



# Assessing Current Implementation of DSCSA Serialization Requirements

## Two pharmaceutical wholesalers take a snapshot of where industry stands on Phase 2 implementation

On November 27, 2017, pharmaceutical manufacturers faced an important deadline: compliance with Phase 2 of the [2013 Drug Supply Chain Security Act \(DSCSA\)](#). Although the FDA recently issued guidance <sup>1</sup> indicating that it will delay enforcement of those requirements until November 2018, the implementation deadline remains in effect.

While Phase 1 of the DSCSA was about the exchange of lot-level chain-of-ownership data among all supply chain partners, Phase 2 focuses on item-level serialization. Pharmaceutical products must be marked with a National Drug Code (NDC), Serial Number, Lot Number, and Expiration Date in both machine-readable and human-readable format. <sup>2</sup>

To assess where the industry stands on Phase 2 implementation, AmerisourceBergen (ABC) and McKesson Pharmaceutical (McKesson), in collaboration with GS1 Healthcare US<sup>®</sup>, conducted DSCSA barcode assessments in May 2017 to obtain a “snapshot of implementation progress” just six months before the FDA deadline.

“We wanted to set a baseline understanding about implementation progress,” says Scott Mooney, vice president of Distribution Operations, Supply Chain Assurance at McKesson. “The assessment would give us early indicators of problems or pitfalls to avoid, and any difficulties with the way products were being marked.”

Assessment results would provide an indicator of how much product in the market today is marked with a barcode containing the four data elements required for DSCSA Phase 2 and that could indeed be read when scanned.

Prior to the assessments, McKesson and ABC had each released a paper for their manufacturers regarding expectations about DSCSA compliance.

With results from the May assessments, ABC and McKesson are now able to follow up and share results with individual manufacturers so that they can make any course corrections—or accelerate implementation—as needed before the November deadline.

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Senior Director of Secure Supply Chain,  
AmerisourceBergen

<sup>1</sup> FDA Draft Guidance: Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy. June 30, 2017.

<sup>2</sup> DSCSA Sec. 582(b)(2)(A).

## Perception and Reality Gap

McKesson chose to assess prescription pharmaceuticals, while ABC focused on specialty medications.

“We decided to concentrate on our specialty products so that the mix of manufacturers and products would be different than at McKesson,” says Matt Sample, senior director of Secure Supply Chain at ABC. “In this way, the combined assessments would cover a wide range of manufacturers and products.”

At both ABC and McKesson, four teams of two people (one from the wholesaler and one from GS1 US) worked down warehouse aisles, removing products from the shelves and scanning every available barcode before returning each product to its proper location. Information from the barcode scans was entered into a GS1 US database for compilation.

“Prior to the assessments, we both estimated the results would be in the mid-teens—about 15 percent,” Sample says.

But the results of the assessments ultimately demonstrated the wide gulf between perception and reality.

## Approach and Results

At McKesson, 13,571 items (66 percent of items at the warehouse) from 364 manufacturers (81 percent of McKesson vendors) were scanned in three days. Included in the scanned products were all refrigerated items, all narcotics, and all mid- and high-turnover items at the warehouse. The only products that were not scanned were the slowest moving items as they are the least likely to carry the new labelling protocol because the turnover is slower.

At ABC, 3,047 items (100 percent of items at the warehouse) from 375 manufacturers (approximately 80 percent of ABC vendors) were scanned. Included were ambient (71 percent of total items scanned) and refrigerated items (29 percent of total items scanned).

“The sample set satisfied our goals for statistical importance,” Mooney says. “In the 80 percent range gives us good indication and direction.”

At McKesson, the success rate was only 6.5 percent: Of the more than 13,000 products scanned by McKesson, just 879 had a readable barcode containing all four DSCSA-required data elements.

At ABC, the results were similar in that only 7.2 percent (or 218 scanned items) had a readable barcode with all of the required information.

“These results were from actual scans of real product, not opinion,” Mooney says.

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Senior Director of Secure Supply Chain, AmerisourceBergen

## Barcode Diversity

As part of the assessments, ABC and McKesson noted the following barcode observations:

Barcode color combinations and sizes varied, causing scanning and data capture issues. When selecting colors and printing the barcode, a black symbol on a white background produced no-fault scanning. However, an orange symbol on a white background would not scan at all. Some symbols were too small, and those products that carried QR and other barcodes could cause confusion and issues at the dispensary level.

GS1 Standards about barcode size and color should be followed to help avoid these issues. (The relevant standards can be found in Chapter 5 of the [GS1 General Specifications](#).)



**607**

Unique manufacturers represented



**16,618**

Packages scanned



**6.6%**

Readable barcodes with all four DSCSA data elements

For the May 2017 assessment, McKesson and ABC assessed barcodes on 16,618 packages. Only 6.6 percent (or 1,097 packages) had readable barcodes with all four DSCSA data elements.

