SERIALIZATION READINESS SURVEY

Executive Summary

HDA RESEARCH FOUNDATION

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INTRODUCTION

The Drug Supply Chain Security Act (DSCSA), enacted in 2013, preempted a 50-state patchwork of pedigree requirements to create one federal traceability solution for prescription medicines. The DSCSA sets out a 10-year phase-in to enable the tracing of prescription medicines throughout the pharmaceutical supply chain, with the final milestone quickly approaching.

For the past seven years, the HDA Research Foundation has conducted a *Serialization Readiness Survey* to benchmark the readiness of manufacturers and distributors to meet the DSCSA's product serialization requirements. The survey further provides healthcare supply chain stakeholders and others information on when distributors can expect to begin receiving serialized product and associated data, as well as perceptions of dispenser readiness.

Update on DSCSA Requirements

After November 27, 2018,[1] all manufacturers and repackagers were required to affix or imprint a product identifier[2] to each package and homogenous case of product intended to be introduced in a transaction into commerce.[3]

Beginning November 27, 2023,[4] before being able to resell a returned product, wholesale distributors must verify that the product identifier on the return is one affixed by the manufacturer [§ 582(c)(4)(D)]. To aid in the verification requirements, HDA facilitated a group of industry participants focused on creating a Verification Router Service (VRS) to help meet this "saleable returns" verification requirement. The final report to industry is available here. HDA and its members are also working with the supply chain on other systems and processes to help prepare trading partners for DSCSA requirements and deadlines.

Section 582(d)(4)(A)(ii)(II) of the law provides that dispensers must be able to verify the product identifier, including the standardized numerical identifier, of at least three packages or 10 percent of such suspect product (whichever is greater) or all packages, if there are fewer than three. Section 582(d)(4)(B)(iii) requires dispensers to verify product when they have received a notification of illegitimate product from FDA or a trading partner. These requirements originally went into effect on November 27, 2020, and FDA extended the compliance date to November 27, 2023.[5] FDA has emphasized that it does not intend to grant enforcement discretion and extend the deadline for compliance with the 2023 requirements.[6]

1. U.S. Food and Drug Administration. "Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry (September 2018)," 83 Fed. Reg. 47625 (September 20, 2018). https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf. The deadline for manufacturers was originally November 27, 2017, but effectively extended a year by the Food and Drug Administration (FDA).

2. §582(b)(2)(A), §582(e)(2)(A) of the Federal Food, Drug and Cosmetic Act (FDC Act).

3. Sections 582(c)(2), (d)(2), and (e)(2)(A)(iii) of the FD&C Act restrict trading partners' ability to engage in transactions involving packages and homogenous cases of product that are not labeled with a product identifier after specific dates, unless the product is grandfathered or subject to a waiver, exception or exemption. Beginning November 27, 2018, repackagers could not receive or transfer ownership of a package or homogenous case of a product that is not encoded with a product identifier; similar restrictions went into effect for wholesale distributors and dispensers on November 27, 2019, and November 27, 2020, respectively. See, e.g., §§ 582(c)(2), (d)(2), and (e)(2)(A)(iii); "Grandfathering Policy for Packages and Homogeneous Cases of Product Without a Product Identifier," 83 Fed. Reg. 47625 September 20, 2018).

4. "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies Guidance for Industry (October 2020)," 85 Fed. Reg. 67550 (Oct. 23, 2020). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/wholesale-distributor-verification-requirement-saleable-returned-drug-product-and-dispenser. The deadline was originally November 27, 2019, but effectively was extended a year by FDA in September of 2019 and then to 2023.

5. "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies Guidance for Industry" (October 2020), 85 Fed. Reg. 67550 (Oct. 23, 2020). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/wholesale-distributor-verification-requirement-saleable-returned-drug-product-and-dispenser.

6. In 2020, FDA extended the compliance date for certain verification obligations for wholesale distributors and dispensers to 2023. See: "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies Guidance for Industry (October 2020)," 85 Fed. Reg. 67550 (Oct. 23, 2020). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/wholesale-distributor-verification-requirement-saleable-returned-drug-product-and-dispenser. In this guidance, FDA emphasized that it was granting enforcement discretion so that industry could concentrate on 2023 implementation. In presentations, FDA has similarly emphasized the importance of 2023 readiness. In July 2022 the agency released a revised draft guidance recommending trading partners adopt and implement the GS1 EPCIS standard to provide and maintain the data associated with transaction information and transaction statements. See Interoperable Data Exchange Guidance.

By 2023, manufacturers, repackagers, wholesale distributors and dispensers must be able to exchange transaction information (including product identifiers) and transaction statements in a secure, interoperable and electronic manner.[7] FDA has recommended that trading partners use the GS1 US Electronic Product Code Information Services (EPCIS) standard to provide and maintain the data associated with transaction information and transaction statements.[8] FDA's announcement has eliminated any lingering uncertainty and should drive trading partner adoption and implementation of this global standard to meet the DSCSA's 2023 requirements.

In addition, trading partners must have systems and processes to promptly respond with the transaction information and transaction statement for a product and to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer— as applicable, and in response to appropriate requests.[9] The questions contained in this survey will address readiness of manufacturers and distributors as well as distributors' perceived readiness of dispensers.

METHODOLOGY

In June 2022, the HDA Research Foundation emailed confidential questionnaires to all manufacturer and distributor member contacts and past survey participants. Further, HDA distributor members were encouraged to distribute the survey link to their manufacturer trading partners.

All data were collected by Industry Insights (a leading and independent third-party research firm) and entered into a proprietary system, where they were blinded by Industry Insights' analysts to help ensure confidentiality. The data were compiled and thoroughly reviewed to help ensure consistency and coherence.

