

Enhanced Drug Distribution Security in 2023 Under the Drug Supply Chain Security Act (DSCSA)

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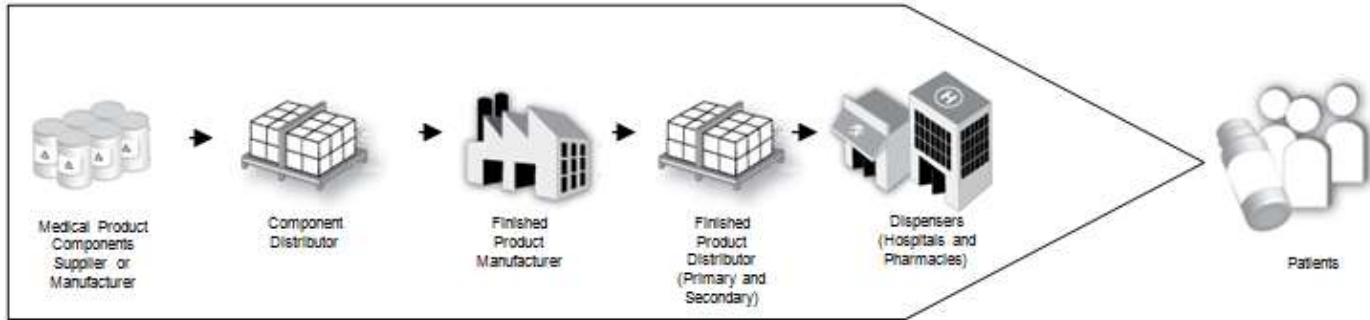
Office of Drug Security, Integrity, and Response
Office of Compliance
CDER | US FDA

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Learning Objectives

- Discuss enhanced drug distribution security requirements that go into effect in 2023 under the Drug Supply Chain Security Act (DSCSA)
- Explain how enhanced drug distribution security will help protect patients from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful
- Summarize updates on implementation of supply chain security requirements under the DSCSA

Pharmaceutical Supply Chain



Maintaining integrity from manufacturer to patient(s)

- Who touches the product?
- Where are the vulnerabilities?
- What are the threats?

Protect the product



Protect the patient

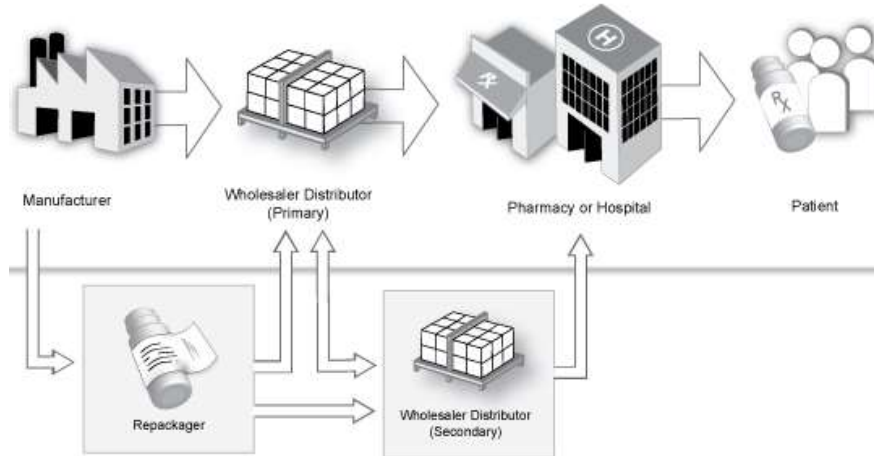
Threats to the Pharmaceutical Supply Chain

Illegitimate product

Counterfeit, diverted, stolen, intentionally adulterated, subject to a fraudulent transaction, or otherwise unfit for distribution that would result in serious adverse health consequences or death to humans

Unscrupulous players

- Distribute illegitimate product
- Don't maintain quality of the product
- Don't maintain security or integrity of the supply chain (examples: are not authorized or do business with entities that are not authorized)



Weakness in the drug supply chain can be anywhere

Recent Counterfeits

Gilead Warns of Counterfeit HIV Medication Being Distributed in the United States

Foster City, Calif., August 5, 2021 – Gilead Sciences has become

Biktarvy tablets (Image from Gilead)



Descovy tablets (Image from Gilead)



Symtuza tablets (Image from Janssen/Johnson & Johnson)



Media Statement

December 24, 2020

Janssen Alerts Counterfeit SYMTUZA® (darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide) is Being Distributed in the United States

Protecting the supply chain ultimately protects patients!

