2020 Update: Progress on 2023 DSCSA Interoperability
Pharmaceutical Industry on Steady March Toward Readiness

A History of the Assessments

In 2017, AmerisourceBergen Corporation and McKesson Pharmaceutical in collaboration with GS1 Healthcare US® launched a program to take “a snapshot of implementation progress” in meeting the requirements of the Drug Supply Chain Security Act (DSCSA)1. In 2018, Cardinal Health joined the effort, with each company taking a different slice of their wholesale operations to assess barcode readability: AmerisourceBergen would assess package (lowest saleable unit) barcoding of specialty pharmaceuticals, those prescribed by specialists and for unique therapeutic uses. To avoid duplication, McKesson would measure packages (lowest saleable units) of prescription (Rx) drugs, those in wide use sent to hospitals and retail pharmacies. Cardinal would evaluate compliance progress with the labeling of homogeneous cases.

Both AmerisourceBergen and McKesson – dealing with some items that could have small packaging profiles – would be gauging the use of a two-dimensional (2D) barcode (e.g., GS1 DataMatrix barcode), while Cardinal would be evaluating either 2D or linear barcodes (e.g., GS1-128 barcode)2. As part of the requirements, both methods of identification must be marked with a U.S. Food and Drug Administration (FDA) National Drug Code (NDC), serial number, lot number, and expiration date. (When using GS1 Standards, the NDC may be represented by a GS1 Global Trade Item Number® or GTIN®.)3

In keeping with recommended COVID-19 safety protocols, GS1 US did not conduct its side-by-side auditing at the wholesalers’ facilities for the 2020 assessment.

2020 Improvements

The 2019 year-over-year assessment showed a steep rise in compliance; 2020 produced still more positive results with proper barcoding on packages coming in at double-digit (19%) gains, rising from 73 percent to 87 percent. Case level improvements rose from 78.7 percent to 93 percent, an 18 percent improvement.

Background

In 2013, the U.S. FDA enacted the DSCSA requiring the pharmaceutical industry to adopt a means of identifying and tracing certain pharmaceuticals distributed throughout the United States. Because of the complexity of the implementation, drug manufacturers were given a ten-year period to come into compliance with the traceability initiative using a phased approach.

Soon after the DSCSA was enacted, the pharmaceutical industry came together and agreed on using GS1 Standards as the platform for DSCSA compliance efforts, a practical decision based on the ubiquity of these standards used in supply chain and trading partner communications throughout the world.

Results from the 2020 Barcode Assessment with the 2D GS1 DataMatrix found that the products properly labeled with all four Application Identifiers (AIs) can be broken out as follows:

- Specialty packages tracked by AmerisourceBergen achieved a 90.1 percent rate of compliance
- Rx packaged drugs tracked by McKesson achieved an 86.6 percent rate of compliance, and
- Homogeneous cases tracked by Cardinal attained a level of 93.1 percent for compliance.

**Progression of Serialized Products With a GS1 DataMatrix Containing Four Application Identifiers**

<table>
<thead>
<tr>
<th>Year</th>
<th>Specialty Products at AmerisourceBergen and Rx Products at McKesson</th>
<th>Homogeneous Cases at Cardinal Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>2018</td>
<td>21%</td>
<td>21%</td>
</tr>
<tr>
<td>2019</td>
<td>73%</td>
<td>79%</td>
</tr>
<tr>
<td>2020</td>
<td>87%</td>
<td>93%</td>
</tr>
</tbody>
</table>

Source: 2020 GS1 US Barcode Assessment

**Figure 1.** Four Application Identifiers (AIs) were complete: GTIN (with embedded NDC), Serial Number, Lot Number and Expiration Date.

“In previous years we were trying to measure the adoption of the 2D barcode and the product identifier,” says Scott Mooney, vice president of distribution operations for McKesson. “But 2020 was the last measurement point before the first required utilization of that barcode in DSCSA, so it was more critical because it presented the ‘last view’ before the interim deadline in November. I had expected the number to have moved up some, but I don’t know that I had expected it to move up almost 20 percent from what we had seen last year. It had significance, because that increase now means that an appreciably higher number of products would be going through the salable returns verification, had that process not recently been deferred by the U.S. FDA.”

**Progress in 2D Barcode Adoption With DSCSA Requirements**

**Specialty Products at AmerisourceBergen and Rx Products at McKesson**

<table>
<thead>
<tr>
<th>Year</th>
<th>Packages Scanned</th>
<th>Readable Barcodes With All Four DSCSA Data Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>16,618</td>
<td>7%</td>
</tr>
<tr>
<td>2018</td>
<td>21,209</td>
<td>21%</td>
</tr>
<tr>
<td>2019</td>
<td>17,859</td>
<td>73%</td>
</tr>
<tr>
<td>2020</td>
<td>21,169</td>
<td>87%</td>
</tr>
</tbody>
</table>

Source: AmerisourceBergen, Cardinal Health, and McKesson Barcode Assessments

**Figure 2.** A steady climb in compliance has been seen on all “lowest saleable units.”
“Every year our barcode assessment shows better and better results. Manufacturers have more time to understand the requirements, more time to get grandfathered products out of the supply chain, more time to act on feedback on what they may be doing wrong and how they can improve on it from all the different downstream partners, including us,” says Trevaun Willey, Cardinal’s senior consultant, Operations Technology.

