Timeline for the Drug Supply Chain and Security Act

(Title II, Drug Quality and Security Act, 2013)

Overview

The Drug Supply Chain and Security Act (Title II, Drug Quality and Security Act, 2013) addresses risks in the pharmaceutical distribution supply chain by establishing a national system that allows stakeholders and regulators to trace each package of product. The serialization and traceability requirements will be phased in over the next 10 years. The law requires all sectors in the supply chain—manufacturers, repackagers, wholesale distributors, and dispensers—to participate.

The following timeline captures key implementation dates for each sector and their relationship to one another in the national system.

The data visualization was updated in January 2015 to reflect changes in the U.S. Food and Drug Administration's enforcement discretion.

Manufacturing

Pharmaceutical manufacturers, the first step in the distribution supply chain, develop and produce prescription drugs for consumers and patients. They ship finished medicines to repackagers, wholesale distributors, and directly to dispensers.

	Description	Relationship to other sectors	Related requirements
 **Trade with authorized trading partners** Jan. 1, 2015	Manufacturers may engage in sales transactions only with appropriately licensed or registered trading partners.	All sectors must follow this requirement.	
 **Provide transaction information to trading partners*** Jan. 1, 2015	Manufacturers must provide transaction information (what drugs were shipped, when, and to whom), transaction history, and a transaction statement for all sales. They must also provide this information to regulators during a recall or investigations of suspect products.	Transaction information provided by manufacturers is the first step in a tracing system. New transaction information from each upstream trading partner is added to create a transaction history extending back to the manufacturer or initial wholesale distributor.	
 **Quarantine and investigate suspect products** Jan. 1, 2015	Manufacturers must have systems in place to investigate product suspected of being potentially counterfeit, diverted, or otherwise unsafe. If a suspect product is identified, it must be quarantined, and the applicable transaction history or transaction information must be validated. Records of an investigation must be kept for six years.	Manufacturers will coordinate with affected trading partners to conduct investigations, including validating the transaction history and transaction information.	
 **Identify and remove illegitimate products, and notify FDA and trading partners** Jan. 1, 2015	Manufacturers must have systems in place to remove from distribution products identified as potentially counterfeit, diverted, or otherwise unsafe, and to notify trading partners of the same. If a manufacturer identifies an illegitimate product, or if there is high risk of illegitimacy, the manufacturer must notify FDA and all immediate trading partners within 24 hours.	Manufacturers will assist trading partners with removing illegitimate products from distribution and will inform immediate trading partners when a notification is no longer necessary and has been terminated.	
 **Serialize with unique product identifier** Nov. 27, 2017	Manufacturers must put a unique product identifier on each drug package and sealed homogeneous case. Product identifiers will be used to verify a drug's legitimacy, and once the system is fully implemented (by 2023), they will enable product tracing in the event of a recall or the identification of a suspect product.	Repackagers must place product identifiers on drug packages one year after manufacturers are required to do so. Use of product identifiers by downstream trading partners will be phased in over time.	