In all, 48 manufacturers and 29 distributors responded to the survey. Respondents included 16 of the 2020 top 20 pharmaceutical manufacturers by sales as listed by IQVIA. Manufacturer and distributor responses are presented in two separate sections within the report.

The statistical information contained in this report is believed to be representative of the manufacturers and distributors responding to the survey. However, statistical validity of any given number varies depending upon sample sizes and the amount of consistency among responses for that item. Industry Insights, therefore, makes no representations or warranties with respect to the results of this study and shall not be liable to the HDA Research Foundation, HDA, its members or anyone else for information inaccuracies, errors or omissions in content. Please note some tables may add up to more than 100 percent due to multiple responses being allowed for that question; tables where this is the case are labeled as such.

7. *See* § 582(g)(1)(A), (B).

8. "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry (July 2022)," 87 Fed. Reg. 40258 (July 6, 2022; Interoperable Data Exchange Guidance). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dscsa-standards-interoperable-exchange-information-tracing-certain-human-finished-prescription-drugs.

9. *See* § 582(g)(1)(D), (E).

MANUFACTURERS

Serialized Data and Data Exchange

Although not legally required to send serialized aggregated data until 2023, some manufacturers are already implementing FDA's July 2022 recommendations in the Interoperable Data Exchange Guidance. Namely, those companies report employing EPCIS to comply with the saleable returns requirement (in whole or in part) or have begun sending transaction data voluntarily to downstream purchasers in advance of the deadline. This section addresses plans to aggregate as well as company plans to send serialized data with product to downstream trading partners.

Among manufacturer respondents, 57.5 percent are aggregating data for all SKUs (unit to case). This is up from 45 percent last year. An additional 6 percent plan to aggregate data for all stock keeping units (SKUs) for each unit to a case by 2022. Among those that are already are aggregating, 72 percent have less than 150 SKUs and 71 percent have less than 15 lines. More than two-thirds (36 percent) noted that they plan to aggregate data for all SKUs by 2023.

Is your company planning to aggregate data (unit to case)?					
	Company Type	**Number of Products/SKUs on Manufacturing Side**		**Number of Product Manufacturing Lines**	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	47	29	18	17	25
Yes, we are already aggregating data for all SKUs (unit to case)	57.5%	72.4%	33.3%	70.6%	48.0%
Yes, all SKUs by 2022	6.4%	6.9%	5.6%	5.9%	4.0%
Yes, all SKUs by 2023	36.2%	20.7%	61.1%	23.5%	48.0%
Yes, some aggregation by 2022	0.0%	0.0%	0.0%	0.0%	0.0%
Yes, some aggregation by 2023	0.0%	0.0%	0.0%	0.0%	0.0%
No	0.0%	0.0%	0.0%	0.0%	0.0%
No, but currently sending data	0.0%	0.0%	0.0%	0.0%	0.0%
Awaiting FDA guidance to determine whether or not we will aggregate	0.0%	0.0%	0.0%	0.0%	0.0%

Thirty-two percent of manufacturers are currently sending serialized data to their wholesale distributor customers upon shipment. Sixty-six percent plan to do so by November 2023. Precariously, another 2 percent are still unsure of when they plan to exchange data with wholesale distributors. This number is down from 16 percent last year, indicating that although few manufacturers are currently sending serialized data today, more have shifted their timeline to send by 2023.

Beyond the use of serialized data in pilots, when do you anticipate first sending serialized data to your wholesale distributor customers upon shipment?					
	Company Type	Number of Products/SKUs on Manufacturing Side		Number of Product Manufacturing Lines	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	47	29	18	17	25
We are currently sending serialized data with shipped product	31.9%	44.8%	11.1%	41.2%	32.0%
We plan to begin to send serialized data with shipped product between 2022 and 2023	66.0%	55.2%	83.3%	58.8%	64.0%
We are unsure of when we will begin to send serialized data	2.1%	0.0%	5.6%	0.0%	4.0%

What percentage of serialized data are you currently providing for at least one product line?					
	Company Type	Number of Products/SKUs on Manufacturing Side		Number of Product Manufacturing Lines	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	46	28	18	17	25
0%	45.7%	35.7%	61.1%	47.1%	40.0%
1–5%	0.0%	0.0%	0.0%	0.0%	0.0%
6–10%	6.5%	0.0%	16.7%	0.0%	8.0%
11–15%	2.2%	0.0%	5.6%	0.0%	4.0%
16–20%	0.0%	0.0%	0.0%	0.0%	0.0%
21–25%	0.0%	0.0%	0.0%	0.0%	0.0%
26–50%	4.4%	7.1%	0.0%	0.0%	8.0%
51–75%	0.0%	0.0%	0.0%	0.0%	0.0%
76–100%	41.3%	57.1%	16.7%	52.9%	40.0%

As the sector nears the deadline, 24 percent of manufacturers plan to send serialized data along with 100 percent of product in 2022. Most manufacturers, 76 percent, anticipate sending 100 percent of data with shipped product by November 27, 2023, when it is legally required.

