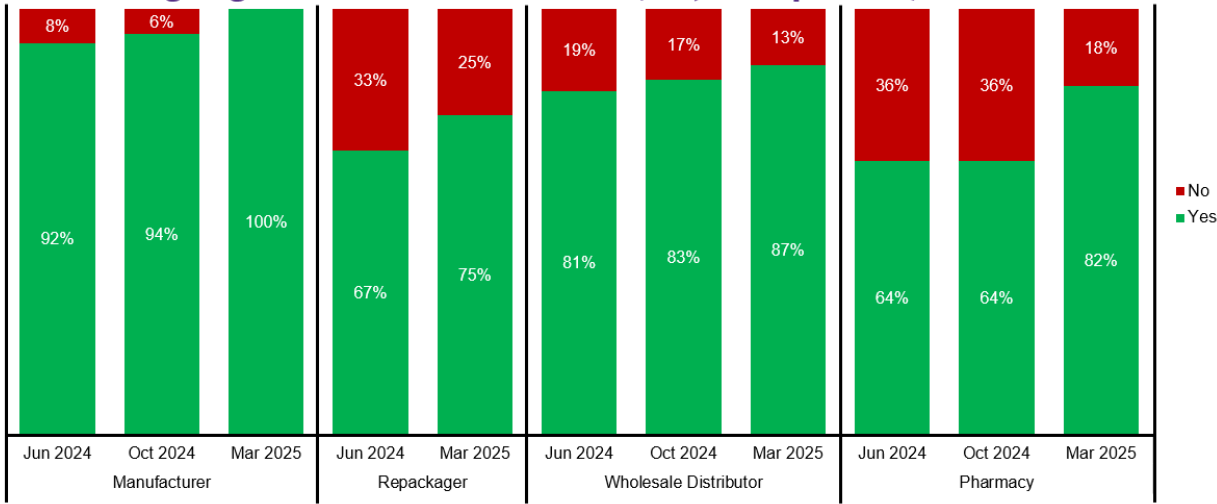
Do you have interoperable electronic systems and processes to facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer (i.e., trace product)?

The DSCSA also requires trading partners to implement electronic interoperable systems and processes to trace product back to the manufacturer.

As of March 2025, all manufacturer respondents—all respondents and the control group—indicated they have implemented electronic systems and processes to trace product in the event of a suspect/illegitimate product investigation or recall. Implementation rates were also high, but steady among repackagers, wholesalers, and dispensers across all three iterations of the survey.

Graph 17 (All Respondents)

Do you have interoperable electronic systems and processes to facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer (i.e., trace product)?

Graph 18 (Control Group)

Do you have interoperable electronic systems and processes to facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer (i.e., trace product)?