



HDMA ASN Exceptions Guidelines for the Drug Supply Chain Security Act



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Introduction

This guideline was developed to address the exceptions that may arise when passing information required by the Drug Supply Chain Security Act (DSCSA). The exceptions covered in this guideline are as follows:

I. There are Errors in the TI; the TI in the ASN Does not Match the Product that is Shipped

1. Overages—the number of containers identified in the TI in the ASN is less than the number of containers shipped.
 - i. The overage is returned.
 - ii. The overage is kept.
2. Shortage process—the number of containers identified in the TI in the ASN is more than the number of containers shipped.
3. When a lot number discrepancy is found.
 - i) The customer wants to keep the shipped product.
 - ii) The customer wants to return the shipped product.
4. NDC does not match.
 - i) The customer wants to keep the shipped product.
 - ii) The customer wants to return the shipped product.

II. Shipping and Data Transmission Errors

1. Lost Shipment—the customer receives the ASN documentation but the shipment is not delivered on the expected date.
2. Shipping error—a shipment intended for Customer Y is sent to Customer X by mistake.
3. Shipment arrives with no TI, TH and TS a shipment arrives at the warehouse receiving dock, and there is no documentation for that shipment.
 - i) The customer wishes to keep the product.
 - ii) The customer does not wish to keep the product.
4. The product arrives before transaction data; there is a time lag in the arrival of the transaction data.
5. There is a buyer/seller EDI error (transmission error), and the TI, TH and TS documentation must be resent.

III. Other Exceptions

1. The product and/or the package is damaged.
 - i) Damage is found at the receiving dock before the product is received.
2. The customer refuses the order; for example, a pharmacy refuses the order and product is returned to the distributor.



About

The HDMA Exceptions Guidelines for the Drug Supply Chain Security Act were prepared by the Healthcare Distribution Management Association (HDMA) Track and Trace Work Group in consultation with its Traceability Implementation Work Group.

The Drug Supply Chain Security Act (DSCSA) requires trading partners to pass Transaction Information (TI), a Transaction History (TH) and the Transaction Statement (TS) when finished, human prescription drugs change ownership in a transaction (as defined in the law). Most shipments arrive with no problems, and transaction data are transferred between trading partners without issue. However, exceptions will occasionally arise that must be handled before one trading partner may accept ownership of drug product from another trading partner.

The Food and Drug Administration (FDA) has not yet addressed discrepancies, exceptions or the need for trading partners to correct information in TI, TH and TS once it is transmitted and product is shipped. These guidelines present HDMA's interpretation of how trading partners might choose to address these exceptions. Other reasonable interpretations are possible.

This document is not legal advice and is based upon evolving requirements. As such, requirements may change as the FDA issues guidance and regulations implementing the DSCSA. Each company must make its own business decisions about passing and accepting TI, TH and TS among its trading partners, and what it will do if there is an exception to the usual sending and receipt of products and their associated data. Please consult your legal counsel and your trading partners for further implementation guidance.

HDMA has published the Electronic Data Interchange (EDI) Guidelines for the 856 Advance Ship Notice to Support Implementation of the DSCSA; these exceptions processes were developed under the assumption that the trading partners would be using the ASN or some other form of electronic transmission of data for shipping and receiving transaction data. The DSCSA, however, does not preclude trading partners from using some form of paper documentation. The method and type of documentation transmitted is agreed upon between trading partners.



Introductory Considerations With All Exceptions

Under the DSCSA, a customer may not accept ownership of a product unless the previous owner, prior to or at the time of the transaction, provides TI, TH and TS [See § 582(c)(1)(A)(i) (wholesale distributors); § 582(d)(1)(A)(i) (dispensers starting July 1, 2015); § 582(e)(1)(A)(i) (repackagers starting January 1, 2015)]. Any exceptions process must be mindful of this requirement. Further, the DSCSA requires that accurate TI, TH and TS be passed, received and stored. If errors in TI, TH or TS are discovered, they will need to be corrected.

The guidelines set forth a variety of possible scenarios in which the transaction data and product shipped do not match precisely, and recommendations for how trading partners may resolve discrepancies.

HDMA further recommends that companies have business processes in place to distinguish simple picking and shipping errors from potential supply chain security issues. These processes also should detail the steps an organization will take to resolve the errors and handle potential supply chain security issues.



Exceptions

I. There are errors in the TI; the TI in the ASN does not match the product that is shipped.

1. Overages—the number of containers identified in the TI in the ASN is less than the number of containers shipped.

i) The overage is returned.

