SERIALIZATION READINESS SURVEY

Executive Summary

HDA RESEARCH FOUNDATION

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INTRODUCTION

For the fifth year in a row, the HDA Research Foundation conducted the *Serialization Readiness Survey* to provide The Healthcare Distribution Alliance (HDA) and its members with unbiased, objective data about the current readiness of manufacturers and distributors to meet the DSCSA's product serialization requirements, when distributors can expect to begin receiving serialized product and associated data, and perceptions of dispenser readiness.

The Drug Supply Chain Security Act (DSCSA) was enacted in 2013, preempting 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 full traceability, and the next milestones are approaching. As originally outlined in DSCSA, beginning November 27, 2019, before being able to resell a returned product, wholesale distributors must verify that the product identifier on the return is the one affixed by the manufacturer [§ 582(c)(4)(D)]. The FDA first granted enforcement discretion, effectively extending the deadline for a year in 2019.[1] On October 22, 2020 the FDA again granted enforcement discretion on these requirements until November 27, 2023.[2] 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" requirement. The final report to industry is available on the HDA website. HDA and its members also are working with the supply chain on other systems and processes to help prepare trading partners for DSCSA requirements and deadlines.

As stated in the DSCSA on November 27, 2020, dispensers only may engage in transactions with products that have a product identifier affixed to the unit or the case, unless a product is grandfathered.[3] Additionally, in the case of a suspect product, dispensers must ensure that the product's lot number corresponds with the lot number of the product and the product identifier of at least three packages — or 10 percent of suspect product, whichever is greater, or all packages if fewer than three — corresponds with the product identifier for such a product. However, on October 22, 2020, FDA granted enforcement discretion to dispensers until November 27, 2023, for this requirement.[4]

By 2023, manufacturers, distributors and dispensers must be able to exchange transaction information, including product identifiers and transaction statements in a secure, interoperable and electronic manner. In addition, trading partners also 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. The questions contained in this survey will address readiness of manufacturers and distributors and perceived readiness of dispensers.

1 *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy Guidance for Industry* (September 2019), https://www.fda.gov/media/131005/download; (Sept. 24, 2019) 84 Fed. Reg. 50044. The deadline was originally November 27, 2019, but effectively extended a year by FDA.

2 *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). https://www.fda.gov/media/131005/download, 85 FR 67550 (October 22, 2020)

3 *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). https://www.fda.gov/media/131005/download, 85 FR 67550 (October 22, 2020)

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*; Availability, 85 FR 67550 (October 22, 2020) https://www.federalregister.gov/d/2020-23524

METHODOLOGY

In May 2020, the HDA Research Foundation distributed confidential questionnaires via email to all manufacturer and distributor member contacts and past survey participants. HDA distributor members also 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, 57 manufacturers and 21 distributors responded to the survey. Respondents included 14 of the 2018 top 20 pharmaceutical manufacturers by sales and nine of the top 20 pharmaceutical manufacturers by prescriptions dispensed 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. Note that 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 have been labeled as such.

It is important to note the greater context in which this survey was disseminated. The global COVID-19 pandemic has severely disrupted normal human interactions and business activities. Some survey responses may have been affected by changes in priorities during this period of enormous uncertainty as the pharmaceutical supply chain pivoted to focus on core activities. Moreover, survey respondents may have altered course since providing their responses due to the need to respond to rapidly changing conditions. The survey reveals in several instances where progress on DSCSA implementation has slowed or even reversed. While concerning, it is the HDA Foundation's belief that these declines reflect the pharmaceutical supply chain's focus upon supporting patients and healthcare professionals during COVID-19 response which has resulted in temporarily shifting some attention and resources away from or delayed DSCSA implementation. DSCSA implementation also has been slowed because many companies have drastically curtailed or eliminated business travel and closed facilities to all but essential workers assigned to those facilities. This has significantly impacted the trading partners' ability to implement new processes and train employees on them.[5]

Additionally, on October 22, 2020 FDA granted enforcement discretion to industry for the wholesale distributor saleable return 2019 requirement and the dispenser 2020 requirements until 2023. The answers to this survey do not reflect this information, since it was collected prior to the announcement.[6]

5 In meetings with the FDA on the progress of the verification network to meet the serialized saleable return deadline in March and August of 2020 industry participants noted these challenges and the impact of COVID 19 on training, IT projects, implementation and their ability to meet the November 2020 deadline.

