



2022 Update: Gearing Up for Interoperability

Pharmaceutical Industry Readies for Full Interoperability Starting in 2023

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 2022 assessment.

2022 Improvements

The results show continued growth for both packages and cases. Proper barcoding on overall packages have increased from 87 percent to 94 percent, with specialty products at AmerisourceBergen rising from 90 to 98 percent and Rx prescription products at McKesson rising from 87 to 93 percent. Case-level improvements at Cardinal Health rose from 93 percent to 96 percent.

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.

¹ Drug Supply Chain Security Act, Pub. Law No. 113-54, 127 Stat 599 (2013).

² Drug Supply Chain Security Act, Pub. Law No. 113-54, § 582(a)(9)[A], 127 Stat 599, 608 (2013).

³ Drug Supply Chain Security Act, Pub. Law No. 113-54, § 582(b)(2)(A), 127 Stat 599, 609 (2013)

Figure 1 Specialty Products at AmerisourceBergen and Rx Products at McKesson

Since 2017

Since 2017, the number of packages scanned with readable barcodes containing all four DSCSA data elements grew by

87% ↑

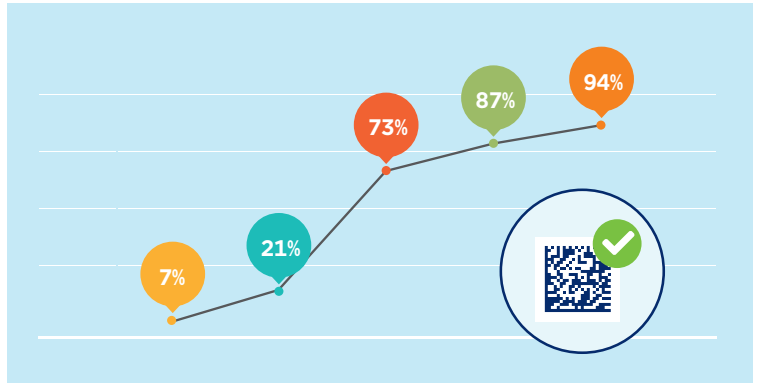
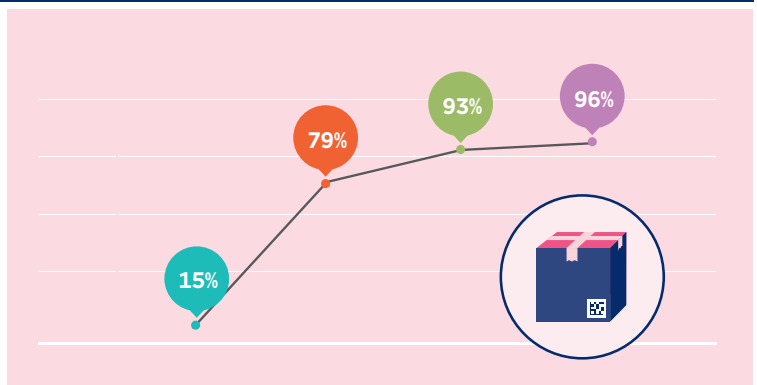


Figure 2 Homogeneous Cases at Cardinal Health

Since 2018

Since 2018, the number of cases scanned with readable barcodes containing all four DSCSA data elements grew by

81% ↑



Source: 2022 GS1 US Barcode Assessment

Flipping the Switch on DSCSA Interoperability

With nearly all regulated pharmaceutical products now entering the supply chain fully serialized and labeled with barcodes, the next challenge is a big one.

Beginning November 27, 2023, pharmaceutical manufacturers, wholesale distributors, and providers/dispensers are required to exchange the serialized item-level product information that has been collected, standardized, and digitized.

This achievement hinges on intensive collaboration that must begin now, if it hasn't already, between manufacturers and their supply chain partners. Even if all products are properly labeled with all the required data in the correct standardized format, with required barcodes scanning reliably and accurately, it will be meaningless unless trading partners' respective systems are compatible to enable interoperability.