A useful tip for the configuration of barcode scanners emerged: most plug-and-play scanners have optional configurations so that scanners can be configured to read not only black-on-white but also white-on-black barcodes, as is often the case.

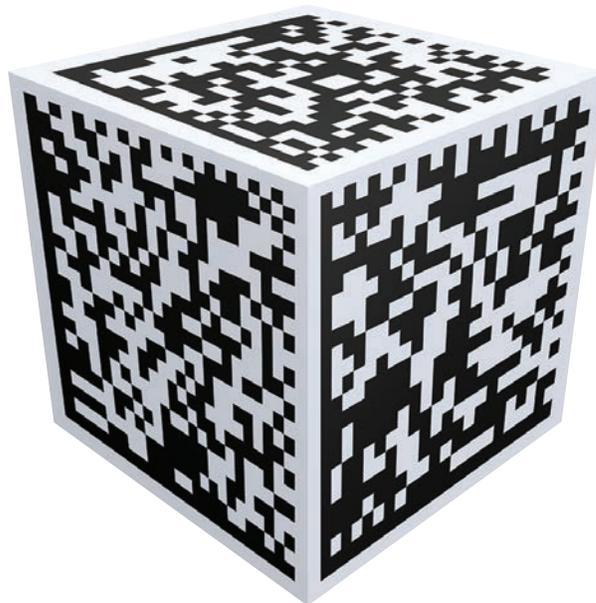
Sample advises, “A pharmaceutical barcode is not about marketing. It’s about moving product through the supply chain with black-and-white and right-sized barcodes.”

Barcode placement ran the gamut of bottoms and tops of bottles or boxes, barcodes printed too close together, smudging on printed boxes, and attached instructional sheets blocking the barcodes. This not only made it difficult to locate and capture the barcode, it prevented data from being automatically captured with a barcode scanner.

GS1 Standards about barcode placement should be followed to help avoid these issues. (The relevant standards can be found in Chapter 6 of the [GS1 General Specifications](#).)

Both McKesson and ABC found manufacturers that were implementing barcodes with the required information, but had faulty applications of the barcode standards. An additional 8 percent in McKesson’s assessment had applied the barcode, but didn’t have all data elements, or the information was encoded incorrectly. Some manufacturers using the barcode will need to refine their operations to get the right four data elements into the right format.

“The beautiful thing about serialization is that you are serializing your product based on one—and only one—barcode,” Sample says. “Historically, we’ve struggled as a supply chain with product packaging standards. The Healthcare Distribution Alliance (HDA) has published labelling guidelines since 2011, yet not one case label in my warehouse looks like another case label. Some have two barcodes and some have none. We have to mature as a supply chain; serialization is going to force us to do so.”



## Colors and Spaces

Best



Next Best



No



“A pharmaceutical barcode is not about marketing. It’s about moving product through the supply chain with black-and-white and right-sized barcodes.” – Matt Sample, Senior Director of Secure Supply Chain, AmerisourceBergen

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“It’s possible to put a zero-zero as the day in a barcode. But when you share digital files between manufacturers, distributors and dispensers, (a requirement mandated by the law at a later time), the zero-zeroes in the date field will error out and not work for anything other than being printed in the barcode. The sooner manufacturers input the appropriate expiration date and not the zero-zero, the better off we all will be.”

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Vice President, Distribution Operations, Supply Chain Assurance,  
McKesson

## 00 Scores a Zero

“We found dates that, while technically correct in terms of putting them into a barcode, will be very problematic when that date is used later in digital data transfer,” Mooney explains. “It’s possible to put a zero-zero as the day in a barcode. But when you share digital files between manufacturers, distributors and dispensers (a requirement mandated by the law at a later time), the zero-zeroes in the date field will error out and not work for anything other than being printed in the barcode.”

GS1 Healthcare US, in its [GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability](#) published in the fall of 2016, recommends that manufacturers input an actual day to avoid confusion and ambiguity, and support transmission of the date through the inventory systems later on.<sup>3</sup>

“The sooner manufacturers input the appropriate expiration date and not the zero-zero, the better off we all will be,” Mooney adds.

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“I think manufacturers are converting their production lines over faster than what the results would indicate. They’re just not shipping the product with the new barcode on it yet. A few manufacturers asked us to informally share any data that we captured, so that tells me they’re interested in the project.”

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Vice President, Distribution Operations, Supply Chain Assurance,  
McKesson

## Reasons for Optimism

Reflecting on the results of the assessments, both Mooney and Sample shared clear perspectives about the need to move quickly—and by using best practices—in implementing DSCSA item-level serialization requirements.

“I think that many manufacturers are waiting to ‘turn the switch:’ they are serializing already, and working out the kinks,” Sample says. “It’s possible that serialized product has not yet reached our distribution centers, but will start arriving soon.”