6 *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*; Availability, 85 FR 67550 (October 22, 2020) https://www.federalregister.gov/d/2020-23524

MANUFACTURERS

Serialized Data and Data Exchange

Although not legally required to send serialized aggregated data until 2023, some manufacturers are employing GS1's Electronic Product Code Information Services (EPCIS) to comply with the saleable returns requirement (in whole or in part). This section addresses plans to aggregate as well as company plans to send serialized data with product to downstream trading partners.

Among respondents, 56 percent plan to aggregate data for all stock keeping units (SKUs) for each unit to a case by 2020. The majority of those who plan to aggregate by 2020 — 72 percent — have less than 150 SKUs and 81 percent have less than 15 lines. One-quarter noted that they plan to aggregate data for all SKUs by 2023. This number is down from one-third last year, however, more companies plan to aggregate by 2021.

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)	57	36	21	26	26
Yes All SKUs by 2020	56.1%	72.2%	28.6%	80.8%	34.6%
Yes All SKUs by 2021	12.3%	11.1%	14.3%	3.9%	19.2%
Yes All SKUs by 2022	3.5%	0.0%	9.5%	0.0%	3.9%
Yes All SKUs by 2023	24.6%	13.9%	42.9%	7.7%	42.3%
No	0.0%	0.0%	0.0%	0.0%	0.0%
Awaiting FDA guidance to determine whether or not we will aggregate	3.5%	2.8%	4.8%	7.7%	0.0%

Eighteen percent of manufacturers are currently sending or plan to send, by the end of 2020, at least some serialized data to their wholesale distributor customers upon shipment. Another 14 percent are still unsure of when they plan to exchange data with wholesale distributors via EPCIS for all products.

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)	56	36	20	26	25
We are currently sending serialized data with shipped product	17.9%	25.0%	5.0%	19.2%	16.0%
We plan to begin to send serialized data with shipped product between 2020 and 2021	32.1%	27.8%	40.0%	30.8%	28.0%
We plan to begin to send serialized data with shipped product between 2021 and 2022	12.5%	8.3%	20.0%	3.9%	24.0%
We plan to begin to send serialized data with shipped product between 2022 and 2023	23.2%	19.4%	30.0%	19.2%	28.0%
We are unsure of when we will begin to send serialized data	14.3%	19.4%	5.0%	26.9%	4.0%

The number of manufacturers who plan to send serialized data along with 100 percent of product in 2020 has decreased from last year's survey from 35 percent to 21 percent. The majority, 54 percent, anticipate sending 100 percent of data with shipped product by 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)	27	14	13	8	16
2020	44.4%	50.0%	38.5%	50.0%	37.5%
2021	11.1%	7.1%	15.4%	0.0%	12.5%
2022	33.3%	21.4%	46.2%	25.0%	43.8%
2023	11.1%	21.4%	0.0%	25.0%	6.3%
50% of shipped product					
(N)	27	15	12	9	15
2020	22.2%	26.7%	16.7%	22.2%	20.0%
2021	18.5%	20.0%	16.7%	22.2%	13.3%
2022	33.3%	20.0%	50.0%	22.2%	40.0%
2023	25.9%	33.3%	16.7%	33.3%	26.7%

75% of shipped product					
(N)	31	16	15	11	15
2020	16.1%	18.8%	13.3%	36.4%	6.7%
2021	12.9%	12.5%	13.3%	0.0%	13.3%
2022	35.5%	31.3%	40.0%	27.3%	33.3%
2023	35.5%	37.5%	33.3%	36.4%	46.7%
100% of shipped product					
(N)	56	35	21	26	25
2020	21.4%	34.3%	0.0%	26.9%	20.0%
2021	16.1%	11.4%	23.8%	19.2%	16.0%
2022	8.9%	8.6%	9.5%	7.7%	4.0%
2023	53.6%	45.7%	66.7%	46.2%	60.0%

More than two-thirds, or 71 percent, of manufacturers are currently using EPCIS version 1.2, which is necessary for 2023 compliance.[7] Eighteen percent are operating on version 1.1. One quarter of those companies intend to switch to 1.2 in 2020, while 25 percent are targeting 2021, 20 percent are targeting 2022 and 30 percent are targeting 2023.