When do you anticipate sending serialized data along with shipped product for:					
	Company Type	Number of Products/SKUs on Manufacturing Side		Number of Product Manufacturing Lines	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
25% of shipped product					
(N)	17	6	11	*	11
2022	82.4%	83.3%	81.8%	*	72.7%
2023	17.7%	16.7%	18.2%	*	27.3%
50% of shipped product					
(N)	21	10	11	*	12
2022	57.1%	60.0%	54.6%	*	66.7%
2023	42.9%	40.0%	45.5%	*	33.3%
75% of shipped product					
(N)	23	10	13	5	13
2022	39.1%	50.0%	30.8%	80.0%	30.8%
2023	60.9%	50.0%	69.2%	20.0%	69.2%
100% of shipped product					
(N)	45	29	16	17	23
2022	24.4%	37.9%	0.0%	41.2%	17.4%
2023	75.6%	62.1%	100.0%	58.8%	82.6%

Note: * indicates insufficient data

Does your company plan to exchange data via EPCIS with distributors for all products with wholesale distributors?					
	Company Type	Number of Products/SKUs on Manufacturing Side		Number of Product Manufacturing Lines	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	47	29	18	17	25
We are currently piloting or testing EPCIS, but not utilizing it in a production environment	25.5%	17.2%	38.9%	17.7%	24.0%
Present-end of 2022	38.3%	51.7%	16.7%	52.9%	32.0%
By 2023	27.7%	24.1%	33.3%	23.5%	36.0%
Unsure	2.1%	0.0%	5.6%	0.0%	4.0%
We do not intend to use EPCIS	2.1%	3.5%	0.0%	5.9%	0.0%
Other	4.3%	3.5%	5.6%	0.0%	4.0%

Most manufacturers (87 percent) are currently using EPCIS version 1.2 — a necessary component for 2023 compliance.[10] Thirteen percent are operating on 1.1 and 1.0 with 17 percent planning to transition to 1.2 in 2022 and 83 percent planning to transition in 2023. Once 1.3 is published, 28 percent of those currently using 1.2 plan to transition with 69 percent still undecided. To learn more about manufacturer and distributor EPCIS connections and perceived benefits, see *HDA's EPCIS Implementation Benchmarking Survey*.

If your company uses EPCIS, please indicate what version:					
	Company Type	**Number of Products/SKUs on Manufacturing Side**		**Number of Product Manufacturing Lines**	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	45	27	18	16	25
EPCIS 1.0	2.2%	0.0%	5.6%	0.0%	4.0%
EPCIS 1.1	11.1%	11.1%	11.1%	18.8%	8.0%
EPCIS 1.2	86.7%	88.9%	83.3%	81.3%	88.0%
If your company uses EPCIS 1.0 or 1.1, please indicate when you will be transitioning to 1.2 in order to meet the 2023 requirements:					
(N)	6	*	*	*	*
2022	16.7%	*	*	*	*
2023	83.3%	*	*	*	*
If your company uses EPCIS 1.2, do you have expectations to move to 1.3 once it is published?					
(N)	39	24	15	13	22
Yes	28.2%	25.0%	33.3%	38.5%	18.2%
No	2.6%	0.0%	6.7%	0.0%	4.6%
Haven't decided	69.2%	75.0%	60.0%	61.5%	77.3%

Note: * indicates insufficient data

10. While the DSCSA does not require EPCIS 1.2, a key requirement is that the standards for the interoperable exchange of transaction data must comply with a form and format developed by a widely recognized international standards development organization [§ 583(h)(4)(A)(i)]. Currently, EPCIS is the only internationally recognized standard that FDA has endorsed to meet DSCSA requirements for the interoperable electronic exchange of transaction data and support the inclusion of product identifiers [see, e.g., § 581(14); § 582(a)(2)(A); § 582(h)(4)(A)(i)].

Saleable Returns Verification & Sending and Receiving Serialized Data

Enforcement discretion granted in 2020 moved the deadline to verify saleable returns to November 27, 2023; however, the association requirement is in place today. Additionally, some wholesalers are currently verifying saleable returns on a voluntary basis. Manufacturers were asked to identify their concerns with supporting the requirement. The majority, 84 percent, have no concerns. Of the 16 percent who did have concerns, viability of the VRS was the predominant concern, followed by lack of or inadequate FDA guidance on the verification requirement, inability to yet send aggregated data and other.

As a manufacturer, do you have concerns about your ability to support your wholesale distributors' 2019 saleable returns verification requirement?					
	Company Type	**Number of Products/SKUs on Manufacturing Side**		**Number of Product Manufacturing Lines**	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	45	28	17	16	24
Yes	15.6%	7.1%	29.4%	6.3%	20.8%
No	84.4%	92.9%	70.6%	93.8%	79.2%
If yes, why? *(multiple responses allowed)*					
(N)	6	*	*	*	*
Challenges with EPCIS	16.7%	*	*	*	*
Concerns with the viability of the Verification Router Service	50.0%	*	*	*	*
Challenges with managing/storing serialized data	16.7%	*	*	*	*
Issues with solution providers	0.0%	*	*	*	*
Lack of or inadequate FDA guidance on the verification requirement	33.3%	*	*	*	*
Inability to yet send aggregated data	33.3%	*	*	*	*
Issues receiving serialized data from CMOs to verify against	16.7%	*	*	*	*
Issues with mechanical product availability and functionality, e.g., cameras, scanners, etc.	16.7%	*	*	*	*
Resource constraints, e.g., qualified systems integration professionals	16.7%	*	*	*	*
Other	33.3%	*	*	*	*

Note: * indicates insufficient data

When asked how their company intends to support verification requests, it is clear multiple methods will be used: 81 percent plan to send EPCIS files with product identifiers[11] (up from 61 percent from last year); 91 percent plan to use the VRS; 36 percent plan to use phone calls or emails; and 11 percent plan to use a portal.

How does your company plan to support verification requests for the saleable returns verification requirement? *(multiple responses allowed)*					
	Company Type	**Number of Products/SKUs on Manufacturing Side**		**Number of Product Manufacturing Lines**	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	47	29	18	17	25
We plan to send EPCIS files with product identifiers to our wholesale distributors	80.9%	82.8%	77.8%	82.4%	80.0%
We plan to utilize the VRS when available	91.5%	86.2%	100.0%	82.4%	96.0%
We plan to build a portal	10.6%	3.5%	22.2%	0.0%	16.0%
We plan to use phone calls/email	36.2%	27.6%	50.0%	29.4%	36.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%

Survey results indicate that manufacturers handle verification requests from non-direct purchasers in a range of ways. Almost a third, 30 percent, have manual processes to support non-direct purchasers; another two-thirds, 68 percent, expect to use a VRS; and 45 percent anticipate that their direct trading partner will conduct a verification request on their behalf.