**Progress in 2D Barcode Adoption With DSCSA Requirements**

<table>
<thead>
<tr>
<th>Homogeneous Cases at Cardinal Health</th>
<th>2018-2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases Scanned</td>
<td></td>
</tr>
<tr>
<td>Cases 2018</td>
<td>6,481</td>
</tr>
<tr>
<td>Cases 2019</td>
<td>7,996</td>
</tr>
<tr>
<td>Cases 2020</td>
<td>10,900</td>
</tr>
</tbody>
</table>

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Source: AmerisourceBergen, Cardinal Health, and McKesson Barcode Assessments

**Expiration and Experience**

The double zero day remains a challenge because it does not fit the data format for the Electronic Product Code Information Services (EPCIS) standard used for exchanging product information. It is discouraged for use in the barcode itself. Again in 2020, the analysis showed that almost two percent of the serialized items had a “00” expiration date. Interestingly, this was four percent on specialty packages, and four percent on the homogeneous cases, while the Rx packages had no 00 expiration dates.

Last year, a significant year-over-year change was seen in the average expiration date of products being 1.6 years in 2019, compared to 2.3 years in 2018. The average expiration date of products in the Big 3 wholesalers’ distribution centers in 2020—1.6 years—is the exact same result as 2019.

A discrepancy between a Universal Product Code (U.P.C.) on a package and a 2D barcode can also cause downstream problems. “GS1 has a standard relating to how these two codes interrelate to each other,” Mooney says, “and when two barcodes have differing GTINs, the opportunity for confusion becomes obvious.”

As competitors, the three wholesalers cannot “compare notes,” but can rely on GS1 US—as a neutral party—to take the lead in communicating data anomalies with the industry.

Aggregated, all 51,400 scans at the Big 3 resulted in a 90.1 percent rate of compliance with three years still remaining until the final DSCSA deadline. Because it is used in a number of commercial ways, not surprisingly the GTIN (with the NDC embedded) was the most consistently found identifier on every unit scanned, ranging from a low of 93.1 percent (Rx packages) to highs of 97.8 (homogeneous cases) and 99.7 percent (specialty). The second most frequent identifier captured varied.

**Average Expiration Date of Packages and Homogenous Cases**

![Graph showing average expiration dates](image)

- **51%** average expiration date of 1.7 years of homogeneous cases expire in 2022.
- **50%** average expiration date of 1.5 years of packages expire in 2021.

Source: 2020 GS1 US Barcode Assessment

**Figure 3.** As the number of cases scanned for assessments has grown, so too has the percentage of cases with all data elements increased.

**Figure 4.** Product expiration dates at all three wholesalers remained consistent, following similar timelines.
Barcode Assessments Reveal Challenges for Industry to Address

**Color and Size.** Initially, 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. Other colors either would not scan at all or produced inconsistent results. Some symbols were too small, and those products that carried QR and other barcodes could cause confusion and issues. GS1 Standards address these issues.

**Placement and Uniformity.** Barcode placement ran the gamut: bottoms or tops of bottles or boxes, wrapping around cases, printed on shiny surfaces, attachments blocking easy access to codes. Some were printed too close together or print was smudged. These issues hinder scanning. On those that require a 2D code along with a retail point-of-sale code (UPC), both must carry the same GTIN.

**00 Dates.** 00 date designations, while technically correct in terms of the barcode, are problematic when that date is used later in digital data transfer. When shared between manufacturers, distributors and dispensers, 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 recommends using an actual day to avoid confusion and ambiguity, and support transmission of the date through inventory systems.

**Special Characters in Lot/Serial Numbers.** The need for continued attention to scanning issues was demonstrated in 2020 when special characters – dots, dashes and slashes – used in the lot and serial number fields posed challenges when data is exchanged between trading partners. Although acceptable by GS1 Standards, computers sometimes interpret the characters as messaging protocols rather than data elements. GS1 is working alongside the industry to develop an acceptable solution to circumvent the issue going forward. Similarly, the use of leading zeros in lot and serial numbers should be avoided to eliminate risk of mismatches if they are dropped.

Still Just A Snapshot

Even with all the issues worked through to date, barcode assessments are just a snapshot of industry adoption and compliance with the DSCSA and will always be an ongoing process. New products coming onto the market, new packaging developed for existing products, third party manufacturers being contracted by pharmaceutical companies all present the potential for tweaks to serialization.

“The assessments are a good representation, but things can go awry,” says Liberty Dewey, senior consultant for Cardinal’s Operations Technology. “For example, a manufacturer proactively reached out to us to let us know their contract manufacturer had put quantity into the barcode and asked if it was going to cause problems with our receiving or our returns verification. The need to continually check compliance will be an ongoing endeavor.”