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)	49	29	20	22	23
EPCIS 1.0	10.2%	10.3%	10.0%	13.6%	8.7%
EPCIS 1.1	18.4%	10.3%	30.0%	9.1%	26.1%
EPCIS 1.2	71.4%	79.3%	60.0%	77.3%	65.2%
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:					
	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)	20	10	10	8	11
2020	25.0%	40.0%	10.0%	25.0%	27.3%
2021	25.0%	20.0%	30.0%	25.0%	18.2%
2022	20.0%	10.0%	30.0%	12.5%	27.3%
2023	30.0%	30.0%	30.0%	37.5%	27.3%

7 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. Currently, EPCIS is the only standard that meets this requirement.

Saleable Returns Verification

Manufacturers noted concerns with their ability to support the wholesale distributors' saleable returns verification requirement.[8] The top three reasons cited were the viability of the verification router service (VRS) (68 percent), issues with solution providers (43 percent) and lack of or inadequate guidance from the FDA (36 percent).

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)	57	36	21	26	26
Yes	49.1%	44.4%	57.1%	46.2%	61.5%
No	50.9%	55.6%	42.9%	53.9%	38.5%

8 Wholesale distributors were required to begin verifying a product's identifier prior to resale beginning November 27, 2019 [§ 582(c)(1)(B)(i)(II); § 582(c)(4)(D)]. FDA, however, granted enforcement discretion for this requirement until at least November 27, 2020. Wholesale Distributor Verification Requirement for Saleable Returned Drug Product—Compliance Policy Guidance for Industry (September 2019) available here. Once FDA lifts its enforcement discretion, a wholesale distributor must be able to verify a return prior to resale; this requirement continues after November 27, 2023 [§ 582(c)(4)(D)].

If yes, why? *(multiple responses allowed)*					
(N)	28	16	12	12	16
Challenges with EPCIS	10.7%	6.3%	16.7%	0.0%	18.8%
Concerns with the viability of the Verification Router Service	67.9%	62.5%	75.0%	58.3%	75.0%
Challenges with managing/storing serialized data	10.7%	0.0%	25.0%	8.3%	12.5%
Issues with solution providers	42.9%	50.0%	33.3%	41.7%	43.8%
Lack of or inadequate FDA guidance on the verification requirement	35.7%	31.3%	41.7%	33.3%	37.5%
Inability to yet send aggregated data	14.3%	6.3%	25.0%	16.7%	12.5%
Issues receiving serialized data from CMOs to verify against	28.6%	18.8%	41.7%	25.0%	31.3%
Issues with mechanical product availability and functionality, e.g., cameras, scanners, etc.	10.7%	12.5%	8.3%	16.7%	6.3%
Resource constraints, e.g. qualified systems integration professionals	25.0%	6.3%	50.0%	16.7%	31.3%
Other	28.6%	37.5%	16.7%	33.3%	25.0%

When asked how their company intends to support verification requests, it is clear multiple methods will be used — 32 percent plan to send EPCIS files (down 11 percent from last year), 86 percent plan to use the VRS, and 39 percent plan to use phone calls or emails (up 17 percent from last year).

How does your company plan to support verification requests for the 2019 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)	57	36	21	26	26
We plan to send EPCIS files with product identifiers to our wholesale distributors	31.6%	38.9%	19.1%	34.6%	30.8%
We plan to utilize the VRS when available	86.0%	80.6%	95.2%	76.9%	92.3%
We plan to build a portal	3.5%	0.0%	9.5%	0.0%	7.7%
We plan to use phone calls/email	38.6%	33.3%	47.6%	38.5%	38.5%
Other	5.3%	5.6%	4.8%	7.7%	0.0%

The survey indicates that manufacturers have various ways of handling verification requests from non-direct purchasers. More than a third, 36 percent, have manual processes to support non-direct purchasers, another two-thirds, 60 percent, expect to use a VRS and 44 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)	55	35	20	25	25
We have a manual process to respond to non-direct purchasers	36.4%	34.3%	40.0%	28.0%	44.0%
We anticipate using a VRS when available	60.0%	57.1%	65.0%	56.0%	68.0%
We anticipate our direct trading partners will conduct a verification request on behalf of non-direct purchasers	43.6%	34.3%	60.0%	44.0%	40.0%
Unsure	9.1%	8.6%	10.0%	4.0%	8.0%
Other	1.8%	0.0%	5.0%	0.0%	0.0%

2023 Interoperability

More than 50 percent of respondents highlighted governance of the system as a key challenge for meeting the 2023 interoperable requirements. Twenty-one percent of respondents cited governance as their biggest concern regarding overall DSCSA implementation, this is a slight decrease from 22 percent in 2019. Other top challenges with meeting the 2023 requirements cited were technical (42 percent) and collaboration with trading partners (37 percent).

