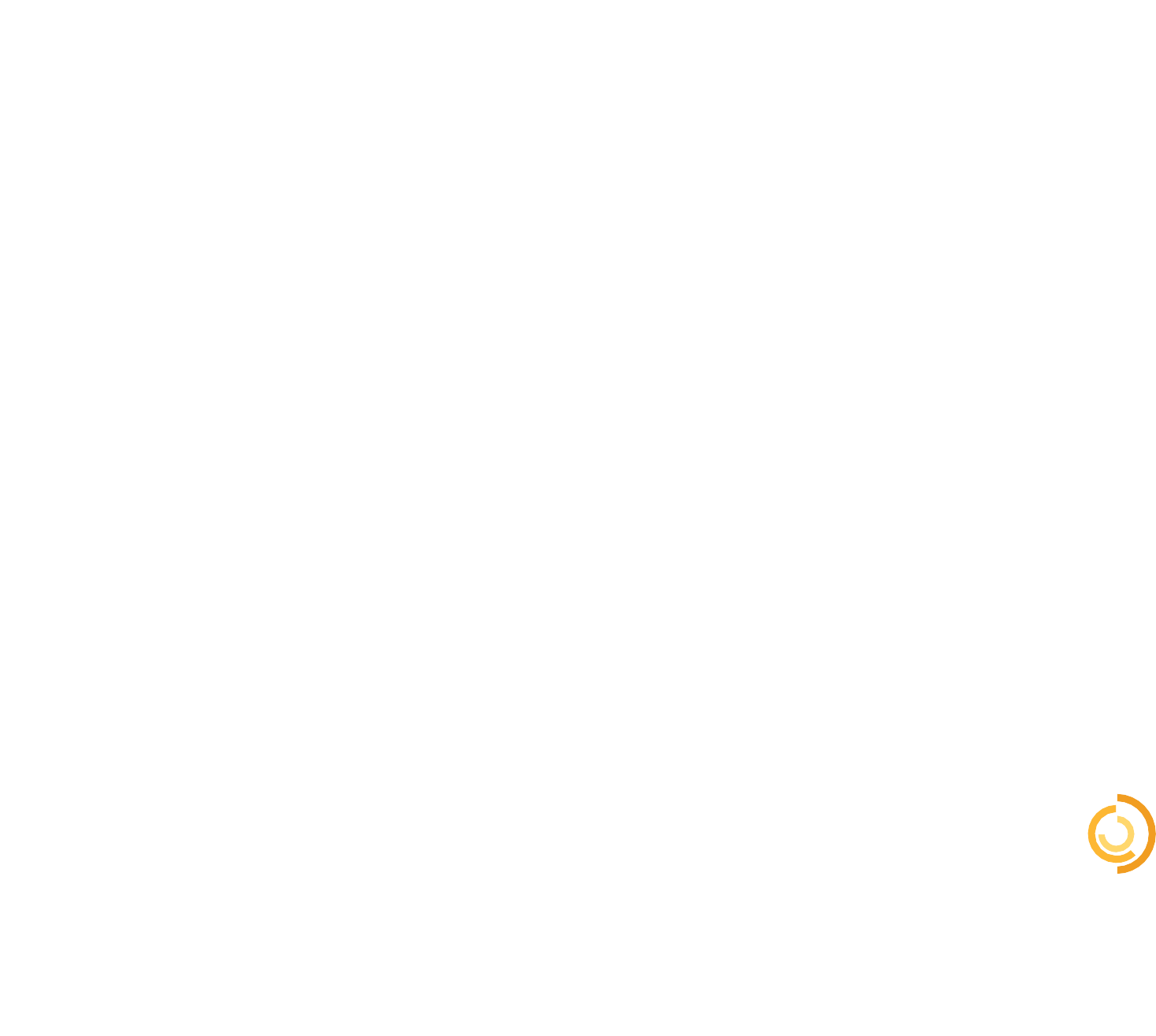
EXCEPTIONS HANDLING GUIDELINES FOR THE DSCSA



**EXCEPTIONS HANDLING GUIDELINES FOR THE DSCSA**

April 2022

HDA has prepared or compiled the information presented herein to inform its members and the general public about the healthcare distribution industry. HDA does not warrant, expressly or implicitly, the accuracy or completeness of this information and assumes no responsibility for its use.