Furthermore, information exchange becomes ineffective if the data itself is flawed.

These two caveats are intricately intertwined. Everything must begin with fully vetted, high-quality, accurate data. Then, trading partners' IT systems must be capable of successfully importing and reading it. Any glitches in this transfer of information, minor errors in the existing data, and any inconsistencies or incompatibilities between systems will prevent effective information sharing and nullify all the benefits. Data quality is essential, and interoperability is complex.

Trading partners need to know they are exchanging reliable, trustworthy data about the products they handle. To that end, each organization must commit to comprehensive

“Throughout the five years of conducting this focused study with GS1 US, we have witnessed drug serialized standards move from essentially uncommon and unfamiliar among our manufacturer trading partners, to almost ubiquitous in our most recent study.”

Sean Murphy
Manufacturer Operations - AmerisourceBergen Corporation

“We are approaching the point where serialized DSCSA transaction data will be exchanged between trading partners and this will depend heavily on the scanning of the product identifiers affixed to the products. Industry has made great progress, however, there are still some 2D DataMatrix barcodes that do not contain all of the required data elements or where the encoding is not done according the GS1 specifications. Those products will experience difficulties as industry moves to the interoperable exchange of serial DSCSA transaction data, which is required in late 2023.”

Scott Mooney

Vice President Distribution Operations, Traceability – McKesson Pharmaceutical

data management and allocate necessary resources to analyze, update, and maintain their product information. The crucial process of creating and maintaining trusted data must be recognized and supported as an ongoing fundamental priority.

Even with impeccable data, each organization must be able to import, understand, update, and share it forward and backward through the supply chain. The U.S. FDA recommends that trading partners use the GS1 Electronic Product Code Information Services (EPCIS) standard to provide and maintain the data associated with transaction information and transaction statements.⁴ A global standard, EPCIS enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain, including the record of transaction data required for DSCSA.

This is the time for companies to fast-track a thorough review of their product and location data, update and improve it, and begin testing their ability to exchange it with supply chain partners. Many companies already immersed in the process stress the importance of collaboration to be sure organizations’ systems work together, understanding there will be a period of trial and error while data systems are being harmonized.

While the process could be lengthy – the resulting visibility will benefit all stakeholders in the healthcare system—delivering operational efficiencies, cost savings, inventory control, and more. And of course, the ultimate gain: beyond providing patients with timely access to needed medications, full traceability will increase patient safety by enabling faster, accurate, efficient removal of products when they expire or if they are recalled.



Learn More

Visit www.gs1us.org/dscsa.

⁴ DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry DRAFT GUIDANCE – July 2022

About the Companies



About AmerisourceBergen

AmerisourceBergen Corporation is one of the world's largest pharmaceutical services companies, serving global markets with a focus on the pharmaceutical supply chain. Servicing pharmacies, providers, and pharmaceutical manufacturers, the company provides global product sourcing and distribution and related solutions designed to improve product access, increase supply chain efficiency, and enhance patient care. www.amerisourcebergen.com



About Cardinal Health

Headquartered in Dublin, Ohio, Cardinal Health, Inc. is a global, integrated healthcare services and products company, providing customized solutions for hospitals, health systems, pharmacies, ambulatory surgery centers, clinical laboratories, and physician offices worldwide. The company provides clinically proven medical products and pharmaceuticals and cost-effective solutions that enhance supply chain efficiency from hospital to home. Backed by nearly 100 years of experience, with approximately 50,000 employees in nearly 60 countries, Cardinal Health ranks among the top 25 on the Fortune 500. www.cardinalhealth.com



About McKesson Pharmaceutical

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



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 help 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 over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1. www.gs1us.org/healthcare



About GS1 US

GS1 US[®], a member of GS1[®] global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth, while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code[®] (UNSPSC[®]). www.gs1us.org

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*If applicable

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