The quantity shipped is more than quantity in the ASN, and the customer does not want to keep the overage. For example, the customer orders and ASN identifies 72 bottles of 300 mg ibuprofen tablets, but customer receives 84 bottles from the supplier. Twelve bottles do not have TI, TH and TS. The customer returns the 12 bottles of 300mg ibuprofen tablets to supplier.

- The supplier sends the ASN to the customer.
- Product is shipped to the customer.
- The customer attempts to receive each product in the shipment against the ASN.
- The number of containers shipped is greater than number of containers identified in the ASN.
- The customer receives the quantity up to the ASN quantity.
- The customer returns the excess product to the supplier pursuant to normal business practices.

Note: Although FDA has not advised on how trading partners should handle this exception, ownership of the excess product cannot pass to the customer until the customer receives the TI, TH and TS for the overage from the supplier. Therefore, when the customer returns the excess product to the supplier, it would not need to provide TI, TH and TS because the supplier still owns the product and there has been no change of ownership as to those products.

ii) The overage is kept.

The quantity shipped is more than quantity in the ASN, and the customer wants to keep the overage. For example, the customer orders 72 bottles of 300 mg ibuprofen tablets and receives 84 bottles from the supplier. Twelve bottles do not have TI, TH and TS. The customer wants to keep the 12 bottles of 300 mg ibuprofen tablets.

- The supplier sends the ASN to the customer.
- The product is shipped to the customer.
- The customer attempts to receive each product in the shipment against the ASN.



- The number of containers shipped is greater than number of containers identified in the ASN.
- The customer receives the quantity up to the ASN quantity.
- The customer quarantines the excess product.
- The customer creates and/or corrects Purchase Order (P.O.) (if necessary).
- The customer contacts the supplier's customer service and communicates the need for a correction and may provide the following: the National Drug Code (NDC), lot number, quantity and P.O. Number, ASN number, shipment date, a description of the issue and a copy of the packing list (if available).
- The supplier sends new TI, TH and TS for overage quantity to customer. The information will be provided based on an agreement between trading partners.

(It is recommended that a new ASN is created for the overage amount. However, there may be some other form of documentation that is agreed upon by the trading partners for communication of the TI, TH and TS for the overage quantities. A new transaction number may be generated.)

- The product is removed from quarantine and is received against new TI, TH and TS.

Note: Although the FDA has not advised on how trading partners should handle this exception, ownership of the quarantined product cannot pass to the customer until the customer receives appropriate TI, TH and TS for the quarantined product. Related to the DSCSA requirements to provide transaction data, under a reasonable interpretation of the statute, the shipment date on the new TI documentation (generated by the supplier) should be the shipment date included on the original TI documentation that accompanied the quarantined product. Further, under a reasonable interpretation of the statute, the transaction date on the new TI documentation should be the date on which the customer will receive the new TI, TH and TS for the quarantined product. Once the customer receives the new TI, TH and TS for the quarantined product, ownership of the quarantined product may pass from the supplier to the customer.

2. Shortage process—the number of containers identified in the TI in the ASN is more than the number of containers shipped.

The quantity shipped is less than the number of containers identified on the ASN. For example, the customer orders 72 bottles of 300 mg ibuprofen tablets and receives 60 bottles from the supplier. The customer will receive the 60 bottles that have TI, TH and TS and will need to resolve the 12 bottles not received pursuant to standard business processes.

- The supplier sends the ASN to the customer.
- The product is shipped to the customer.



- The customer attempts to receive each product in the shipment against the ASN.
- The number of containers shipped is less than number of containers identified in the ASN.
Note: The quantity shipped has the required TI/TH/TS and can be received by the customer.
- Trading partners should use standard business processes to reconcile the quantity not received.
- The financial processes between trading partners will address assuring that the customer pay only for the number of containers received.

3. When a Lot number discrepancy is found.

A customer discovers that the lot number on a product in the shipment does not match the ASN. For example, the customer orders 72 bottles of 300 mg ibuprofen tablets. The ASN communicates lot number 418053C, however, product shipped has a different lot number and this discrepancy is discovered by the customer.

i) The customer wants to keep the shipped product.