© Copyright 2022 Healthcare Distribution Alliance

All rights reserved. No part of this book may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording or by an information storage and retrieval system, without permission in writing from HDA.

ISBN: 979-8-9850427-3-3

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation’s pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA’s nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

CONTENTS

REVISIONS

[INTRODUCTION 4](#_Toc128644341)

[GENERAL PRINCIPLES 1](#_Toc128644342)

[EXCEPTIONS 2](#_Toc128644343)

1. [Data Issue 2](#_Toc128644344)

[2. Product, No Data 6](#_Toc128644345)

[3. Data, No Product 13](#_Toc128644346)

[4. Packaging and Labeling 16](#_Toc128644347)

[5. Product Hold 20](#_Toc128644348)

Revisions since last publication:

# INTRODUCTION

The *HDA Exceptions Guidelines for the DSCSA*1 was prepared by the Healthcare Distribution Alliance’s (HDA) Exceptions Handling Work Group. These guidelines were developed to address exceptions that may arise when passing (or failing to pass) information required by the Drug Supply Chain Security Act (DSCSA). The exceptions covered fall within the following categories:

* Data Issue
* Product, No Data
* Data, No Product
* Packaging and Labeling
* Unavailable for Distribution - Product Indicated to be recalled, suspect or illegitimate.

The DSCSA requires trading partners to provide Transaction Information (TI), Transaction History (TH) and the Transaction Statement (TS) when finished prescription drugs covered under the law change ownership in a transaction.2 By November 27, 2023, each authorized trading partner, when engaging in a transaction, must provide TI that contains data on each serialized product and a TS to the receiving authorized trading partner “in a secure, interoperable, electronic manner” in accordance with standards established by guidance [§ 582(g)(1)(A)]. The requirement to pass TH sunsets and is no longer required after November 27, 2023.3

Trading partners have been providing and receiving lot-level transaction data since 2015, and most shipments arrive with minimal problems. However, as the supply chain moves to serialized compliance requirements, the mandatory interoperable exchange of serialized data adds significant complexity to sector operations. When issues with transaction data arise, they generally must be handled and resolved before a trading partner can sell that product to a downstream customer (depending on the type of exception and when the exception is discovered).

In summer 2021, the U.S. Food and Drug Administration (FDA) addressed the discrepancies that might arise in a draft guidance, “Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act,” 86 Fed. Reg. 30053 (June 4, 2021; EDDS Draft Guidance). Among other issues, the agency stated that it “expects the product tracing information to be true, accurate, and complete.” However, the agency also “recognizes that there may be situations where there is a clerical error or discrepancy in the product tracing information that may not be indicative of a suspect product.” If a trading partner “identifies a potential clerical error or other discrepancy in the product tracing information it received, that trading partner should resolve the error or discrepancy within [three] business days.” The draft guidance directs trading partners to work together and that the product “should not be sold to the next trading partner until the error or discrepancy has been resolved.”4

1. The DSCSA (Title II of Public Law 113-54) was signed into law on November 27, 2013. The DSCSA amended the Federal Food, Drug and Cosmetic Act (FDC Act) and added, among other things, new definitions and product tracing requirements in § 581 and § 582 of the FDC Act, 21 U.S.C. § 360eee and § 360eee-1, respectively.
2. See § 582 requirements to provide and receive transaction data: § 582(b)((1)(A) (manufacturers); § 582(c)(1)(A) (wholesale distributors); § 582(d)(1)(A) (dispensers); § 582(e)(1)(A).
3. § 582(k)(1).
4. EDDS Draft Guidance at lines 353–361.

Following FDA’s recommendations in the EDDS Draft Guidance, this document presents consensus guidelines from the Exceptions Handling Work Group on what trading partners will do to address the various exceptions expected to arise. Trading partners of the work group concur, as presented in these guidelines, that product should not be sold until the exception is resolved. However, many including HDA urged the agency to abandon the three-day limit as both unrealistic and unnecessary for supply chain security and patient safety; it is hoped that FDA will eliminate this time limit should the agency revise the draft guidance. Trading partners should to be re-worded

The development of these guidelines and the discussion of the many scenarios have demonstrated that resolving discrepancies can be complex and time-consuming. Trading partners should use their best efforts to resolve them — without arbitrary deadlines — so that deliberative, informed steps may be taken to determine what happened and to avoid future errors. So long as product subject to a discrepancy remains in quarantine, it is the position of the Exceptions Handling Work Group that trading partners should continue to resolve the discrepancy even if those efforts extend beyond three business days and, if the matter is resolved satisfactorily, the product should be removed from quarantine and can be sold (assuming of course, there are no other signs of it being suspect or illegitimate, such as evidence of tampering or counterfeiting, or otherwise should not be distributed — for instance, when product is damaged, expired or under recall).