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)	57	36	21	26	26
Collaboration with trading partners	36.8%	38.9%	33.3%	38.5%	34.6%
Collaboration with solution providers	28.1%	36.1%	14.3%	38.5%	19.2%
Defining a vision	15.8%	13.9%	19.1%	3.9%	23.1%
Technical challenges	42.1%	41.7%	42.9%	46.2%	42.3%
Establishing standards	33.3%	25.0%	47.6%	34.6%	34.6%
Governance of the interoperable system for 2023	54.4%	50.0%	61.9%	46.2%	61.5%
Connectivity and related security (communication and connections)	29.8%	30.6%	28.6%	26.9%	34.6%
Differences in interpretation of the law	29.8%	19.4%	47.6%	26.9%	26.9%
Other	3.5%	5.6%	0.0%	3.9%	0.0%

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)	56	36	20	26	25
Collaboration with trading partners	10.7%	11.1%	10.0%	11.5%	8.0%
Collaboration with solution providers	5.4%	5.6%	5.0%	3.9%	8.0%
Defining a vision	8.9%	8.3%	10.0%	0.0%	20.0%
Technical challenges	16.1%	25.0%	0.0%	26.9%	4.0%
Establishing standards	14.3%	11.1%	20.0%	15.4%	12.0%
Governance of the interoperable system for 2023	21.4%	13.9%	35.0%	15.4%	28.0%

Connectivity and related security (communication and connections)	7.1%	11.1%	0.0%	3.9%	12.0%
Differences in interpretation of the law	12.5%	8.3%	20.0%	15.4%	8.0%
Other	3.6%	5.6%	0.0%	7.7%	0.0%

Two-thirds are conducting pilots (almost double last year's numbers) the majority of which are external focused on returns verification requirements, 2023 interoperability or other pilots.

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)	57	36	21	26	26
Yes	59.7%	58.3%	61.9%	46.2%	69.2%
No	40.4%	41.7%	38.1%	53.9%	30.8%
If yes, check all that apply: *(multiple responses allowed)*					
Internal					
(N)	34	21	13	12	18
2019 wholesale distributor returns verification	23.5%	28.6%	15.4%	25.0%	16.7%
2020 dispenser requirements	8.8%	14.3%	0.0%	0.0%	16.7%
2023 interoperability	11.8%	9.5%	15.4%	0.0%	11.1%
Other DSCSA related pilot topics	2.9%	4.8%	0.0%	0.0%	5.6%
External *(with trading partners)*					
2019 wholesale distributor returns verification	73.5%	61.9%	92.3%	58.3%	77.8%
2020 dispenser requirements	5.9%	4.8%	7.7%	0.0%	11.1%
2023 interoperability	41.2%	33.3%	53.9%	16.7%	55.6%
Other DSCSA- related pilot topics	20.6%	23.8%	15.4%	33.3%	16.7%

DISTRIBUTORS

This is the second year that distributors have been included in the survey. The goal of their participation is to understand their readiness for the saleable returns requirement, perceptions of dispenser readiness and looking forward to 2023 interoperability.

Saleable Returns Verification

Are you able to accept serialized data today?	
	Company Type
	Distributor
(N)	21
Yes	66.7%
No	33.3%
If no, when do you anticipate being able to accept serialized data:	
(N)	6
2020	16.7%
2021	50.0%
2022	33.3%
2023	0.0%

Forty-eight percent of distributors have concerns with meeting the saleable returns verification requirement.[9] The preferred approaches to complying with the 2019 requirement are VRS (76 percent), followed by EPCIS (52 percent), phone calls or emails (24 percent) and portals (19 percent). Distributors noted that the most important factors in identifying preferred approaches were efficiency (80 percent), automated approach (70 percent) and volume whether low or high (55 percent).