How does your company plan on supporting verification requests for non-direct purchasers (e.g., a dispenser that purchases product from one of your wholesale distributor trading partners)? *(multiple responses allowed)*					
	Company Type	**Number of Products/SKUs on Manufacturing Side**		**Number of Product Manufacturing Lines**	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	47	29	18	17	25
We have a manual process to respond to non-direct purchasers	29.8%	37.9%	16.7%	35.3%	28.0%
We anticipate using a VRS when available	68.1%	65.5%	72.2%	58.8%	76.0%
We anticipate our direct trading partners will conduct a verification request on behalf of non-direct purchasers	44.7%	51.7%	33.3%	64.7%	36.0%
Unsure	8.5%	10.3%	5.6%	5.9%	8.0%
Other	6.4%	3.5%	11.1%	0.0%	8.0%

11. This method of verification, sometimes referred to as "verification against replicate data," allows a wholesale distributor to verify a product identifier on a saleable return against the data it received from the manufacturer in certain defined circumstances.

2023 Interoperability

Manufacturers noted several key challenges for meeting the DSCSA's 2023 requirements. The top three reasons cited were collaboration with trading partners (51 percent), governance of the interoperable system for 2023 (49 percent) and differences in interpretation of the law (34 percent).

Other key challenges noted included: technical challenges, concerns about resources, dispenser readiness, regulatory guidances, data quality and supply chain shortages. Full open-ended responses can be found in the Appendix.

From your perspective, what are the key challenges for meeting the DSCSA's 2023 requirements? *(multiple responses allowed)*					
	Company Type	**Number of Products/SKUs on Manufacturing Side**		**Number of Product Manufacturing Lines**	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	47	29	18	17	25
Collaboration with trading partners	51.1%	41.4%	66.7%	47.1%	56.0%
Collaboration with solution providers	21.3%	24.1%	16.7%	23.5%	24.0%
Defining a vision	12.8%	10.3%	16.7%	5.9%	20.0%
Technical challenges	31.9%	17.2%	55.6%	11.8%	44.0%
Establishing standards	21.3%	24.1%	16.7%	23.5%	20.0%
Governance of the interoperable system for 2023	48.9%	51.7%	44.4%	52.9%	44.0%
Connectivity and related security (communication and connections)	19.2%	20.7%	16.7%	23.5%	16.0%
Differences in interpretation of the law	34.0%	41.4%	22.2%	41.2%	28.0%
Other	19.2%	13.8%	27.8%	11.8%	20.0%

What is currently your biggest concern regarding overall DSCSA implementation?					
	Company Type	**Number of Products/SKUs on Manufacturing Side**		**Number of Product Manufacturing Lines**	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	47	29	18	17	25
Collaboration with trading partners	17.0%	17.2%	16.7%	23.5%	16.0%
Collaboration with solution providers	2.1%	3.5%	0.0%	0.0%	4.0%
Defining a vision	0.0%	0.0%	0.0%	0.0%	0.0%
Technical challenges	14.9%	6.9%	27.8%	5.9%	20.0%
Establishing standards	6.4%	3.5%	11.1%	5.9%	4.0%

What is currently your biggest concern regarding overall DSCSA implementation? *(continued)*					
	Company Type	**Number of Products/SKUs on Manufacturing Side**		**Number of Product Manufacturing Lines**	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
Governance of the interoperable system for 2023	25.5%	31.0%	16.7%	29.4%	28.0%
Connectivity and related security (communication and connections)	12.8%	10.3%	16.7%	11.8%	8.0%
Differences in interpretation of the law	8.5%	10.3%	5.6%	11.8%	8.0%
Other	12.8%	17.2%	5.6%	11.8%	12.0%

Forty percent of manufacturers are conducting pilots. Most of these pilots are externally focused on returns verification requirements and 2023 interoperability; other pilots are testing credentialing, tracing pilots, drop ships and enhanced recalls.

Is your company conducting or participating in DSCSA related pilots?					
	Company Type	**Number of Products/SKUs on Manufacturing Side**		**Number of Product Manufacturing Lines**	
	Manufacturer	Less than 150	150 or More	Less than 15	15 or More
(N)	47	29	18	17	25
Yes	40.4%	37.9%	44.4%	23.5%	48.0%
No	59.6%	62.1%	55.6%	76.5%	52.0%
If yes, check all that apply: *(multiple responses allowed)*					
(N)	19	11	8	*	12
Internal					
Wholesale distributor returns verification	21.1%	27.3%	12.5%	*	25.0%
Dispenser requirements	0.0%	0.0%	0.0%	*	0.0%
2023 interoperability	10.5%	18.2%	0.0%	*	8.3%
Other DSCSA-related pilot topics	5.3%	9.1%	0.0%	*	8.3%
External *(with trading partners)*					
Wholesale distributor returns verification	73.7%	72.7%	75.0%	*	75.0%
Dispenser requirements	10.5%	9.1%	12.5%	*	16.7%
2023 interoperability	36.8%	36.4%	37.5%	*	41.7%
Other DSCSA-related pilot topics	31.6%	18.2%	50.0%	*	41.7%

Note: * indicates insufficient data

DISTRIBUTORS

This is the fourth year that distributors have been included in the survey. The goal of their participation is to understand their ability to send and receive serialized data (to implement verification of saleable returns requirements and 2023 interoperable data exchange), whether they are using or intend to use the VRS for verification saleable returns and distributors' perceptions of dispenser readiness.