Investigate and properly handle suspect and illegitimate products



Suspect Product: *reason to believe* that product potentially is:

- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Illegitimate Product: *credible evidence* shows that the product is:

- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans

Notify FDA of Illegitimate Product within 24 hours (Form FDA 3911) and other trading partners within 24 hours

The Drug Supply Chain Security Act

DSCSA

- Enacted November 27, 2013
- Outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the U.S.
- Enhances ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful
- Improves detection and removal of potentially dangerous drugs from the drug supply chain

DSCSA Goals

1. Implement interoperable, electronic tracing of products at the package level by 2023 that will:

Enable secure tracing of product at the package level

Use product identifiers to verify product at the package level

Enable prompt response to suspect and illegitimate products when found

Improve efficiency of recalls

2. Establish national standards for licensure for wholesale distributors and third-party logistics providers (3PLs)

DSCSA Key Requirements

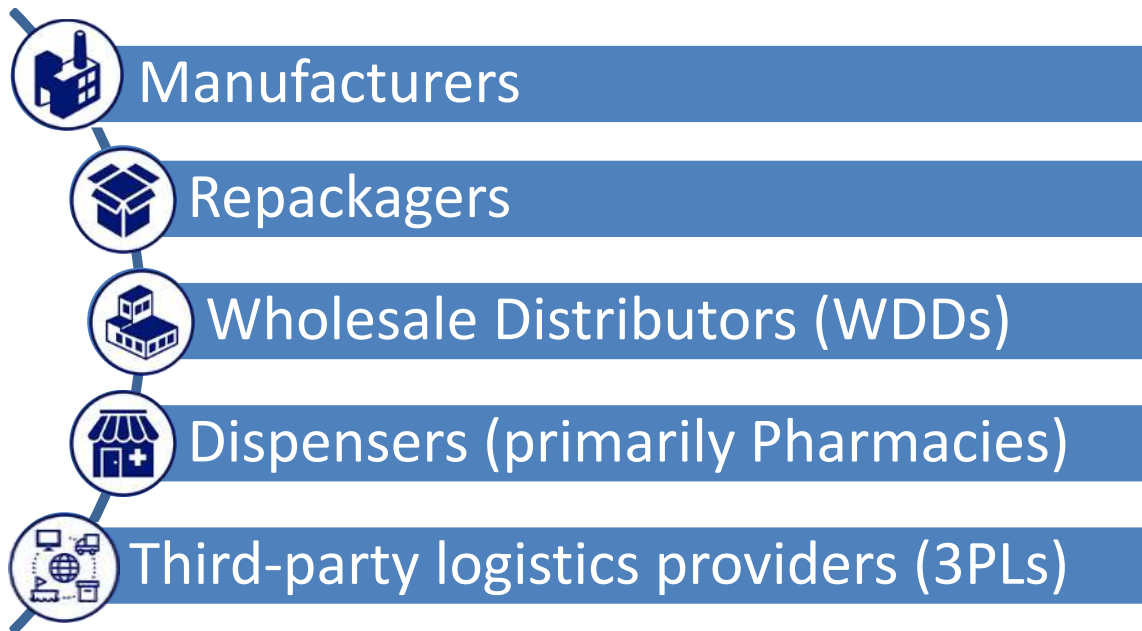
Product
Tracing

Verification

Product
Identifier

Authorized
Trading
Partner

Trading Partners under DSCSA



Products

- What's covered:

Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)

- What's not covered:

- Blood or blood components intended for transfusion
- Radioactive drugs or biologics
- Imaging drugs
- Certain IV products
- Medical gas
- Homeopathic drugs
- Lawfully compounded drugs

Refer to the definition for “product” in section 581(13) of the FD&C Act for specific information regarding exceptions.

Transactions

- Involve transfers of product where a *change of ownership* occurs

- Excludes:

- Intracompany distributions
- Distribution among hospitals under common control
- Public health emergencies
- Dispensed pursuant to a prescription
- Product sample distribution
- Blood and blood components for transfusion
- Minimal quantities by a licensed pharmacy to a licensed practitioner
- Certain activities by charitable organizations
- Distributions pursuant to a merger or sale
- Certain combination products
- Certain medical kits
- Certain IV products
- Medical gas distribution
- Approved animal drugs

Refer to the definition for “transaction” in section 581(24) of the FD&C Act for specific information regarding exclusions.