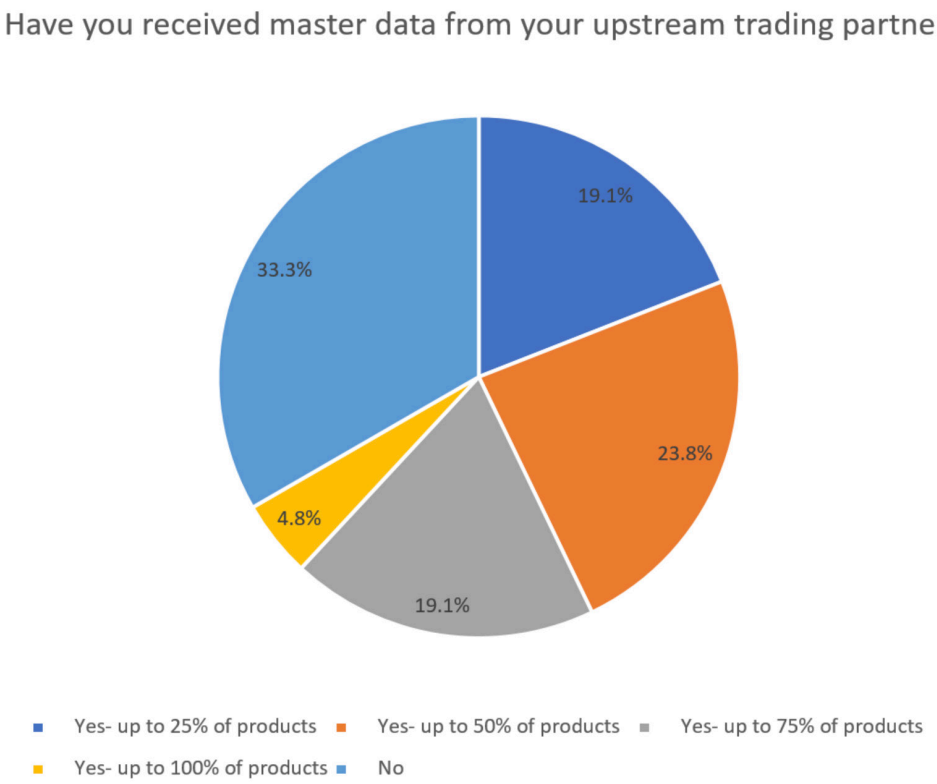
9 FDA - granted enforcement discretion on the verification of saleable returns on September 23, 2019, and the requirement now comes into effect on November 27, 2020, unless another request is granted.

As a distributor, do you have concerns about meeting the 2019 saleable return verification requirement?	
	Company Type
	Distributor
(N)	21
Yes	47.6%
No	52.4%
If yes, why? *(multiple responses allowed)*	
(N)	10
Operational concerns e.g. ability to conduct verification requests	30.0%
Internal constraints e.g., resources to acquire suitable scanners; personnel/training	30.0%
Challenges receiving EPCIS files	30.0%
Challenges with/viability of the VRS	60.0%
Accuracy and completeness of data exchange	80.0%
Complete availability of master data	70.0%
Other	30.0%

What are your company's preferred approaches to complying with the 2019 saleable returns verification requirement? *(multiple responses allowed)*	
	Company Type
	Distributor
(N)	21
We plan to check against EPCIS files received from manufacturers	52.4%
The VRS when available	76.2%
A manufacturer's portal	19.1%
Phone calls/email	23.8%
Other	19.1%

In identifying your preferred approaches to complying with the 2019 saleable returns verification requirement, what factors are most important? *(multiple responses allowed)*	
	Company Type
	Distributor
(N)	20
Volume (low or high)	55.0%
Efficiency	80.0%
Automated approach	70.0%
Less error prone	30.0%
Lower cost	25.0%
Prefer to house data internally/concern about external points of failure	20.0%
Utilizes existing process	10.0%
Other	0.0%

Only 19 percent of distributors have received master data for up to 25 percent of products. A third of the distributors reported receiving no master data. The most popular method for submitting master data was spreadsheets (64 percent) followed by the HDA new product form (50 percent) and GS1 Global Data Synchronization Network (GDSN) (29 percent).



