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Review of Drug Quality and Security Act of 2013: *The Drug Supply Chain Security Act (DSCSA)*

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In November 15, 2012, Dr. Margaret Hamburg a Commissioner of Food Drug Administration (FDA) testified before Congress regarding the tragic fungal meningitis outbreak associated with compounded methylprednisolone acetate, a steroid injectable product distributed by the New England Compounding Center in Framingham, Massachusetts that led to the death of 64 people.[1] A year later, in November 27, 2013 President Obama signed into law the Drug Quality and Security Act (DQSA). Title 1 of DQSA addresses compounding provisions through the Compounding Quality Act (CQA) which was motivated by the Framingham tragedy. [2] The Drug Supply Chain Security Act (DSCSA) is one of the two titles that comprises DQSA and it creates a uniform, national standard for tracing drug products through the supply chain. The goal of DQSA is to enhance FDA's ability to help protect consumers by detecting and removing potential dangerous products from the pharmaceutics distribution supply chain. DQSA outlines all the steps of a new electronic, interoperable system that will identify and trace certain prescription medication while distributed in the United States. The development of this system will be phased in with specific requirements over a 10 year period. It will be a cooperation between FDA and drug manufactures, wholesale drug distributors, repackagers and dispensers (primarily pharmacies).[3] Table 1. outlines all the services that the DQSA's new system will provide.

The implementation of the DSCSA is based on several law requirements and FDA has developed a schedule with time frames for each of them to be executed over a 10 year period. There are 15 key activities of the FDA plan that will guarantee an efficient and effective implementation described in table 2.[4]

Moreover, there are certain key provisions of the DSCSA which will be implemented over the next 10 years that require:

I. **Product identification**: Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.

II. **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.

III. **Product verification**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.

IV. **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.

V. **Notification**: Manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.

VI. **Wholesaler licensing**: Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.

VII. **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. [2]

In order to understand FDA requirements for the authorized trading partners, such as manufacturers, wholesaler drug distributors, repackagers, and dispensers it is important to understand the DSCSA definition for each of them. Under the DSCSA:

I. Manufacturer is a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product; if such product is not the subject of an approved application or license, the manufacturer is defined as the person who manufactured the product, a co-licensed partner that obtains the product directly, or an affiliate.

II. Wholesale distributor is a person (other than the manufacturer, a manufacturer's co-licensed partner, a third party logistics provider or repackager) who is engaged in the wholesale distribution. Whole sale distribution is the distribution of a prescription product to an entity or person other than the patient.

III. Dispenser is an entity that is authorized to dispense or administer prescription drugs and the affiliated warehouses or distribution centers of such entities:

- A retail pharmacy
- A hospital pharmacy
- A group of chain pharmacies that does not act as a wholesale distributor
- Any other person authorized by the law to dispense or administer prescription drugs
- Affiliated warehouses or distribution centers of such entities under common control that do not act as a wholesale distributor[2]

In addition, the DSCSA implementation plan includes some important dates for the authorized partners requirements described in the Table 3.[4]

The DSCSA traceability process includes only prescription drugs in the finished form for human use. There are certain products that are excluded from the DSCSA list. Table 4 includes all these products. [5]

Product tracking and tracing requirements are two important features of DSCSA. Transaction records as a part of DSCSA includes 3 components: transaction history (HI), transaction information (TI) and transaction statement (TS).[5]
TI must include:

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code (NDC) of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the shipment, if more than 24 hours after the date of transaction
- Business name and address of the person from whom and to whom ownership is being transferred

All sellers must provide the TI, TH, and TS to the subsequent owner for each transaction and each buyer must store the information received. All trading partners must store the records for a period of 6 years and make them available to a FDA audit.[2] Most of the data is stored through web-based portals. There are some changes regarding the dispenser (primarily pharmacies) where the lot number, transaction date and shipment date are required only if the pharmacy purchase a product from a second distributor instead of the primary distributor that buys directly from a manufacturer. In addition, the dispenser can return saleable products or non-saleable products to the trading partners without providing the requisite information; however by 2019 wholesale distributors will accept return products only if they contain the required product identifier.[2]

Tracing exceptions comprises another important feature of the DSCSA that are presented as following:

- Intracompany distribution of any product between members of an affiliate or within a manufacturer
- Distribution of product between hospitals or health care entities under common control
- Distribution of product for emergency medical reasons, which includes a public health emergency and excludes a drug shortage, unless caused by such a public health emergency
- Distribution of minimal quantities by a licensed retail pharmacy or licensed practitioner for office use. ("Minimal quantities" is not defined by the DSCSA, but many states define this as 5% or less of a pharmacy's sales. Pharmacists and pharmacy technicians should check with their state boards of pharmacy or appropriate regulatory bodies to verify the definition of "minimal quantities")
- Dispensing pursuant to a prescription
- Pharmacy sale to another pharmacy for a "specific patient need." A specific patient need means that an identified patient exists; it does not include transfers for the purpose of increasing or replenishing the quantity of a product in anticipation of a potential need[2]

In order to help trading partners, FDA has issued a document, FDA Guidance on Identifying Suspect Product and Notification that provides information about the risk of suspect drugs entering the supply chain. Some example scenarios include product sourcing, supply, demand, history, and value of the product, and product appearance. When dealing with product sourcing trading partners should be careful when they purchase from a new and unknown source, receive products from an unknown source, or purchasing from a trading partner who is involved in selling or delivering illegitimate products. In addition, the trading partner has a history of potentially false transaction histories (misspelled words or incomplete information), is reluctant to provide TH, or a TI, TS, and /or TH appears to be suspicious. Another scenario provided in the FDA guidance document is related to supply, demand, history, and value of the product. They include products that are in high demand, have a high sales volume, and have been previously counterfeited. Also, products that have been or are currently the subject of drug

shortage, have been subject of illegitimate product notification, and have been the subject of an FDA counterfeit or cargo theft alert. The last FDA example scenario recommends additional caution to a product appearance. Suspicious appearance includes: a transport container with a non-standard label (color, font, images), drug identification number that is different from NDC, missing information (lot number or expiration date), missing counterfeit technologies (holograms, color shifting inks, or watermarks), and a finished product that has different shape or color, unusual imprint or odor, and chips or cracks in the tablet coatings.[6]