Product Tracing Information

Transaction Information (TI):

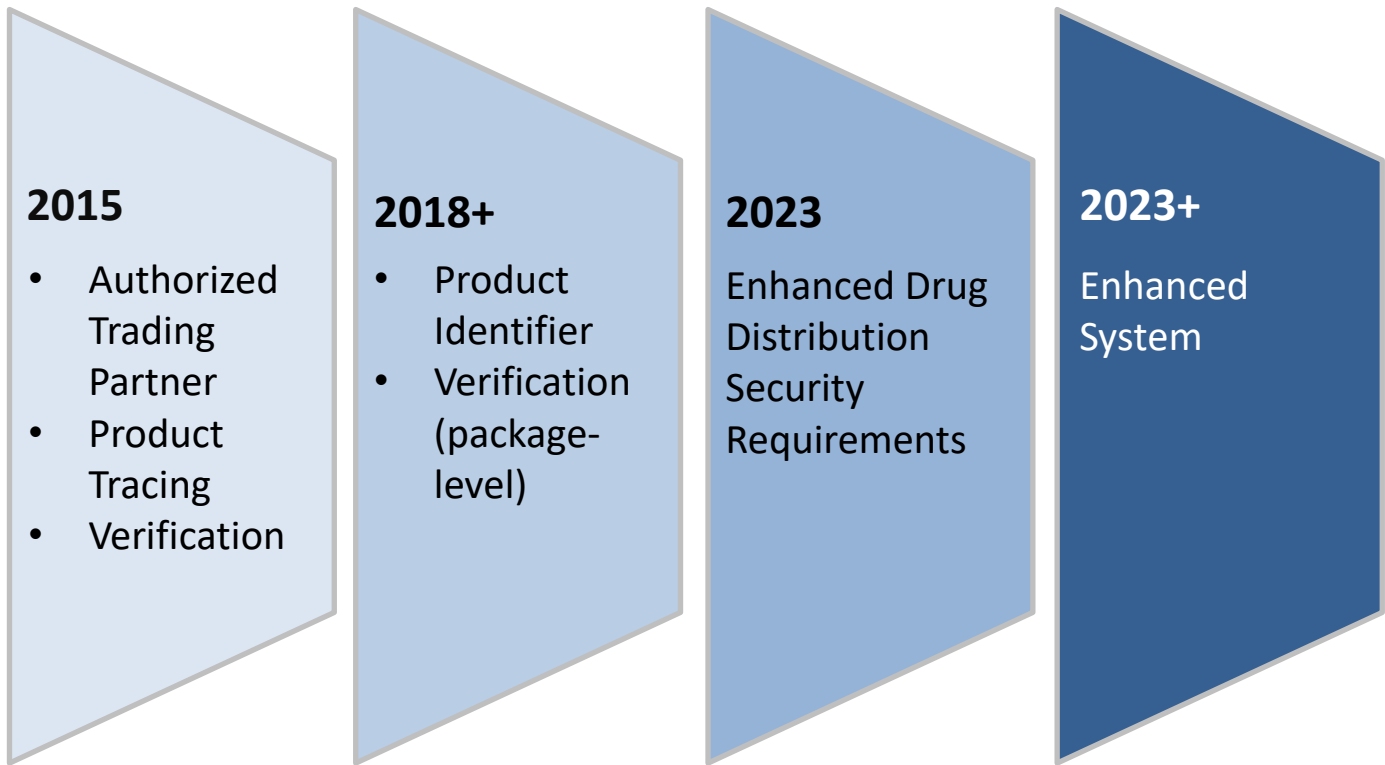
- Proprietary or established name or names of the product;
- Strength and dosage form of the product;
- National Drug Code number of the product;
- Container size;
- Number of containers;
- Lot number of the product;
- Date of the transaction;
- Date of the shipment, if more than 24 hours after the date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

Transaction History (TH): A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product