McKesson’s Mooney agrees: “I think manufacturers are converting their production lines over faster than what the results would indicate. They’re just not shipping the product with the new barcode on it yet. A few manufacturers asked us to informally share any data that we captured, so that tells me they’re interested in the project.”

It is also possible that manufacturers underestimated the scope of the effort. “It’s a multi-year project,” Sample says. “While manufacturers may be tempted to put off the investment until the last possible moment, a limited universe of vendors and consultants may further delay a last-minute implementation. Even with the contributing factors, six or seven percent is still a long way from full compliance.”

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Senior Director of Secure Supply Chain, AmerisourceBergen

## Accelerating the Effort

Although the FDA recently indicated that it is according pharmaceutical manufacturers a “period of enforcement discretion,”—a grace period of one year—before it imposes any penalties or fines for non-compliance, the time is now upon the industry to accelerate its implementation.

Mooney emphasizes that this is not a deadline extension. “Manufacturers are still required to meet their obligations under the DSCSA but will not face 483s, warning letters, or potential monetary penalties for the time being. In other words, manufacturers should use this reprieve wisely.”

Sample agrees. “By offering feedback now, we can help manufacturers become DSCSA compliant.” Sample is finding manufacturers receptive to the feedback and advice, but encourages caution: “We may need to start score-carding, quantifying the impacts of noncompliance, and maybe using that approach to getting this moving.”

Both distributors pledge their willingness to help and GS1 Healthcare US offers guidelines, advice, training, workgroups, and other resources to support manufacturers in using GS1 Standards for DSCSA requirements.

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<sup>3</sup> See Section 6.1.1.6 of the [GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability](#)

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## ABC and McKesson Barcoding Recommendations for DSCSA

Both ABC and McKesson are consistent in their individual recommendations:

- Do not take the FDA's enforcement discretion as an extension of implementation. The **deadlines remain the same**.
- If you haven't started yet, you had better line up your resources now, because your **business may be profoundly affected**.
- If you have started, reach out to trading partners to test what you've implemented so you can continue to press forward. It's clearly **best to test before you've barcoded tens of thousands of units**.
- **Use the recommendations** offered thus far in terms of printing, legibility, placement, and actual expiration date.
- **Refer to and implement GS1 Standards** for barcode size, color, placement, encoding, and more to avoid readability issues.
- **Circulate your samples**. Let others review and scan using different equipment to be sure you have a universally readable barcode.

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Mooney at McKesson has prepared communications for manufacturers highlighting particular challenges—and issuing kudos for those well on their way. He plans to continue to communicate and participate in activities like the assessment for the next 18 months.

"We're in a unique position to help," Sample says, "And we have people dedicated to doing analysis. If the three big wholesalers can't read your barcode, it's certainly not going to work for the 200,000 prescribers using barcode scanners. This is not about the wholesalers. It's about the entire supply chain."

"There is a hard stop. Our present understanding is that we cannot sell product without the new barcode after November 27, 2019," Mooney says. "We will need to start 'purifying' our inventory at some point, selling through non-compliant products."

"We don't want to get stuck with product in the supply chain that we can't sell. But even more importantly, we want to make sure we don't have patients in the healthcare system running out of medicine because it lacks the required barcode."

### Learn More

Visit [www.gs1us.org/dscsa](http://www.gs1us.org/dscsa).

### About the Drug Supply Chain Security Act

In 2013, members of the U.S. drug supply chain requested that Congress create a law that would govern the identification, management, and traceability of all drug products within the United States. The [2013 Drug Supply Chain Security Act \(DSCSA\)](#) aims to facilitate the exchange of information at the individual package level about where a drug has been in the supply chain to: enable verification of the legitimacy of the drug product identifier down to the package level; enhance detection and notification of illegitimate products in the drug supply chain; and facilitate more efficient recalls of drug products.

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## About the Companies

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McKesson Corp. is a global health services and information technology company, which provides medicines, pharmaceutical and care management products. It operates through the McKesson Distribution Solutions and McKesson Technology Solutions segments. The McKesson Distribution Solutions, which includes McKesson US Pharmaceutical, distributes ethical and proprietary drugs, medical-surgical supplies and equipment and health and beauty care products throughout North America. This segment also provides specialty pharmaceutical solutions for biotech and pharmaceutical manufacturers, provides financial, operational and clinical solutions for pharmacies. [www.mckesson.com](http://www.mckesson.com)

### About GS1 Healthcare US

GS1 Healthcare US® is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of more than 30 local GS1 Healthcare user groups around the world that support the adoption and implementation of global standards developed by GS1®. For more information, visit [www.gs1us.org/healthcare](http://www.gs1us.org/healthcare).

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#### GS1 US Corporate Headquarters

Princeton Pike Corporate Center, 1009 Lenox Drive, Suite 202  
Lawrenceville, NJ 08648 USA  
T +1 937.435.3870 | E [info@gs1us.org](mailto:info@gs1us.org)  
[www.gs1us.org](http://www.gs1us.org)

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