	Description	Relationship to other sectors	Related requirements
 **Provide transaction information to trading partners in electronic format** Nov. 27, 2017	Manufacturers must provide transaction information (what drugs were shipped, when, and to whom), transaction history, and transaction statement (confirming that the manufacturer is licensed and did not knowingly supply false information) in an electronic document to trading partners for all sales.	Other sectors are not required to provide transaction information in an electronic format until the full electronic traceability system begins in Nov. 2023.	
 **Respond to verification requests from trading partners** Nov. 27, 2017	Manufacturers must respond to requests from trading partners that they verify a product identifier within 24 hours of receipt or another reasonable time to be determined by FDA.	Other trading partners may request that a manufacturer verify a product identifier. The manufacturer must have systems in place to comply with such requests.	
 **Verify unique product identifier of suspect products at package level** Nov. 27, 2017	Manufacturers must verify the product identifier, which includes the standardized numerical identifier, or SNI, for product they suspect is counterfeit, diverted, or otherwise unsafe.	Repackagers (starting in 2018), wholesale distributors (2019), and dispensers (2020) must verify the product identifier of suspect products.	
 **Verify the unique product identifier of returned products intended for resale** Nov. 27, 2017	Manufacturers must verify the product identifier, including the SNI, of the returned product intended for resale.	Repackagers (starting in 2018) and wholesale distributors (2019) must verify the product identifier of returned products intended for resale.	
 **Participate in electronic package-level traceability system** Nov. 27, 2023	Manufacturers must exchange transaction information and statements in an interoperable electronic manner, and transaction information must include product identifiers. Manufacturers must put in place systems and processes for electronic package-level verification and provide traceability information to allow regulators to have access to a drug's full distribution history during a recall or when investigating suspect products.	Repackagers, wholesale distributors, and dispensers must participate in an electronic package-level traceability system.	

* FDA announced in Dec. 2014 that it will exercise enforcement discretion and allow a four-month grace period until May 1, 2015 for the exchange of certain product-tracing data.

Repackagers

Manufacturers may not always offer product in the package types that downstream trading partners demand. Repackagers address this supply need by repacking and relabeling pharmaceutical product for further sale or distribution.

	Description	Relationship to other sectors	Related requirements
 **Trade with authorized trading partners** Jan. 1, 2015	Repackagers may engage in sales transactions only with appropriately licensed or registered trading partners.	All sectors must follow this requirement.	
 **Provide transaction information to trading partners and regulators upon request*** Jan. 1, 2015	Repackagers must not accept ownership of a product unless the previous owner provides transaction information, transaction history, and a transaction statement, and must provide this information for all sales. They must also provide this information to regulators during a recall or investigations of suspect products.	For each subsequent transaction, new transaction information received from upstream trading partners is added to create a transaction history extending back to the manufacturer or initial distributor.	
 **Quarantine and investigate suspect products** Jan. 1, 2015	Repackagers must have systems in place to investigate products suspected of being potentially counterfeit, diverted, or otherwise unsafe. If a suspect product is identified, it must be quarantined and the applicable transaction history or transaction information must be validated. Records of an investigation must be kept for six years.	Repackagers will coordinate with affected trading partners to conduct investigations, including validating the transaction history and transaction information.	
 **Identify and remove illegitimate products, and notify FDA and trading partners** Jan. 1, 2015	Repackagers must have systems in place to remove from distribution a product identified as potentially counterfeit, diverted, or otherwise unsafe, and must notify trading partners of the same. If a repackager identifies an illegitimate product, it must notify FDA and all immediate trading partners within 24 hours.	Repackagers will assist other trading partners with removing illegitimate product from distribution.	
 **Serialize with unique product identifier** Nov. 27, 2018	Repackagers must put a unique product identifier on each drug package and sealed homogeneous case, and it must be associated with the original manufacturer's product identifier. These will be used to verify a drug's legitimacy and enable product tracing in the event of a recall or the identification of a suspect product.	Manufacturers must place product identifiers on drug packages one year prior to repackagers. Use of product identifiers by downstream trading partners will be phased in over time.	