With more than a single recipient or destination for the serialized information, accuracy and consistency become vital. The need to address a data issue no matter its seeming significance – small or large, showstoppers or hiccups – is paramount to smooth interoperability downstream.

“There are a lot of different systems exchanging data. Data posted in one system and then extracted and sent to another system – even within the same company – has enormous implications for harmonizing data,” says Ameer Ali, senior director of Manufacturer Operations at AmerisourceBergen.
“There’s the warehouse management system, the repository, the ERP, and the data exchange systems. There are some hard errors – showstoppers – while others are simply not in accordance with the guidelines or recommendations, like leading zeros in serial or lot numbers. These soft errors may cause a problem in the future if not addressed.”

“The assessments are a good representation, but things can go awry ... The need to continually check compliance will be an ongoing effort.”

Liberty Dewey
Senior Consultant, Operations Technology, Cardinal Health

Digital Twins Close Loop

A wholesaler cannot receive serialized product from a manufacturer, until serialized data accompanies it. A “digital twin” allows the industry to move to the next step of capturing serialized sales to the entity dispensing the drug. An individual unit can only be identified when it carries a readable GS1 2D DataMatrix barcode. Until the loop is completed you cannot provide a purchaser with serialized DSCSA information.

“We are quickly approaching the point in time where the majority of the items have the barcode and it’s accurate,” Mooney says, “and it’s repeatable from package to package. Now we can begin to move on to those data-capture, data-sharing events that are necessary to finish out the DSCSA.”

For the Big 3, the DSCSA requirements can improve productivity. “If manufacturers are using 2D barcodes, it only requires one scan as opposed to two scans to get all four product identifiers from two linear barcodes. If they have all product identifiers encoded—especially in a 2D barcode—it can be a very easy receiving process.” says Josh Dritz, director of operations technology at Cardinal.

“Get it done, get it tested, and have a high degree of confidence that when 2023 arrives, your products can continue to move.”

Scott Mooney
Vice President, Distribution Operations, McKesson Pharmaceutical

“And it creates an exacerbated productivity issue and it also creates inventory issues because product is either quarantined or morgued, depending on the result of the return verification. This is an issue with individual products rather than at the case level,” Dewey says.

Patient Safety and Beyond

GS1 Standards are one of the reasons for commonalities in successful serialization within the industry. With so many data points, so many application locations, and so much individualized inventory, the guidance provided by GS1 will eventually bring thousands of products through thousands of supply chain checkpoints with nearly complete visibility and traceability.

A mismatch or a failure to verify a product disrupts the supply chain operation whether at the wholesale distributor, at the receiving dock, at the drug dispensary or at the point of returns. One error causes a ripple effect, upstream and downstream.

“Compliance is a prerequisite to verification, to the accurate exchange of data and to achieve full traceability in 2023.”

Ameer Ali
Senior Director of Manufacturer Operations at AmerisourceBergen

“The top priority is compliance – but barcode compliance is just part of a multi-phased plan. The proper physical labelling and barcoding is going to set up the next phase: data exchange and traceability from beginning to end of the supply chain,” Ali says. “Compliance is a prerequisite to verification, to the accurate exchange of data and to achieve full traceability in 2023.”
Expert Advice: Communication and Focus

Communicate. All three wholesalers communicate with their manufacturer partners on the progress being made on DSCSA requirements. Each company communicates with manufacturers with specifics about their product data. AmericsourceBergen, for instance, developed a mobile application that enables it to photograph products with problematic barcodes, thereby attaching a visual representation of the precise concern to the appropriate supplier.

“I encourage manufacturers to review the information in our published reports. In each of the years to-date, the analytics have identified trends or patterns, which could be problematic. The information is very valuable for their understanding of the barcoding they’re applying,” Mooney says.

Focus. The Big 3 are unified in their advice to manufacturers to stay focused on serialization programs. While some may wish to defer compliance efforts because of accelerated costs, it’s a risky decision.

Perhaps a character set is encoded incorrectly or a GTIN is not based on an U.S. FDA NDC number. When those issues arise, the manufacturer will get feedback to correct the errors before they become endemic to its entire portfolio.

“Get it done, get it tested, and have a high degree of confidence that when 2023 arrives, your products can continue to move,” says Mooney.

“If you’re talking about the ability to apply serialized barcodes to products per DSCSA, I think there’s a wider understanding than ever before,” Dritz says. “But if you talk about the readiness to create interoperable systems inclusive of saleable returns verification … I think that we remain concerned about the amount of work that lies ahead of us. Thankfully, the U.S. FDA’s enforcement discretion allows the industry to focus more attention on 2023 interoperability.”

Following standards faithfully is critical to success in any industry, but especially in such a global one that deals in life-saving products. “Manufacturers have different ways of doing things or different interpretations, which could result in variation and downstream exceptions that disrupt product flow. This was likely a driver behind DSCSA language requiring conformance to international standards, like the ones developed by GS1,” Ali says.

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