Saleable Returns Verification & Sending and Receiving Serialized Data

Forty-five percent of distributors have concerns with meeting the saleable returns verification requirement. Complete availability of master data (including lookup directory connectivity) ranked the highest as reason for concern with meeting the saleable return verification requirement,[12] followed by accuracy and completeness of data exchange, challenges receiving EPCIS files and concerns of challenges with or viability of the VRS.

The preferred approaches to complying with the saleable returns verification requirement are VRS (69 percent), followed by EPCIS (65 percent), phone calls or emails (28 percent up from 16 percent in 2021) and portals (24 percent). Distributors noted that the most important factors in identifying preferred approaches were efficiency (83 percent), automated approach (79 percent) and less error prone (38 percent).

As a distributor, do you have concerns about meeting the saleable return verification requirement?	
	Company Type
	Distributor
(N)	29
Yes	44.8%
No	55.2%
If yes, why? *(multiple responses allowed)*	
(N)	13
Operational concerns, e.g., ability to conduct verification requests	38.5%
Internal constraints, e.g., resources to acquire suitable scanners; personnel/training	30.8%
Challenges receiving EPCIS files	53.9%
Challenges with/viability of the VRS	53.9%
Accuracy and completeness of data exchange	69.2%
Complete availability of master data	84.6%
Other	15.4%

12. FDA granted enforcement discretion on the verification of saleable returns on September 23, 2019, and, in October 2020, extended compliance to November 27, 2023.

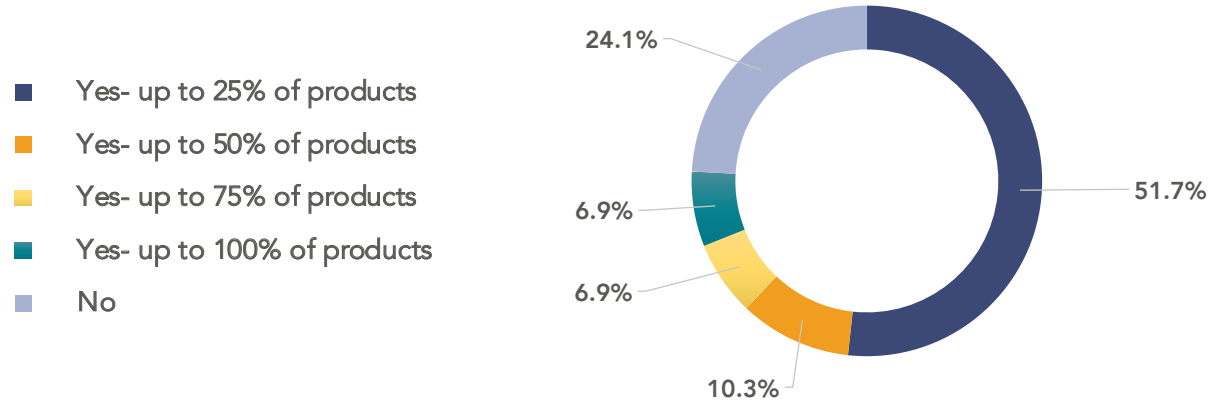
What are your company's preferred approaches to complying with the saleable returns verification requirement? *(multiple responses allowed)*	
	Company Type
	Distributor
(N)	29
We plan to check against EPCIS files received from manufacturers	65.5%
The VRS when available	69.0%
A manufacturer's portal	24.1%
Phone calls/email	27.6%
Other	10.3%

In identifying your preferred approaches to complying with the saleable returns verification requirement, what factors are most important? *(multiple responses allowed)*	
	Company Type
	Distributor
(N)	29
Volume (low or high)	34.5%
Efficiency	82.8%
Automated approach	79.3%
Less error prone	37.9%
Lower cost	10.3%
Prefer to house data internally/concern about external points of failure	17.2%
Utilizes existing process	3.5%
Other	0.0%

Are you able to accept serialized data today?	
	Company Type
	Distributor
(N)	29
Yes	62.1%
No	37.9%
If no, when do you anticipate being able to accept serialized data:	
(N)	11
2022	63.6%
2023	36.4%

Having access to and provision of accurate master data is necessary for both VRS and interoperable exchange of transaction data in 2023. Fifty-two percent of distributors have received master data for up to 25 percent of products, up from 44 percent in 2021. A quarter of distributors (24 percent) reported receiving no master data, down from 36 percent in 2021. The most popular method for submitting master data was spreadsheets (59 percent), followed by the HDA new product form (55 percent) and, the GS1 Global Data Synchronization Network (GDSN) (32 percent).

Have you received master data from your upstream trading partners?



If yes, what method or format is your supplier utilizing? *(multiple responses allowed)*	
	Company Type
	Distributor
(N)	22
Spreadsheets	59.1%
HDA new product form	54.6%
GS1 GDSN	31.8%
Other format	13.6%

While receiving EPCIS files is the preferred approach of some distributors, only 62 percent can accept serialized data today. Notably, 100 percent of respondents have already migrated to EPCIS version 1.2, which is necessary for 2023 compliance, with 21 percent planning to move to 1.3 once published.

If your company uses EPCIS, please indicate what version:	
	Company Type
	Distributor
(N)	20
EPCIS 1.0	0.0%
EPCIS 1.1	0.0%
EPCIS 1.2	100.0%

If your company uses EPCIS 1.2, do you have expectations to move to 1.3 once it is published?	
(N)	19
Yes	21.1%
No	0.0%
Haven't decided	79.0%

According to distributors, few manufacturers are sending serialized data today via EPCIS. Eighteen percent are receiving no serialized data at all today. Only 7 percent of distributors noted that 76–100 percent of their manufacturer suppliers are providing serialized data on at least one product line.

