Drug Supply Chain Security Act (DSCSA) Frequently Asked Questions

What is the Drug Supply Chain Security Act?
The Drug Supply Chain Security Act (DSCSA) was signed into law by President Obama on November 27, 2013. Title II of the Drug Quality and Security Act (DQSA), DSCSA, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

What does this mean for the future of drug supply chains?
Ten years after the enactment of DSCSA, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain. The new system will:

- 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.

How does this affect me?
Drug manufacturers, wholesale drug distributors, repackagers and many dispensers (primarily pharmacies) will be called on to work in cooperation with the U.S. Food and Drug Administration (FDA) to develop the new system over the next 10 years.

Among key provisions that will be implemented over the next 10 years are requirements for:

- **Product tracing:** Manufacturers, wholesaler drug distributors, repackagers and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- **Detection and response:** Manufacturers, wholesaler drug distributors, repackagers and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved or potentially dangerous.
- **Notification:** Manufacturers, wholesaler drug distributors, repackagers and many dispensers (primarily pharmacies) to establish systems and processes to notify the FDA and other stakeholders if an illegitimate drug is found.
- **Wholesaler licensing:** Wholesale drug distributors to report their licensing status and contact information to the FDA. This information will then be made available in a public database.
- **Third-party logistics provider licensing:** Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

Why is this system being implemented?
This system will enhance the FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful. The system will improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers. Failure to comply with the requirements of the law can result in penalties.

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