FDA Delays Drug-Tracking Pilot Programs
Industry Seeking Clarification of Terms and Requirements

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The deadline for companies in the drug supply chain to implement interoperable tracking of pharmaceuticals is five years off. That would seem to be a reasonable amount of time for the Food and Drug Administration (FDA) to nail down the essential requirements imposed by Congress when it passed the Drug Supply Chain Security Act (DSCSA) in 2013.

But FDA efforts to get the process moving by establishing pilot projects have run into opposition from sectors of the pharmaceutical industry.

In April 2016, the agency announced that it wanted to set up pilot projects that would test electronic tracking of drug packages up and down the distribution chain. It gave interested parties 30 days to comment after holding a public hearing at that time. Many of the comments were uncharitable.

For the next year, there wasn’t a peep from the agency on the pilot projects. Then, on April 30, 2017, the FDA announced that it was starting the information-gathering process all over again. Companies were given a year to provide thoughts on the pilot projects’ makeup.

Pharmacists are particularly unaware of the DSCSA requirements, many of which take effect for “dispensers” (pharmacists) in 2020. American Pharmacists Association (APhA) members “indicated that they were unaware that FDA is exploring pilot projects and stated that their participation in such projects was highly unlikely, often because of resource constraints or concern over interrupted workflow,” says Thomas E. Menighan, BSPharm, APhA Executive Vice President and CEO.

Since January 2015, participants in the drug distribution chain have had to exchange lot-level transaction information (TI), transaction history (TH), and transaction statement (TS) at each sale or ownership transfer. That can be done via paper or electronically. Also as of January 2015, manufacturers, packagers, wholesalers, and pharmacies must notify the FDA and any trading partners that a product in their possession or control is not legitimate. Starting in November 2017, pharmaceutical manufacturers’ 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.

That is the big step: printing all that information on package labels, the totality of the digits adding up to the product identifier, which many refer to as the Global Trade Item Number (GTIN) specified by GS1, the standards organization. The GTIN consists of a 2D bar code, serial number, lot, and expiry. A company assigns its own GTINs, which are often based on the product’s NDC. Janssen (which has been very active) uses that data to create what it calls a “serialization license plate.”

But requirements going forward are much more complex—hence the importance of pilot projects. All players in the drug chain will not only have to query one another electronically when establishing or verifying the identity of a product, they must also be able to trace a particular package to the carton and pallet it was in when it came off the manufacturer’s packaging line. Here the term “aggregation” comes up, often described as a child-parent-grandparent hierarchical relationship, from the package to the case to the pallet.

“Experience has shown that aggregation is achievable and sustainable; however, it is complex and costly. In terms of installation, the cost and time to implement serialization and aggregation on an existing packaging line varies widely and is dependent upon several variables, including age of the line and current technology, number of SKUs packaged on the line, and number of markets served by that line,” explains Michael P. Rose, Vice President of Supply Chain Visibility for Johnson & Johnson Supply Chain. Retrofitting a line with serialization alone requires approximately 50% less time and approximately 70% less money than retrofitting a line with both serialization and aggregation, he notes.

At its April 2016 workshop, the FDA previewed key technical terms that are specified in the 2013 law, such as data requirements for TI, TS, TH, aggregation, inference, and interoperability. The Healthcare Distribution Management Association (HDMA), for one, says that confusion over DSCSA requirements reigned at the workshop, and as a result, the FDA is nowhere near ready to begin pilot tests of an interoperable system until it specifies exactly what the terms above mean, and the requirements surrounding them. The HDMA mainly represents pharmaceutical distributors, big and small.

“Without this essential groundwork, it will not be possible to develop useful pilots that will instruct on methods to establish a secure, interoperable, electronic system,” says Anita Ducca, HDMA Senior Vice President for Regulatory Affairs. “Failing to reach agreement on a common understanding of the DSCSA would also contribute to another potential pitfall, what HDMA refers to as ‘scope creep.’”

Perhaps it would make sense for the FDA to pin down the requirements for interoperability before it starts the pilot projects. That should be done quickly, so the pilots can begin. Otherwise the industry will approach 2023 scratching its collective head in confusion and worrying about FDA enforcement penalties.

REFERENCES