Twenty-nine percent of distributors reported that they are currently receiving serialized data from 1–5 percent of manufacturers on at least one product line, followed by 6–10 percent of manufacturers (14 percent of distributors) and 26-50 percent of manufacturers (11 percent of distributors).

What percentage of your manufacturer suppliers are currently providing serialized data for at least one product line?	
	Company Type
	Distributor
(N)	28
0%	17.9%
1–5%	28.6%
6–10%	14.3%
11–15%	7.1%
15–20%	7.1%
21–25%	3.6%
25–50%	10.7%
51–75%	3.6%
76–100%	7.1%

Nearly half of distributors (46 percent) indicate that none of their transactions are accompanied by serialized data today with another 46 percent of distributors receiving serialized data for 1–5 percent of transactions.

What percentage of the transactions are currently accompanied by serialized data?	
	Company Type
	Distributor
(N)	28
0%	46.4%
1–5%	46.4%
6–10%	0.0%
11–15%	3.6%
15–20%	0.0%
21–25%	0.0%
25–50%	3.6%
51–75%	0.0%
76–100%	0.0%

New to the survey, 46 percent of distributors stated that between 1–5 percent of manufacturers are providing serialized data for total product lines, while 25 percent noted that no manufacturers are providing these data today.

What percentage of your manufacturer suppliers are currently providing serialized data for total product lines?	
	Company Type
	Distributor
(N)	28
0%	25.0%
1–5%	46.4%
6–10%	10.7%
11–15%	3.6%
15–20%	0.0%
21–25%	3.6%
25–50%	3.6%
51–75%	3.6%
76–100%	3.6%

2023 Interoperability

From a distributor perspective, the top four challenges to meeting 2023 interoperability are collaboration with trading partners (90 percent), technical challenges (72 percent), establishing standards (48 percent) and connectivity and related security (48 percent). Among these challenges, distributors' key concerns are collaboration with trading partners (41 percent) and technical challenges (21 percent).

From your perspective, what are the key challenges for meeting the DSCSA's 2023 requirements? *(multiple responses allowed)*	
	Company Type
	Distributor
(N)	29
Collaboration with trading partners	89.7%
Collaboration with solution providers	44.8%
Defining a vision	31.0%
Technical challenges	72.4%
Establishing standards	48.3%
Governance of the interoperable system for 2023	44.8%
Connectivity and related security (communication and connections)	48.3%
Differences in interpretation of the law	37.9%
Other	17.2%

What is currently your biggest concern regarding overall DSCSA implementation?	
	Company Type
	Distributor
(N)	29
Collaboration with trading partners	41.4%
Collaboration with solution providers	6.9%
Defining a vision	0.0%
Technical challenges	20.7%
Establishing standards	10.3%
Governance of the interoperable system for 2023	6.9%
Connectivity and related security (communication and connections)	3.5%
Differences in interpretation of the law	6.9%
Other	3.5%

Distributor Perceptions of Dispensers

Dispensers must be able to verify the product identifier, including the standardized numerical identifier, of at least three packages or 10 percent of such suspect product (whichever is greater), or all packages, if there are fewer than three, further, dispensers are required to verify product when they have received a notification of illegitimate product from FDA or a trading partner. These requirements originally went into effect on November 27, 2020, but FDA extended the compliance date to November 27, 2023.[13] To measure the perceived readiness of dispensers, distributors were asked two distinct questions:

- Do they think their dispenser customers understand the current requirements (to only accept product with product identifiers and conduct suspect product investigations)?
- Do they think their dispenser customers understand what is required of them in the future for 2023 requirements?

Forty-five percent of responding distributors stated that their dispenser customers' understanding of DSCSA requirements for 2023 varies considerably. Roughly a third of responding distributors do not believe their dispenser customers understand what is required and 17 percent are unsure of whether their customers understand the 2023 obligations. None of the surveyed distributors reported that it believed its dispenser customers understand their current obligations (regarding acceptance of products with product identifiers and suspect product investigations). Similarly, no wholesale distributor reported that its dispenser customers understand what is required of them for 2023 and beyond.

Do your dispenser customers understand what's required of them to only accept products with product identifiers and to investigate a suspect product? *(These are the 2020 requirements that FDA announced are subject to enforcement discretion until 2023)*	
	Company Type
	Distributor
(N)	29
Yes	0.0%
No	27.6%
Varies considerably	55.2%
Unsure	17.2%

Do your dispenser customers understand what's required of them in 2023 and beyond?	
	Company Type
	Distributor
(N)	29
Yes	0.0%
No	37.9%
Varies considerably	44.8%
Unsure	17.2%

13. "Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies Guidance for Industry (October 2020)" 85 Fed. Reg. 67550 (Oct. 23, 2020). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/wholesale-distributor-verification-requirement-saleable-returned-drug-product-and-dispenser.

When asked to identify the customer segments most or least educated about the DSCSA implementation requirements, independent pharmacies were identified most frequently, with 67 percent of distributors reporting that independent pharmacy customers do not understand what is expected of them. Health systems (75 percent), chain drug stores (74 percent) and hospitals (70 percent) all ranked higher with distributors reporting they are somewhat educated on DSCSA requirements.