Transaction Statement (TS): A statement, in paper or electronic form, that the--

- Entity transferring ownership in a transaction is authorized as required under DSCSA;
- Received the product from a person that is authorized as required under DSCSA;
- Received transaction information and a transaction statement from the prior owner of the product, as required under the law;
- Did not knowingly ship a suspect or illegitimate product;
- Had systems and processes in place to comply with verification requirements under the law;
- Did not knowingly provide false transaction information; and
- Did not knowingly alter the transaction

DSCSA Implementation



DSCSA Implementation

2015

Authorized Trading Partners

- Manufacturers and Repackagers: valid registration with FDA
- WDDs & 3PLs: valid State or Federal license and compliance with reporting requirements
- Dispensers: valid State license

2015

Product Tracing

- Lot-level
- Provide and receive transaction documentation with each sale
- Respond to request for information
- Store records
- Paper and electronic formats

2015

Verification

- Quarantine and investigate suspect product
- Investigation illegitimate product
- Notify FDA and trading partners of illegitimate product
- Response to verification requests
- Store records

DSCSA Implementation

2018

Product Identification (Serialization)

- Manufacturers & repackagers encode product identifiers on prescription drug packages on the smallest individual saleable unit

Product Identifier: National Drug Code (NDC), Serial Number, Lot, Expiration Date)

2018+

Verification

- Serialized product can be verified down to the package level using the product identifier
- Saleable returns
- Compliance policies issued that provide additional time

DSCSA Implementation

2023

Enhanced Drug Distribution Security Requirements

- All electronic
- Enhanced product tracing at the package level (i.e., includes product identifier)
- Enhanced verification

2023 & Beyond

Enhanced System

- Enhanced drug distribution security
- Across the pharmaceutical supply chain
- Improved inspections and investigations
- Improved data analytics
- Continued compliance and enforcement



Challenge Question #1

Key supply chain security requirements under DSCSA include which of the following?

- A. Product Tracing
- B. Verification
- C. Product Identifier
- D. Authorized Trading Partner
- E. All of the above

DSCSA Key Requirements

Product
Tracing

Verification

Product
Identifier

Authorized
Trading
Partner

2023 Enhanced Drug Distribution Security

Effective 11/27/2023



Section 582(g) Enhanced Drug Distribution Security -

- (1) In general.--On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:
- (A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.
 - (B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.
 - (C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.
 - (D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.
 - (E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required-
 - (i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or
 - (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).
 - (F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.



System Attributes

- Transaction Information (TI) and Transaction Statement (TS) will be exchanged in a secure, interoperable, electronic manner...
- TI will include the product identifier at the package level for each package included in the transaction.
- Systems and processes for verification of product at the package level, including the standardized numerical identifier...which may include the use of aggregation and inference as necessary.
- Systems and processes necessary to promptly respond with the TI and TS for a product upon a request by FDA (or other appropriate Federal or State official) in the event of a recall or for investigating a suspect product or an illegitimate product
- Systems and processes necessary to promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer, as applicable (upon a request by FDA...or an authorized trading partner...)
- Systems and processes in place to allow acceptance of saleable returns and only if such person can associate the saleable return product with the TI and TS associated with that product.

Aggregation and Inference

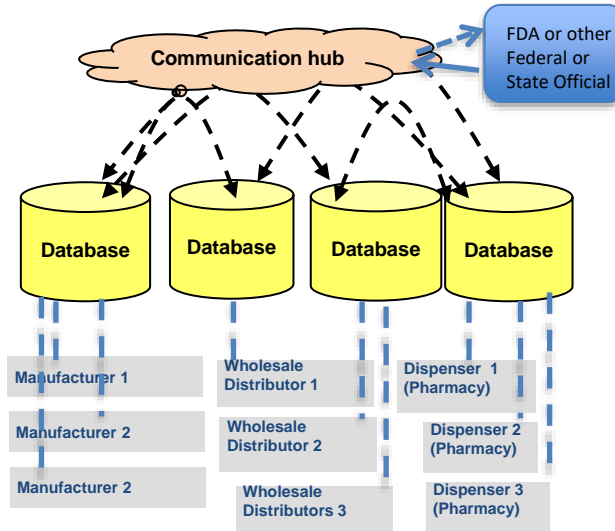
- Aggregation is the process of building a relationship between unique identifiers assigned to packaging containers.



- Inference involves examining information for a higher level of packaging to infer information about the next level of packaging and its contents.