- The supplier sends the ASN to the customer.
- The product is shipped to the customer.
- The customer attempts to receive each product in the shipment against the ASN.
- The customer discovers that the lot number does not match the ASN for a subset of the shipped products.
- The customer quarantines products with incorrect lot numbers.
- The customer contacts the supplier and communicates the need for corrected transaction data, and may provide the following: NDC, lot number, quantity and P.O. number, ASN number, shipment date, a description of the issue and a copy of the packing list (if available).
- The supplier sends new TI, TH and TS with correct lot number to customer.
This information will be provided based on the agreement between trading partners.
- The product is removed from quarantine and is received against new TI, TH and TS.

Note: Although the FDA has not advised on how trading partners should handle this exception, ownership of the quarantined product cannot pass to the customer until the customer receives appropriate TI, TH and TS for the quarantined product. Related to the DSCSA requirements to provide transaction data, under a reasonable interpretation of the statute, the shipment date on the new TI documentation (generated by the supplier) should be the shipment date included on the original TI documentation that accompanied the quarantined product. Further, under a reason-



able interpretation of the statute, the transaction date on the new TI documentation should be the date on which the customer will receive the new TI, TH and TS for the quarantined product. Once the customer receives the new TI, TH and TS for the quarantined product, ownership of the quarantined product may pass from the supplier to the customer.

ii) The customer wants to return the shipped product.

- The supplier sends the ASN to the customer.
- The product is shipped to the customer.
- The customer attempts to receive each product in the shipment against the ASN.
- The customer discovers that the lot number does not match the ASN.
- The customer returns product to supplier pursuant to normal business practices.

Note: Although FDA has not advised on how trading partners should handle this exception, ownership of the product cannot pass to the customer until the customer receives the TI, TH and TS with the correct lot number. Therefore, when the customer returns the products to the supplier, it would not need to provide TI, TH and TS, because the supplier still owns the product and there has been no change of ownership for those products.

4. NDC does not match.

A customer discovers that the NDC number on a product in the shipment does not match the ASN. For example, the customer orders 72 bottles of 300 mg ibuprofen tablets; the ASN communicates NDC 09999166272, but the product shipped has a different NDC 09999166230 and this discrepancy is discovered by the customer.

i) The customer wants to keep the shipped product.

- The supplier sends the ASN to the customer.
- The product is shipped to the customer.
- The customer attempts to receive each product in the shipment against the ASN.
- The customer discovers that the NDC number does not match the ASN for a subset of the shipped product.
- The customer quarantines product with an incorrect NDC number.
- The customer contacts the supplier and communicates the need for corrected transaction data and may provide the following: NDC, lot number, quantity and P.O. number, ASN number, shipment date, a description of the issue and a copy of the packing list if available.
- The supplier sends the customer a new TI, TH and TS with the corrected NDC number. Information will be provided based on the trading partner agreement.



- The product is removed from quarantine to the receiving dock and is received against new TI, TH and TS.

Note: Although the FDA has not advised on how trading partners should handle this exception, ownership of the quarantined product cannot pass to the customer until the customer receives appropriate TI, TH and TS for the quarantined product. Related to the DSCSA requirements to provide transaction data, under a reasonable interpretation of the statute, the shipment date on the new TI documentation (generated by the supplier) should be the shipment date included on the original TI documentation that accompanied the quarantined product. Further, under a reasonable interpretation of the statute, the transaction date on the new TI documentation should be the date on which the customer will receive the new TI, TH and TS for the quarantined product. Once the customer receives the new TI, TH and TS for the quarantined product, ownership of the quarantined product may pass from the supplier to the customer.

ii) The customer wants to return the shipped product.

- The supplier sends the ASN to the customer.
- The product is shipped to the customer.
- The customer attempts to receive each product in the shipment against the ASN.
- The customer discovers that the NDC number does not match the ASN for a subset of the shipped product.
- The customer returns the product to the supplier pursuant to existing standard business processes.

Note: Although the FDA has not advised on how trading partners should handle this exception, ownership of the product cannot pass to the customer until the customer receives the TI, TH and TS with the correct NDC number. Therefore, when the customer returns the products to the supplier, it would not need to provide TI, TH and TS, because the supplier still owns the product and there has been no change of ownership for those products.



II. Shipping And Data Transmission Errors

Generally, it is recommended that a company have business processes in place to distinguish simple data and shipping errors from potential supply chain security issues. These processes also should detail the steps your organization will take to resolve the errors and handle potential supply chain security issues.

1. Lost Shipment— the customer receives the ASN documentation but the shipment is not delivered on the expected date.

Trading partners should use standard business processes to resolve the lost shipment.

