ARE YOU PREPARED FOR THE 2023 DSCSA DEADLINE?

From updating processes to identifying security gaps, the time to prepare for the Nov. 27, 2023 deadline is now.

June 7, 2022 • Contract Pharma • Gina Parry

Cyber Monday 2023 has added significance for stakeholders along the pharmaceutical supply chain—it's the FDA's deadline for compliance with the Drug Supply Chain Security Act (DSCSA). Nearly a decade after the first phase of the DSCSA went into effect, phase two will mandate pharma stakeholder compliance with interoperability requirements.

The purpose of the DSCSA is to enable a secure, confidential flow of data along the pharma supply chain to identify and protect patients from illegitimate prescription drugs more easily. According to the FDA, this deadline is firm. While Nov. 27, 2023 may seem far away, the time to prepare is now. From updating processes to identifying security gaps, there are quite a few boxes that need to be checked before this deadline.

Why the DSCSA?

The public health threat of counterfeit drugs infiltrating the U.S. supply chain is intensifying. The gray market is a contributing factor to this threat, which arises when companies operate outside of legitimate drug distribution channels. Additionally, it's relatively easy for consumers to purchase drugs illegally from illegitimate online pharmacies.

Consumers mistakenly think these drugs are safe because they are so readily available—in reality they're unauthorized and sometimes even lethal. In response to the growing volume of counterfeit drugs entering the market, the FDA introduced the first phase of the DSCSA in 2013. Congress then signed the act in 2015, which requires products to be traceable at the lot level with the intent of increasing visibility in the pharma supply chain.

This act has expedited the shift toward drug supply chain digitization, but it's not enough. Cases of drug counterfeiting doubled in size from 2014 to 2019, reaching an all-time high of 4,405 cases in 2019. The same year, North America saw a record-high number of drug-related seizures stemming from illegitimate pharmaceuticals.

The bottom line? The U.S. pharmaceutical supply chain remains a significant public threat and more action is needed to mitigate these deadly, counterfeit drugs from reaching consumers.

The 2023 DSCSA requirements explained

To improve traceability along the pharma supply chain, the second phase of the DSCSA will require interoperable, electronic tracing of products at the package level. With a firm deadline of Nov. 27,

2023, the act will provide a higher level of visibility into the drug supply chain to identify counterfeit products more easily.

For pharmaceutical stakeholders such as manufacturers, distributors, wholesalers, and dispensers to continue operating along the supply chain, the FDA will now require:

1. Interoperable exchange: Authorized trading partners are required to share transaction information (TI) and transaction statements (TS) securely and electronically. The TI should include the product identifier (PI) at the individual package level.
2. Interoperable verification: Partners must interoperably and electronically verify the PI at the unit level. Essentially, they must confirm that the shipments they receive match the corresponding electronic data.
3. Interoperable tracing: Unit-level traceability (i.e., serialization) is required so that each individual product can be traced throughout the supply chain. A PI includes the product's standardized numerical identifier (SNI), an expiration date, and a lot number.

These rulings are intended to create a comprehensive, digital source of information for pharmaceuticals in the U.S. supply chain. Streamlining traceability and securing the pharma supply chain protects patients by preventing counterfeit medications from entering the market. But the only way for the DSCSA to be effective is for every stakeholder to comply.

Communication is key for compliance

Nearly half of pharma manufacturers failed to meet the DSCSA's initial deadline in 2018, largely due to confusion about the requirements and whose job it was to meet them. This was partially because the FDA failed to provide clear guidelines, but inadequate internal communication also played a role.

Consider these steps to guarantee comprehension of the DSCSA requirements and the roles and responsibilities necessary to remain compliant:

- Ensure an understanding of guidelines. It is up to the FDA to communicate its guidelines regarding the DSCSA, but you should also monitor updates on the FDA's website, which provides helpful resources and guidance. One option is to appoint a task force to stay abreast of FDA updates and distribute the information to relevant stakeholders within the organization. Regardless, make sure you understand the DSCSA requirements sooner rather than later to leave time for follow-up questions and clarifications.
- Communicate internally. Confusion about the FDA's licensure standards—and whose responsibility it is to address them—can result in doing redundant work or missing a task completely. Create a company-wide plan that includes a clear timeline for when each action item must be completed, clearly defined roles and responsibilities for teams and individuals, and a place to direct questions or concerns.
- Converse with trading partners. Each stakeholder group should be prepared to exchange data by the end of 2022 to allow a buffer period in which you can address issues before interoperability compliance is required. Communicate now with your authorized trading partners—including manufacturers, distributors, and dispensers—to ensure each group is taking the necessary steps to digitize processes.

Failure to meet the 2023 deadline can result in reputational damage, lost business, federal fines, and even imprisonment. Clear internal and external communication is key to avoiding these repercussions and setting your organization up for success.

5 questions to ensure preparedness for the DSCSA 2023 deadline

Once you gain an understanding of the interoperability requirements and communicate with internal and external stakeholders, review your tech stack as well as your current processes and systems. To make sure you are ready, ask yourself the following questions:

1. Are your serialization protocols up to date? As of 2015, manufacturers, packagers and wholesalers exchanged TI and TS at the lot level. However, starting in 2023 you will need serialization down to the package level to enable unit-level traceability.
2. Do your current systems support new requirements? New DSCSA guidelines require supply chain systems to be able to process transaction history, exchange 3T documentation and read various file formats including CSV and EPCIS. Can your system send and receive serialized and aggregated data? Are you able to compare physical shipments with electronic data? Cloud-based technologies such as enterprise resource planning (ERP) enable real-time access to product information. Consider investing in software that makes staying compliant seamless, rather than making it an extra step in your process.
3. Do you need new hardware? In the past, outbound shippers would scan a linear barcode and the shipment of products would be good to go. Now, the outbound process involves a different type of barcode—which likely means you need new hardware. If the current barcode scanners your company uses are not able to process this new type of 2D barcodes, research other options and invest accordingly. Additionally, if you are incorporating new software or other digital tools into your tech stack you must also make sure its corresponding hardware is up to date.
4. Are your operations secure? Security is front and center as the pharma supply chain turns increasingly digital—consider both your cybersecurity posture and the partners you work with. Your digital tools and processes must be secure to avoid falling victim to cybercrime, especially considering the rise in attacks in recent years. Since phase two of the DSCSA requires trading partners to be authorized, make sure your trading partners are fully authorized to manufacture, package, distribute, and dispense pharmaceuticals. You should also verify they are operating in a secure manner.
5. Is an audit necessary? Consider turning to a third-party auditor to ensure full compliance before the 2023 deadline. To prepare for the assessment, create a list of DSCSA requirements that impact your business and what you are doing to meet them. You should also document procedures and perform mock audits using internal resources and personnel.

The pharma supply chain is a complex operation, but digitizing the data tied to it will do more than just help you reach compliance—it will also increase visibility and your bottom line. Greater visibility into pharma supply chain operations will improve traceability and accuracy in prescription drug orders.

The result is that it will be easier for stakeholders to identify counterfeit pharmaceuticals, enabling faster recalls and better access to safe prescription drugs. Ultimately, operations will become more efficient and all stakeholders will reap the benefits.

Prepare now: 2023 is not all too far away

The DSCSA is an ever-evolving regulation that will undoubtedly continue to expand and iterate. Don't view the push to achieve compliance by 2023 as a one-time initiative. Instead, view it as a roadmap of developing and continuously improving the processes and systems your organization needs to operate. The sooner you start moving toward electronic and interoperable data exchange, the better off you will be in Nov. 2023.