The scenarios described above should not be view as an exhaustive list of all potential scenarios, but pharmacists and pharmacy technicians can use them to identify suspect products being delivered to their pharmacy. Accessing the DSCSA online resources on the FDA website is another way for dispensers to be up-to date with the implementation plan requirements.

Implementing the DSCSA law requirements is a challenging and complicated process. In order to receive valuable feedback from stakeholders, FDA held a public workshop on "Proposed Pilot Project under the Drug Supply Chain Security Act" in Silver Spring, MD, on April 5-6, 2016. Many participants including drug manufacturers, repackagers, wholesale distributors, third-party logistics providers, dispensers (pharmacies), and consultants shared their input related to the product identifiers, barcodes, interoperability, aggregation, database issues, and verification and notification issues. Moreover, the implementation of DSCSA requirements are not cheap, some of them include costs of $150-300,000 per packaging line and installation of IT systems to store and transmit data just to name a few.[2] I believe that a unified system will provide easier data exchange and fewer errors, will increase the safety and security of the pharmaceutical distribution supply chain. In addition, it will improve the supply-demand balance, allow better control of inventory, facilitate easier returns and recalls, decrease drug diversion and uncontrolled pricing.

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Table 1. DQSA national system services

DQSA National Electronic System
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
Facilitate more efficient recalls of drug products

Table 2. DSCSA implementation plan

Activities	Planned FDA Implementation Period	Planned Stakeholder Implementation Period
Issue notice of public docket to collect stakeholder comments on standards for interoperable exchange of transaction information, history and statement in paper or electronic format	Beginning of 2014 through early 2014	
Publish guidance on identification of suspect product and termination of notifications of illegitimate product for finished human prescription drugs	Beginning of 2014 through mid-2014	
Publish draft guidance establishing standards for interoperable exchange of transaction information, history, statement in paper or electronic format	Beginning of 2014 through late 2014	
Establish a system for third-party logistic provider reporting to FDA	Beginning of 2014 through late 2014	
Establish a system for wholesale drug distributor reporting to FDA and public database with licensing information.	Beginning of 2014 through late 2014	
Establish a system for wholesale drug distributor reporting to FDA and public database with licensing information	Beginning of 2014 through the end of 2014	
Develop regulations establishing standards for licensing of wholesale drug distributors.	Beginning of 2014 through late 2015	Late 2015 through late 2017
Develop regulations establishing standards for licensing of third-party logistics providers	Beginning of 2014 through late 2015	Late 2015 through late 2016
Publish guidance on processes for waivers, exceptions, exemptions	Beginning of 2014 through late 2015	Late 2015 through mid-2017
Publish final guidance on grandfathering product	Beginning of 2014 through late 2015.	
Conduct at least five public meeting	Beginning of 2015 through mid-2021	
Establish one or more pilot projects in coordination with stakeholders to explore and evaluate methods to enhance the safety and security of supply chain	Beginning of 2015 through end of 2020	
Conduct and complete a technology and software assessment on feasibility of small dispensers to conduct drug tracing at the package level.	Beginning of 2017 through end of 2020	
Publish final guidance on system attributes necessary to enable secure tracing at the package level	Beginning of 2018 through late-2022	Late 2022 through late 2023
Publish final guidance on the standards for interoperable data exchange to enhance secure tracing of product at package level	Beginning of 2018 through late-2022	Late 2022 through late 2023
Develop regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level	Beginning of 2017 through late-2021	Late 2021 through late 2023

Table 3. DSCSA key dates for partners

Authorized Partners	Action Required	Dates
Manufactures and distributors	Send and receive tracking and tracing documents. Suspect and illegitimate products requirements became effective	January 1, 2015
Dispensers	Receive tracking and tracing documentation, capture information, and maintain documentation for 6 years	July 1, 2015
FDA	Establish national standards for tracking , and tracing documentation in paper and electronic format, and waivers, exceptions, exemptions, and grandfathered guidance	November 27, 2015
Manufacturers	All product must be serialized	November 27, 2017
Repackagers	All product must be serialized	November 27, 2018
Wholesalers	Engage only in transactions with serialized products	November 27, 2019
Dispensers	Engage only in transactions with serialized products, and pharmacy lot-level traceability is required	November 27, 2020
All	Unit-level traceability required	November 27, 2023

Table 4. Products not included in the DSCSA

Products excluded from DSCSA list	
Over the counter medications	Compounded drugs
Blood or blood components for transfusion	Dialysis solutions
Radioactive drugs or radioactive biological products	Sterile water (irrigation or injectable), IV products intended for replenishment of fluids and electrolytes (sodium, chloride, potassium, etc.) or calories (dextrose, amino acids, lipids)
Imaging drugs	Combination kits or trays that do not include a controlled substance, i.e., first aid kits, suture kits
Medical gases	Drug samples
Drug samples	Minimal quantities of product from a licensed retail pharmacy to a licensed practitioner for office use
Distribution between facilities under common ownership	Dispensing or administering the product to the patient
Distribution to another dispenser for a specific patient need	