2. Shipping error—a shipment intended for Customer Y is sent to Customer X by mistake.

- The product is shipped to Customer X.
- Customer X has no ASN and no TI, TH and TS for the shipment, and the shipment is not received.
- Trading partners should use standard business processes to resolve the shipment error.

Note: Customer X cannot take ownership of the product as it has not received TI, TH and TS from the supplier. Therefore, when the customer returns the products to the supplier, it would not need to provide TI, TH and TS because the supplier still owns the product and there has been no change of ownership for those products.

3. Shipment arrives with no TI, TH and TS—a shipment arrives at the warehouse receiving dock, and there is no documentation for that shipment.

i) The customer wishes to keep the product.

- The product is shipped to the customer.
- The customer attempts to receive the product but does not receive TI, TH and TS.
- The customer quarantines the product.
- The customer contacts the supplier and communicates need for TI, TH and TS and may provide the following: NDC, Lot number, Quantity and P.O. number, shipment date, a description of the issue and a copy of the packing list (if available).
- The supplier sends the TI, TH and TS.
- The product is removed from quarantine and is received against the TI, TH and TS.

Note: Although the FDA has not advised on how trading partners should handle this exception, ownership of the quarantined product cannot pass to the customer until the customer receives appropriate TI, TH and TS for the quarantined product. Related to the DSCSA requirements to provide transaction data, under a reasonable interpretation of the statute, the shipment date on the



new TI documentation (generated by the supplier) should be the shipment date included on the original TI documentation that accompanied the quarantined product. Further, under a reasonable interpretation of the statute, the transaction date on the new TI documentation should be the date on which the customer will receive the new TI, TH and TS for the quarantined product. Once the customer receives the new TI, TH and TS for the quarantined product, ownership of the quarantined product may pass from the supplier to the customer.

ii) The customer does not wish to keep the product.

- The product is shipped to the customer.
- The customer attempts to receive the product, and there is no TI, TH and TS.
- The customer quarantines the product.
- The customer returns the product to the supplier pursuant to standard business processes.

Note: Although FDA has not advised on how trading partners should handle this exception, ownership of the product cannot pass to the customer until the customer receives the TI, TH and TS from the supplier. Therefore, when the customer returns the products to the supplier, it would not need to provide TI, TH and TS, because the supplier still owns the product and there has been no change of ownership as to those products.

4. The product arrives before transaction data; there is a time lag in the arrival of the transaction data.

- The supplier sends the ASN to the customer.
- The product is shipped to the customer.
- The customer attempts to receive the product but has not received TI, TH and TS.
- Customer quarantines product
- The customer contacts the supplier and communicates the need for TI, TH and TS and may provide the following: NDC, lot number, quantity and P.O. number, shipment date, a description of the issue and a copy of the packing list if available
- The supplier sends or resends the TI, TH and TS.
- The product is removed from quarantine and is received against the TI, TH and TS.

5. There is a buyer/seller EDI error (transmission error), and the TI, TH and TS documentation must be resent.

- The supplier sends the ASN to the customer.
- The product is shipped to the customer.



- The customer attempts to receive the product, but there is a transmission error and it does not receive TI, TH and TS.
- The customer quarantines the product.
- The customer contacts the supplier and communicates the need for TI, TH and TS and may provide the following: NDC, lot number, quantity and P.O. number, shipment date, a description of the issue and a copy of the packing list (if available).
- The buyer or seller resolves the EDI error.
- If needed, the supplier resends or sends the TI, TH and TS.
- The product is removed from quarantine and is received against the TI, TH and TS.



III. Other Exceptions

1. The product and/or the package is damaged.

A customer orders 72 bottles of 300 mg ibuprofen tablets.

i) **Damage is found at the receiving dock before the product is received.**

- The supplier sends the ASN to the customer.
- The product is shipped to the customer.
- The customer discovers that the product is damaged.
- The courier/shipper is contacted to return and pick up shipment;

Or,

- The shipment is refused and returned on the truck that it arrived on.
- Trading partners should use standard business processes to resolve the damaged product or package.

Note: Although FDA has not advised on how trading partners should handle this exception, ownership of the product cannot pass to the customer until the customer receives the TI, TH and TS from the supplier. Therefore, when the customer returns the damaged product to the supplier, it would not need to provide TI, TH and TS, because the supplier still owns the product and there has been no change of ownership as to those products.

2. **The customer refuses the order; for example, a pharmacy refuses the order and product is returned to the distributor.**

Will be handled using standard business processes.



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