System Structure

Semi - centralized Model



Centralized

- Trading partners provide data into a central repository (database)
- Product tracing and verification is performed by querying the central repository

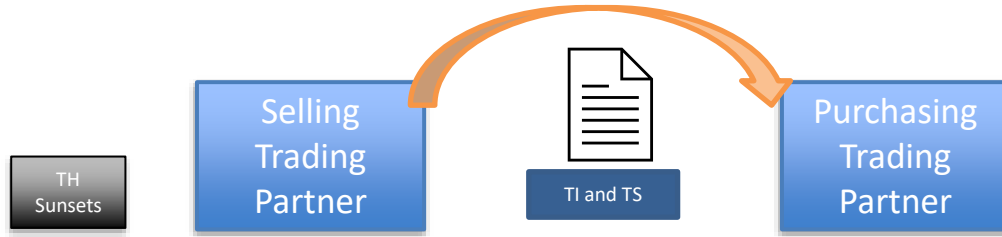
Decentralized

- Trading partners maintain their data in their own local database or a data storage provider's database
- Product tracing and verification is performed by querying the multiple databases
- A communications hub (active or passive) connects different databases

Semi – Centralized

- Trading partners maintain data into a few centralized databases or data storage provider(s) database(s)
- Product tracing and verification is performed by querying the each databases
- A communications hub connects different databases

Enhanced Product Tracing: Exchange of Transaction Information & Statement



Beginning 11/27/2023 -

- Exchange of transaction information and transaction statements must be in a secure, interoperable, electronic manner
- Additional requirement to promptly facilitate the gathering of information necessary to produce the transaction information for each transaction going back to the manufacturer

Product Identifier (Serialization)



Manufacturers/Repackagers (November 2018)

- Encode product identifiers on prescription drug packages
- Determine smallest individual saleable unit
- Verification requirements changes once products are serialized with product identifier



Product Identifier

- National Drug Code (NDC)
- Serial Number
- Lot Number
- Expiration Date

Human and machine readable formats

Machine readable barcodes:

- 2D data matrix for packages
- Linear or 2D data matrix for homogenous cases

Packages Without Product Identifiers

Excluded Products

Not all prescription drugs are required to have a product identifier and are excluded.

Grandfathered

Some products will be in the supply chain before the product identifier requirement took effect.

Waiver, Exception or Exemption

Some products were granted a waiver, exception or exemption from the product identifier requirement.

If you are unsure whether a product should have a product identifier, verify with the manufacturer or repackager.

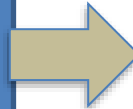
Enhanced Product Tracing: Serialized Transaction Information

Beginning 11/27/2023, the exchange of transaction information (TI) shall include the **product identifier** at the package level.

Pre-November 2023

Transaction Information:

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

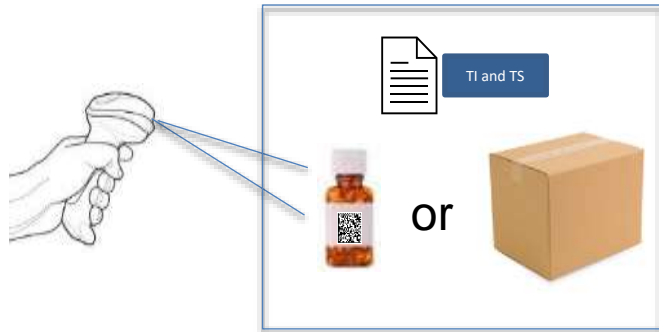


November 2023+

Transaction Information:

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

Enhanced Product Tracing: Reconciliation of Data and Product



Selling Trading Partner

- Read product identifier (barcode) on the outbound package(s) or homogenous case(s) to fulfill an order
- Capture this data for the product tracing information (TI/TS) to be sent to the purchasing trading partner
- Provide data (TI/TS) and product(s) to purchasing trading partner

Purchasing Trading Partner

- Receive data (TI/TS) and product(s) from selling trading partner
- Read product identifier (barcode) on the inbound package(s) or homogenous case(s) received in an order
- Capture this data and reconcile with associated product tracing information (TI/TS) received from the selling trading partner



Enhanced Product Tracing: Handling Aggregation Errors & Other Discrepancies

- Product tracing information should be true, accurate, and complete.
- There may be a clerical error or discrepancy in product tracing information that may not be indicative of a suspect product.
- If a trading partner purchases product and identifies a potential clerical error or other discrepancy in product tracing information it received, that trading partner should resolve the error or discrepancy.
 - Immediately contact the trading partner that provided product tracing information
 - Do not sell product until the error or discrepancy has been resolved
 - If the error or discrepancy cannot be resolved and the product is determined to be a suspect or illegitimate product, follow steps for verification if applicable (e.g., quarantine and investigation)