	Description	Relationship to other sectors	Related requirements
 **Respond to verification requests from trading partners** Nov. 27, 2018	Repackagers must respond to requests from trading partners for a product identifier within 24 hours of receipt or other reasonable time to be determined by the FDA.	Other trading partners may request that a repackager verify a product identifier. The repackager must have systems in place to comply with such requests.	
 **Verify unique product identifier of suspect products at package level** Nov. 27, 2018	Repackagers must verify the product identifier, which includes the standardized numerical identifier, or SNI, for product they suspect is counterfeit, diverted, or otherwise unsafe.	Manufacturers (starting in 2017), wholesale distributors (2019), and dispensers (2020) must verify the product identifier of suspect products.	
 **Verify the unique product identifier of returned products intended for resale** Nov. 27, 2018	Repackagers must verify the product identifier, including the SNI, of the returned product intended for resale.	Manufacturers (starting in 2017) and wholesale distributors (2019) must verify the product identifier of returned products intended for resale.	
 **Participate in electronic package-level traceability system** Nov. 27, 2023	Repackagers must exchange transaction information and statements in an interoperable electronic manner, and transaction information must include product identifiers. Repackagers must put in place systems and processes for electronic package-level verification and provide traceability information to regulators to permit creation of a drug's full distribution history when investigating suspect product or during a recall.	Manufacturers, wholesale distributors, and dispensers must participate in an electronic package-level traceability system.	

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Wholesale Distributors

Medicines may pass through a series of wholesalers before being delivered to a pharmacy, hospital, physician, or other dispenser. Wholesale distributors purchase pharmaceutical products from manufacturers, repackagers, or other wholesale distributors, and provide them to a variety of customers in the supply chain, including pharmacies, hospitals, and long-term care or other medical facilities.

	Description	Relationship to other sectors	Related requirements
 **Trade with authorized trading partners** Jan. 1, 2015	Wholesalers may engage in sales transactions only with appropriately licensed or registered trading partners.	All sectors must follow this requirement.	
 **Provide transaction information to trading partners and regulators upon request*** Jan. 1, 2015	Wholesalers must not accept ownership of a product unless the previous owner provides transaction information, transaction history, and a transaction statement, and this must be provided for all sales (with some exceptions). Wholesalers must also provide this information to regulators during a recall or when investigating suspect products.	For each subsequent transaction, new transaction information received from upstream trading partners is added to create a transaction history extending back to the manufacturer or initial distributor.	
 **Quarantine and investigate suspect products** Jan. 1, 2015	Wholesalers must have systems in place to investigate products that they suspect are potentially counterfeit, diverted, or otherwise unsafe. If a suspect product is identified, it must be quarantined, and the applicable transaction history or transaction information must be validated. Records of an investigation must be kept for six years.	Wholesalers will coordinate with affected trading partners to conduct investigations, including validating the transaction history and transaction information.	
 **Identify and remove illegitimate products, and notify FDA and trading partners** Jan. 1, 2015	Wholesalers must have systems in place to remove from distribution any product identified as potentially counterfeit, diverted, or otherwise unsafe, and to notify trading partners of the same. If a wholesaler identifies an illegitimate product, it must notify FDA and all immediate trading partners within 24 hours.	Wholesalers will assist other trading partners with removing illegitimate product from distribution.	
 **Accept only serialized product** Nov. 27, 2019	Wholesalers may engage only in transactions of products encoded with unique product identifiers, which will be used to verify a drug's legitimacy and enable product tracing in the event of a recall or the identification of a suspect product.	Manufacturers and repackagers must place product identifiers on drug packages. For downstream trading partners, this step will be phased in over time.	

	Description	Relationship to other sectors	Related requirements
 **Match original transaction information with returned products that will be resold** Nov. 27, 2019	Wholesalers may accept returned products for resale only if they can associate the returned product with the original transaction information and transaction statement for that product.	Other sectors are not required to associate saleable returns with original transaction information until the full electronic traceability system begins in Nov. 2023. Manufacturers, repackagers, and wholesalers must provide transaction information, transaction history, and transaction statements when returning saleable products.	
 **Verify unique product identifier of suspect products at package level** Nov. 27, 2019	Wholesalers must verify the product identifier, which includes the standardized numerical identifier, or SNI, for products they suspect are potentially counterfeit, diverted, or otherwise unsafe.	Manufacturers (starting in 2017), repackagers (2018), and dispensers (2020) are also required to verify the product identifier of suspect products.	
 **Verify the unique product identifier of returned products intended for resale** Nov. 27, 2019	Wholesalers must verify the product identifier, including SNI, of returned products intended for resale.	Manufacturers (starting in 2017) and repackagers (2018) are also required to verify the product identifier of returned products intended for resale.	
 **Participate in electronic package-level traceability system** Nov. 27, 2023	Wholesalers must exchange transaction information and statements in an interoperable electronic manner, and the transaction information must include product identifiers. Wholesalers must put in place systems and processes for electronic package-level verification and provide traceability information to regulators to permit access to a drug's full distribution history when investigating a suspect product or during a recall.	Manufacturers, repackagers, and dispensers must participate in an electronic package-level traceability system.	