How would you rate the understanding of the following customer segments?	
	Company Type
	Distributor
Independent pharmacies	
(N)	27
Educated on DSCSA requirements	3.7%
Somewhat educated on DSCSA requirements	29.6%
Does not understand DSCSA requirements	66.7%
Chain stores	
(N)	23
Educated on DSCSA requirements	17.4%
Somewhat educated on DSCSA requirements	73.9%
Does not understand DSCSA requirements	8.7%
Health systems	
(N)	24
Educated on DSCSA requirements	8.3%
Somewhat educated on DSCSA requirements	75.0%
Does not understand DSCSA requirements	16.7%
Hospitals	
(N)	23
Educated on DSCSA requirements	13.0%
Somewhat educated on DSCSA requirements	69.6%
Does not understand DSCSA requirements	17.4%
Other	
(N)	*
Educated on DSCSA requirements	*
Somewhat educated on DSCSA requirements	*
Does not understand DSCSA requirements	*

Note: * indicates insufficient data

There were several open-ended responses around the biggest perceived challenges facing dispenser customers. Dispenser education and technical challenges were noted issues. Limitations — such as not having infrastructure or software in place, not understanding the system and process changes needed to implement 2023 requirements and reconciliation of data/product discrepancies — were common themes. Additional open-ended responses are available in the Appendix.

To promote DSCSA-related education and overall awareness within the dispenser community, HDA and a group of pharmaceutical organizations developed a website to compile a range of resources for dispensers. The page includes checklists, podcasts and webinars to ensure dispensers are prepared to comply with the law. The page also provides an overview of DSCSA; key milestones (including when manufacturers, distributors and dispensers must provide and receive transaction information and statements in a secure, electronic and interoperable manner); and which dispensers are covered by the DSCSA's requirements.

CONCLUSION

In the final stretch of DSCSA implementation, there continues to be uneven readiness as supply chain partners prepare for the 2023 milestone. FDA's granting of enforcement discretion in 2020 until 2023 for certain wholesale distributor and dispenser requirements, while very beneficial for the industry, has resulted in a perception among some trading partners that they can defer necessary 2023 investments and onboarding to the deadline. As this survey has shown over the past several years, there are those who plan to implement and onboard ahead of schedule and those continuing to prepare for implementation as laid out in the law.

Notably, 2 percent of manufacturers are still unsure of when they plan to exchange data with wholesale distributors. While this number is down from 16 percent last year, it is concerning. An additional 32 percent of manufacturers are currently sending serialized data to their wholesale distributor customers upon shipment and 66 percent plan to do so by November 2023.

In a positive shift from 2021, most manufacturer respondents are planning to aggregate all SKUs by this year. Fifty-eight percent are already aggregating and another 6 percent plan to do so in 2022. While this number is starting to trend upwards, there are still 36 percent planning to do so by 2023. Since aggregation is a necessary pre-requisite to sending data, it still calls into question when in 2023 manufacturers will be able to send corresponding data along with shipped product.

This year, 24 percent of manufacturers plan to send serialized data along with 100 percent of product in 2022. Another 76 percent indicate that they anticipate sending serialized data with 100 percent of shipped product in 2023, when it is legally required.

Distributors are also still preparing for data exchange with 100 percent of distributors using EPCIS 1.2. However, only 62 percent can accept serialized data today. For those that cannot accept data today, 64 percent plan to be ready sometime in 2022 and 36 percent plan to be ready in 2023. In a new data point, 46 percent of distributors stated that between 1–5 percent of manufacturers are providing serialized data for total product lines with 25 percent noting that no manufacturers are providing data for total product lines. Even though most distributors can accept serialized data, many of their manufacturer suppliers are not providing data for total product lines, which calls into question the operational impact of receiving all data by November 27, 2023.

Top reported concerns regarding overall implementation were governance of the interoperable system, collaboration with trading partners and technical challenges. Moreover, dispenser knowledge of DSCSA requirements continues to be an additional highlighted concern for distributors. The perceived knowledge across industry segments continues to be low, especially among independent pharmacies. As the open-ended comments indicated, educating dispensers with accurate information is critical and will continue to present issues going forward.

APPENDIX

Manufacturer Responses	
3. As a manufacturer, do you have concerns about your ability to support your wholesale distributors' saleable returns verification requirement? Other explanation or comment.	Trying to kill VRS Important manufacturing tool
3. If yes, "other" concerns	There are HDA members that will be doing self verifying but a majority will be using VRS including dispensers. This tool is very important
	We have a VRS in place currently, while our 3PL implements connections with our customers.
	We have been live with the VRS
	What we're experiencing now is that we will not be able to complete the EPCIS implementation connections with all of our partners because of resource constraints and timeline/availability coordination among our serialization data provider, our 3PL and our partner's *[sic.]* system teams. In other words, they all need to be available to support testing and implementation at the same time.
9. Does your company plan to exchange data via EPCIS with distributors for all products with wholesale distributors? If so, when? "Other" responses.	1-Mar-23 (Before compliance deadline)
	EPCIS has been used for several years, also to exchange data with external parties (3PLs, CMO business). The traceability aspect for DSCSA has not been activated as of now.
	We would monitor industry progression in terms of data exchange requirements to meet 2023 deadline and align with existing solution providers in the market
10. How does your company plan to support verification requests for the saleable returns verification requirement? "Other" responses.	Our VRS is active and available
11. How does your company plan on supporting verification requests for non-direct purchasers? "Other" responses..	Our VRS is active and available
	SAP Portal
	We hope that VRS solution is extended beyound saleable returns use case, and in this case to support dispenser verification directly with a manufacturer
13. From your perspective, what are the key challenges for meeting the DSCSA's 2023 requirements? "Other" responses.	3PL is not ready
	Concerned about Dispenser readiness and timely release of regulatory guidances (+ state regulator readiness and how FDA will interact with industry)
	Cost
	Data quality and PDG not presenting a true picture of the systems and what in production and developed with the FDA observing
	Establishing standards in governance of the interoperability and differences in interpretation of the law.
	Large financial burden/additional man hours needed placed on us
	Resources and uncertainty on what to build for a tracing system
	Supply Chain Shortages and Equipment Delays
	Unknowns with new process