Examples:

Aggregation Errors

- **Missing product:** Product tracing information reflects 10 bottles of product and purchasing trading partner only received 9 bottles
- **Extra product:** Product tracing information reflects 10 bottles of product and purchasing trading partner received 12 bottles
- **Duplicate data:** Product tracing information contains the same product listed twice
(This should not be confused with duplicate serial numbers listed for two packages of a product; this scenario should be considered as suspect.)
- **Missing data:** Product identifier for the homogeneous case is missing so there is no other identifier to associate with product identifiers of the packages of product physically received within the case

Examples: Other Discrepancies

Other discrepancies may occur during the ordering, shipment, or receipt of product. For example:

- The transaction information is missing the address of the purchasing trading partner.
- The transaction information misstates the address of the purchasing trading partner.
- The transaction information is missing the quantity of product, but the purchasing trading partner received the quantity of product that it ordered.

Recommendations:

How to Resolve Errors & Discrepancies

- Immediately contact the selling trading partner that provided product tracing information and determine the reason for the error
- Work together to resolve the error and document through current business practices (e.g., nature of error, how error was resolved, names of persons involved, date of resolution)
- If the product is determined to be a suspect or illegitimate, follow steps for applicable verification requirements (e.g., quarantine, investigation, and proper disposition)



Challenge Question #2

Which of the following statements is **NOT** true about DSCSA requirements?

- A. Verification includes quarantine and investigation of suspect product and quarantine and disposition of illegitimate product.
- B. When a trading partner identifies illegitimate product, it must notify FDA and other immediate trading partners within 24 hours of making the determination.
- C. For products under DSCSA, it is optional to encode packages with a product identifier that includes the NDC, serial number, lot number and expiration date.
- D. Product tracing changes in 2023 and the transaction information will need to include the data elements of the product identifier at the package level for each package.

Product Identifier (Serialization)



Manufacturers/Repackagers (November 2018)

- Encode product identifiers on prescription drug packages
- Determine smallest individual saleable unit
- Verification requirements changes once products are serialized with product identifier



Product Identifier

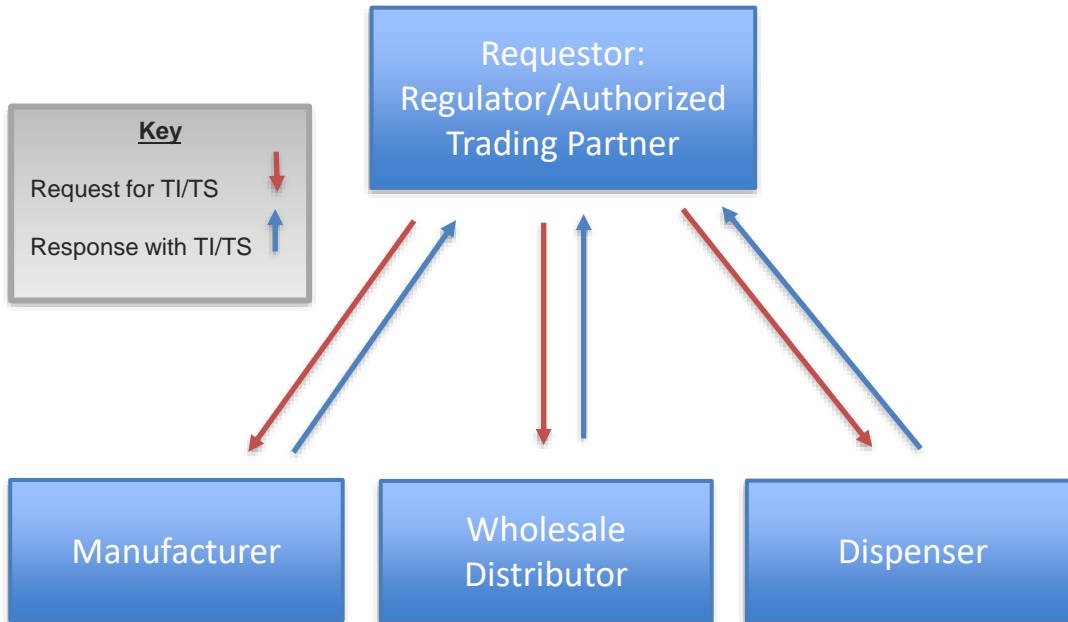
- National Drug Code (NDC)
- Serial Number
- Lot Number
- Expiration Date