* FDA announced in Dec. 2014 that it will exercise enforcement discretion and allow a four-month grace period until May 1, 2015 for the exchange of certain product-tracing data.

Dispensers

As the last step in the pharmaceutical distribution supply chain, dispensers serve an important role in safely getting medicine to patients. The term "dispensers" can apply to retail and hospital pharmacies, physicians, and others authorized by law to dispense or administer prescription drugs (though most of the requirements placed on dispensers do not apply to physicians).

	Description	Relationship to other sectors	Related requirements
 **Trade with authorized trading partners** Jan. 1, 2015	Dispensers may engage only in sales transactions with appropriately licensed or registered trading partners.	All sectors must follow this requirement.	
 **Provide transaction information to trading partners and regulators upon request** July 1, 2015	Dispensers must only accept products with transaction information, transaction history, and a transaction statement. This information must be provided for all sales, except when dispensing to patients, returning products, or selling to another dispenser fulfilling a specific patient need. They must give this information to regulators during recalls or when investigating suspect products, with exceptions.	For each subsequent transaction, new transaction information received from upstream trading partners is added to create a transaction history extending back to the manufacturer or initial distributor.	
 **Quarantine and investigate suspect products** Jan. 1, 2015	Dispensers must investigate products suspected of being potentially counterfeit, diverted, or otherwise unsafe. If a suspect product is identified, it must be quarantined and the applicable transaction history or transaction information must be validated. Records of an investigation must be kept for six years.	Dispensers will coordinate with affected trading partners to conduct investigations, including validating the transaction history and transaction information.	
 **Identify and remove illegitimate products, and notify FDA and trading partners** Jan. 1, 2015	Dispensers must have systems in place to remove from distribution any product identified as potentially counterfeit, diverted, or otherwise unsafe, and they must notify trading partners of the same. If a dispenser identifies an illegitimate product, it must notify FDA and all immediate trading partners within 24 hours.	Dispensers will assist trading partners with removing illegitimate product from distribution.	

	Description	Relationship to other sectors	Related requirements
 **Accept only serialized products** Nov. 27, 2020	Dispensers may engage in transactions only of a product encoded with a unique product identifier, which will be used to verify a drug's legitimacy and enable product tracing in the event of a recall or identification of a suspect product.	Manufacturers and repackagers must place product identifiers on drug packages. Use of product identifiers by downstream trading partners will be phased in over time.	
 **Verify unique product identifier of suspect products at package level** Nov. 27, 2020	Dispensers must verify the product identifier, which includes the standardized numerical identifier, or SNI, for products they suspect are potentially counterfeit, diverted, or otherwise unsafe at the package level for at least three packages or 10 percent of suspect products, whichever is greater.	Manufacturers (starting in 2017), repackagers (2018), and wholesale distributors (2019) are required to verify the product identifier of suspect products.	
 **Participate in electronic package-level traceability system** Nov. 27, 2023	Dispensers must exchange transaction information and statements in an interoperable electronic manner, and transaction information must include product identifiers. Dispensers must put in place systems and processes for electronic package-level verification and provide regulators with traceability information to allow for access to a drug's full distribution history during a recall or when investigating a suspect products.	Manufacturers, repackagers, and wholesale distributors must participate in an electronic package-level traceability system.	

For further information, please visit:

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