Manufacturer Responses *(continued)*	
14. What is currently your biggest concern regarding overall DSCSA implementation? "Other" responses.	Concerned about Dispenser readiness and timely release of regulatory guidances (+ state regulator readiness and how FDA will interact with industry)
	Cost
	Exception Handling
	Lack of adequate personnel and training
	Lack of US FDA oversight in establishing the system poses a compliance risk and engagement in the Partnership for DSCSA Governance. Lack of proactive guidance with regard to serialized but not aggregated product grand-fathering from the FDA.
	Our 3PL is not ready, and doesn't believe they need to be until 2023.
	Unknowns with new process
15. Is your company conducting or participating in DSCSA related pilots? "Other" responses	AB Data Exchange Pilot, Tracing Pilots (NABP and PDG), Credentialing
	Credentialing
	Data Analytics
	NABP, PDG, XATP
	PDG table top exercise
	Tracing, drop ships and enhanced recalls

Distributor Responses	
1. As a distributor, do you have concerns about meeting the saleable return verification requirement? "Other" responses.	Partner readiness
If yes, why? "Other" responses.	Also, lack of clarity of dispenser requirements from the FDA.
	As a direct purchasing distributor we will be verifying against replicate data for the most part. As we can only accept a return for product we previously sold, there is a high correlation between receiving serial transaction data and the verification requirement.
	From what we are hearing it seems like many manufacturer's still have quite a bit to work to do before the November 2023 deadline. We are working with LSPedia to meet the deadline on our behalf.
2. What are your company's preferred approaches to complying with the saleable returns verification requirement? "Other" responses.	GS1 website and Internal transactions from ASN's, 856's and Lot numbers
	Systemic checks
	VRS is primary but will use EPCIS or MFR portal if required by MFR not using VRS
10. If yes, what method or format is your supplier utilizing? "Other" responses.	Email notifications
	Sometimes just a PDF of data
	TraceLink

Distributor Responses *(continued)*	
11. From your perspective, what are the key challenges for meeting the DSCSA's 2023 requirements? "Other" responses.	Exception handling
	Exception Processes - Data doesn't match product
	Resources of employees to implement
	Timing of when all data must be sent is a concern. Many suppliers want to wait until close to 11/2023.
	Workload
	Exception Processes - Data doesn't match product
13. Is your company conducting or participating in DSCSA related pilots? "Other" responses.	2023 scanning and data exchange
14. Has the delay in FDA's issuance of national licensure standards for wholesale distributors adversely affected your business? If yes, in what ways?	Confusion with some States adapting to DSCSA and others not. Comes in to play when [there are] differences between home State and out of State requirements. Delays licensing and causes extra work.
	Not serious, but the vast differences across states require a LOT of phone calls for our compliance team to ensure we are compliant in each state.
	Redundant license costs
	the differences in the approach by each state, NABP and state inspection variability, the time and effort to implement what will be in the FDA license requirement this is exasperated with what we are doing to implement EPCIS for 2023
	We are still required to go through the NABP reaccreditation inspections and pay all of their fees annually as a requirement to obtain a couple of our state licenses.
16. How would you rate the understanding of the following customer segments? "Other" responses.	Dispensing physicians (MDs)
18. What do you perceive to be the biggest challenge for your dispenser customers?	Ability to use automation and electronically handle transactions so that it does not become a burden in their already chaotic and busy environment as well as fully understanding suspect product protocols and procedures. Furthermore I do not believe the education of the laws and requirements and implications have reached to downstream team members in the dispenser segment, e.g. Dispenser Buyer understands what is needed in documentation and suspect product protocols however the actual receiver of the product sometimes a nurse or other staff member does not fully understand and therefore creates an immediate danger for the entire effort of serialization to collapse at the very most important moment, i.e right before the patient receives treatment of prescribed medication.
	Compliance.
	Consistency in process across many various suppliers.
	Data sync
	Education.
	Getting the attention of the dispensers to be able to assist in educating or to point them in the right direction.
	Getting them the knowledge and having the understanding of how DSCSA will affect their business.

Distributor Responses *(continued)*	
18. What do you perceive to be the biggest challenge for your dispenser customers? *(continued)*	Having any infrastructure/software in place to receive the data. Also, I have not talked to a single independent pharmacist who actually knows exactly what they need to do, they are busy filling prescriptions.
	Not aware or focused on meeting requirements.
	Not understanding the system and process changes that they have to implement to meet requirements. Also the technical challenges of implementing these processes. Additionally, there are different interpretations of the law which make it difficult to define a standard process for all dispensers.
	Reconciliation of data/product discrepancies. Potential delays in availability of product to patients. Resources (people and hardware/systems).
	Segregating myth from fact on their obligations. Service companies are selling into fear and lack of understanding by the dispenser. Dispenser obligation is quite narrow, most important is suspect and illegitimate investigation requirements and having SOPs to comply and for audit needs.
	Technological compliance
	Technology limitations and knowledge of regulations especially in the rural, independent pharmacy setting.
	The extra time it will take to deal with checking in product and verifying serial numbers, data points and exceptions. Plus the lack of skilled IT staff to navigate system integrations.
	The technology to comply with the requirements.
	They have no idea what is required of them to meet DSCSA requirement
	Understanding that they need to validate product received from distributors. And planning for the additional time/cost incurred in their receiving process.
	Understanding the regulation and what they are responsible for in regards to the requirements, especially independent pharmacies.
	Understanding what is expected of them and meeting the technical requirements
	What is and is not required by wholesalers and obtaining their transactional information online

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