If yes, what method or format is your supplier utilizing? *(multiple responses allowed)*	
	Company Type
	Distributor
(N)	14
HDA Origin	14.3%
GS1 GDSN	28.6%
Spreadsheets	64.3%
HDA new product form	50.0%
Other format	7.1%

The accuracy and completeness of data exchange ranked the highest as reason for concern with meeting the saleable return verification requirement, followed by availability of complete master data and challenges with or viability of the VRS.

While receiving EPCIS files is the preferred approach of some distributors, only 67 percent can accept serialized data today. However, 93 percent have already migrated to EPCIS version 1.2, which is necessary for 2023 compliance.

If your company uses EPCIS, please indicate what version:	
	Company Type
	Distributor
(N)	15
EPCIS 1.0	6.7%
EPCIS 1.1	0.0%
EPCIS 1.2	93.3%

According to distributors, few manufacturers are sending serialized data today via EPCIS. Fourteen percent are receiving no serialized data at all today. Forty-eight percent of distributors noted that they are currently receiving serialized data from 1–5 percent of manufacturers on at least one product line. Fourteen percent of distributors stated that 51–75 percent of manufacturers are providing serialized data on at least one line, nearly double what was reported in 2019. And only 19 percent of distributors noted that 76–100 percent of their manufacturer suppliers are providing serialized data on at least one product line. The majority of transactions (76 percent) are not accompanied by serialized data today.

What percentage of your manufacturer suppliers are currently providing serialized data for at least one product line?	
	Company Type
	Distributor
(N)	21
0%	14.3%
1-5%	47.6%
6-10%	4.8%
11-15%	0.0%
15-20%	0.0%
21-25%	0.0%
25-50%	0.0%
51-75%	14.3%
76-100%	19.1%

What percentage of the transactions are currently accompanied by serialized data?	
	Company Type
	Distributor
(N)	20
0%	35.0%
1-5%	40.0%
6-10%	0.0%
11-15%	0.0%
15-20%	0.0%
21-25%	0.0%
25-50%	10.0%
51-75%	5.0%
76-100%	10.0%

2023 Interoperability

From a distributor perspective, the top four challenges to meeting 2023 interoperability are collaboration with trading partners (67 percent), establishing standards (67 percent), governance of the 2023 interoperable system (57 percent) and differences in interpretation of the law (52 percent). Among these challenges, distributors' key concerns are collaboration with trading partners (29 percent), governance of the 2023 interoperable system (24 percent) and differences in interpretation of the law (19 percent).

From your perspective, what are the key challenges for meeting the DSCSA's 2023 requirements? *(multiple responses allowed)*	
	Company Type
	Distributor
(N)	21
Collaboration with trading partners	66.7%
Collaboration with solution providers	38.1%
Defining a vision	33.3%
Technical challenges	47.6%
Establishing standards	66.7%
Governance of the interoperable system for 2023	57.1%
Connectivity and related security (communication and connections)	42.9%
Differences in interpretation of the law	52.4%
Other	9.5%

What is currently your biggest concern regarding overall DSCSA implementation?	
	Company Type
	Distributor
(N)	21
Collaboration with trading partners	28.6%
Collaboration with solution providers	0.0%
Defining a vision	4.8%
Technical challenges	4.8%
Establishing standards	9.5%
Governance of the interoperable system for 2023	23.8%
Connectivity and related security (communication and connections)	4.8%
Differences in interpretation of the law	19.1%
Other	4.8%

Dispenser Perceptions

Only five percent and 10 percent, respectively, of responding distributors, up from zero last year, believe that their dispenser customers understand what is required of them in 2020 or 2023. Nearly two-thirds, 62 percent, reported that it varies considerably among dispensers on their understanding of 2020 and 2023 obligations.

Do your dispenser customers understand what's required of them in 2020 regarding DSCSA compliance?	
	Company Type
	Distributor
(N)	21
Yes	4.8%
No	14.3%
Varies considerably	61.9%
Unsure	19.1%

Do your dispenser customers understand what's required of them in 2023 and beyond?	
	Company Type
	Distributor
(N)	21
Yes	9.5%
No	14.3%
Varies considerably	61.9%
Unsure	14.3%

When asked to identify which customer segments were the most or least educated about the DSCSA implementation requirements, independent pharmacies were identified most frequently, with 50 percent of distributors reporting that independent pharmacy customers do not understand what is expected of them, followed by hospitals (27 percent) and health systems (20 percent). Chain drug stores, health system and hospitals all ranked higher with distributors reporting they are somewhat educated on DSCSA requirements by 79, 73 and 60 percent of distributors, respectively.