Human and machine readable formats

Machine readable barcodes:

- 2D data matrix for packages
- Linear or 2D data matrix for homogenous cases

Gathering of Relevant Product Tracing Information

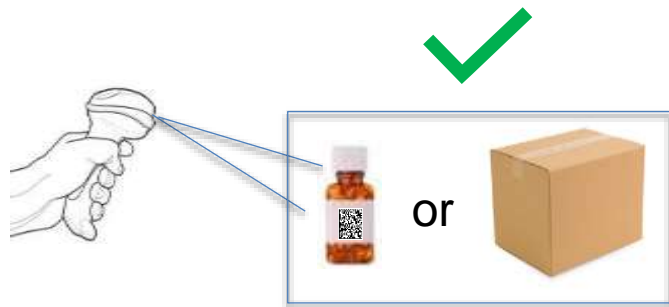


Under sections 582(g)(1)(D) and (E) of the FD&C Act:
 ...promptly respond with the TI and TS...upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required...

and

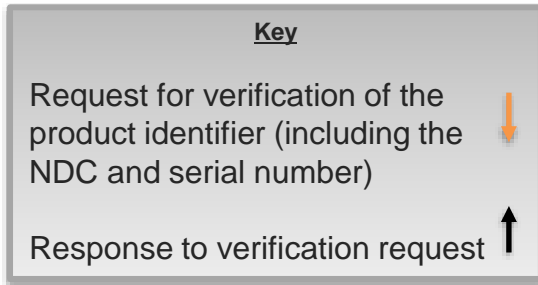
...promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer... (i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

Enhanced Verification: Package-Level



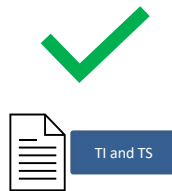
Requestor:
FDA/Authorized
Trading Partner

Authorized Trading
Partner



Under section 582(g)(1)(C) of the FD&C Act: systems and processes for verification of product at the package level, including the standardized numerical identifier shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h)...which may include the use of aggregation and inference as necessary.

Enhanced Verification: Saleable Returns



Authorized Trading Partner:
who is accepting
returned product

Under Section 582(g)(1)(F) of the FD&C Act: Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.



Challenge Question #3

Is the following statement true or false?

Enhanced drug distribution security requirements that go into effect in 2023 include the exchange of transaction information and transaction statements in a secure, interoperable, electronic manner.

- A. True
- B. False



2023 Enhanced Drug Distribution Security

Effective 11/27/2023

Under section 582(g)(1) of the FD&C Act requirements for interoperable, electronic tracing of product at the package level go into effect :

- (A) the exchange of transaction information and transaction statements in a secure, interoperable, electronic manner;
- (B) transaction information that includes the data elements of the product identifier at the package level for each package included in the transaction;
- (C) systems and processes for verification of product at the package level;
- (D) systems and processes necessary to promptly respond with the relevant transaction information and transaction statement for a product upon request by FDA or appropriate Federal or State official in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product;
- (E) systems and processes necessary to promptly facilitate the gathering of the information necessary to produce the transaction information for each transaction going back to the manufacturer...upon request by FDA or other appropriate Federal or State official in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product, or upon request of an authorized trading partner...for the purposes of investigating a suspect product or an illegitimate product or assisting FDA or other appropriate Federal or State official with a request; and
- (F) systems and processes to associate a saleable return product with its applicable transaction information and transaction statement to allow a trading partner to accept the returned product

**Effective
November 27, 2023**


**Enhanced Drug
Distribution
Security**


Electronic


Interoperable

System across the pharmaceutical
distribution supply chain

How DSCSA Protects Patients

- 

Prevent harmful drugs from entering the supply chain.
- 

Detect harmful drugs if they enter the supply chain.
- 

Respond rapidly when harmful drugs are found.

FDA Resources

- DSCSA main webpage

<https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>

- DSCSA regulatory documents (i.e., regulations, guidances, federal register notices, pilot programs)

<https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm>



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