How would you rate the understanding of the following customer segments?	
	Company Type
	Distributor
Independent pharmacies	
(N)	18
Educated on DSCSA requirements	0.0%
Somewhat educated on DSCSA requirements	50.0%
Does not understand DSCSA requirements	50.0%
Chain stores	
(N)	14
Educated on DSCSA requirements	14.3%
Somewhat educated on DSCSA requirements	78.6%
Does not understand DSCSA requirements	7.1%
Health systems	
(N)	15
Educated on DSCSA requirements	6.7%
Somewhat educated on DSCSA requirements	73.3%
Does not understand DSCSA requirements	20.0%
Hospitals	
(N)	15
Educated on DSCSA requirements	13.3%
Somewhat educated on DSCSA requirements	60.0%
Does not understand DSCSA requirements	26.7%
Other	
(N)	*
Educated on DSCSA requirements	*
Somewhat educated on DSCSA requirements	*
Does not understand DSCSA requirements	*

Note: * indicates insufficient data

CONCLUSION

This year's survey highlights some interesting trends around how the supply chain is preparing for milestones and how their plans and concerns have or have not changed over time. There are early adopters, those who appear to have delayed plans to implement ahead of schedule, and those continuing to prepare for implementation as laid out in the law.

For example, in last year's survey, more than half of manufacturers (56 percent) noted that they planned to aggregate by 2019. The same number responded that they plan to aggregate by the end of 2020, indicating there has not been much additional progress over the past year. The number of manufacturers who plan to aggregate by 2023 is down to a quarter from a third, indicating other companies have shifted their timelines up and will aggregate between now and then.

The number of manufacturers currently sending serialized data via EPCIS has remained unchanged this year, at only 18 percent of manufacturers, while last year 35 percent of manufacturers said they plan to send serialized data to wholesale distributors as their method for compliance with the 2019 saleable returns requirement. Now, 54 percent plan to send 100 percent of serialized data via EPCIS in 2023, and 14 percent are unsure of when they plan to send data with shipped product. While slightly less than a quarter are sending serialized data now, 32 percent plan to first send data with shipped products between 2020 and 2021, 13 percent plan to first send data with shipped products between 2021 an 2022 and 23 percent plan to do so between 2022 and 2023. This serialized unit-level data is not required until 2023, but investments and testing are required to be able to meet the 2023 deadline. These numbers indicate that manufacturers will be sending their first instance of serialized data along with shipments earlier, but this capability will be completed on a rolling basis until they reach data send with 100 percent of products.

Manufacturers and distributors appear to be mixed in terms of how confident they are that various sectors can meet DSCSA requirements. Generally, there was more confidence that they could meet the serialized saleable returns deadline this year after a being granted a period of enforcement discretion. Still, almost half of manufacturers and distributors responded that they had concerns with their ability to either support or meet the wholesale distributors' saleable returns verification requirement, which is a high number given that this survey was conducted six months out from the deadline now updated per FDA's latest guidance. slt is noteworthy that COVID-19 was cited as a reason for concern about meeting the requirements, among other reasons, because it has constrained the ability to gain entry to sites and train employees. Since the survey was sent, FDA granted a second request for enforcement discretion effectively moving the requirement to verify serialized saleable returns to 2023.

Distributors continued to note challenges in this year's survey with master data collection and data exchange. A third of distributors have not received any master data. Around one-quarter have received master data for 25 to 75 percent of products. Manufacturers are currently sending serialized data for about 18 percent of product. However, one-third plan to use serialized data exchange via EPCIS to meet the 2019 saleable returns requirement, which indicates a gap that would need to be resolved by November 27, 2020.

Collaboration with trading partners, governance, differences in legal interpretation of the DSCSA and establishing standards were all cited concerns as the industry moves to create an interoperable system for 2023. Challenges will increase as dispensers begin to work on their 2020 requirements, which have effectively been extended to 2023 given FDA's subsequent enforcement discretion. As most wholesale distributors have noted, dispenser knowledge of DSCSA requirements is not consistent across industry segments and is generally low. As the open-ended comments indicated, educating dispensers, and achieving alignment among sectors on what is and is not required for operational and regulatory compliance is critical and will continue to present issues going forward.

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