These guidelines are voluntary and do not constitute and are not intended to represent legal advice and are based on evolving understanding of DSCSA requirements. As such, the recommendations presented here may change as the FDA issues additional guidance, finalizes the EDDS Draft Guidance, or releases other regulations. Each company must make its own business decision about passing and accepting transaction data among trading partners — and what it will do if there is an exception to the usual sending and receiving of products and their associated data. Companies should consult with their legal counsel, regulatory compliance specialists and trading partners for further implementation guidance.

# GENERAL PRINCIPLES

These guidelines represent an effort to anticipate the exceptions that, at this time, trading partners believe may occur when manufacturers and distributors exchange serialized data and outline pathways for their resolution. The recommendations likely will evolve as systems and DSCSA experience matures — and as additional FDA requirements and guidance are issued. This document seeks to define the various exceptions and associated resolution steps, employing standard and defined processes so that trading partners and regulators understand the types of exceptions that can occur and common ways to resolve them.

This Work Group has approached exceptions resolution with the following principles in mind:

* Keep good product moving forward in the supply chain to avoid disruptions, reduce the risk of increased “non-saleable” product and minimize impact to patient availability.
* Seek electronic, automated solutions where possible to resolve issues in a timely manner that minimizes supply chain latency.
* Maintain documentation regarding exceptions, data requirements and business practices consistent with FDA laws, regulations and guidance documents.
* Recognize that there are situations in which a manufacturer may determine that a product should remain on the market. For example, in instances of a product shortage, or when a product has expired but FDA has extended the product’s expiration date. In such cases, it is important for the manufacturer to communicate this information to downstream trading partners, so it is clear they are not receiving suspect product. The wholesale distributor will document and rely on the manufacturer’s instruction in these situations.
* Use or develop standards and processes where possible to ensure that supply chain partners are approaching and resolving issues in a consistent way that creates continuity and efficiency for all direct trading partners. This may include but not be limited to determining the root cause and putting in place mitigation steps to avoid future incidents.
* Follow GS1 barcode standards and HDA implementation barcode guidelines.
* If the product is determined to be suspect or illegitimate after communicating with the manufacturer, then the wholesale distributor will follow the relevant SOPs it has in place.

General Data Remediation Practices

Product, No data remediation

The manufacturer will send the incremental TI & TS via EPCIS to the wholesale distributor to accurately reflect what was sold and shipped to the wholesale distributor using the date the exception correction was made.5 Note that ONLY the missing product identifiers can be contained in the new EPCIS message, or the file will be rejected. If full shipment data are resent, the file will fail. Follow the corresponding Gs1 guidelines for exception handling.

1. The definition of TI in § 581(26)(G) and (H) provide that TI need only include date of shipment when it is 24 hours later than the date of the transaction.

Additionally, if it takes longer than an agreed to time frame to reconcile and send the TI & TS, the wholesale distributor will likely remove the product from quarantine and work with the manufacturer to further disposition it. Suitable time frames will be determined in business discussions between trading partners. Resolution of the discrepancy will likely be a manual review process before corrected TI is sent. The manufacturer will need to reference the original PO in the new EPCIS file with the missing serial numbers. In some instances, manufacturers may use a new delivery number or choose to connect old and new numbers in some way to indicate an update but use the original PO. As part of its investigation, the manufacturer should confirm that the serialized data was not already provided to another distributor. If so, the manufacturer will have to reconcile the data within its system before providing a new EPCIS file with that serialized data for the overage product to the distributor.

Data, No Product Remediation

Data, no product exception scenarios pose unique challenges to all trading partners. In general, they are not easily detected by comparison. However, once they are discovered, trading partners should follow the Gs1 Exception Handling addendums in taking steps regarding data remediation exception scenarios. Post data remediation, EPCIS records must accurately reflect what was physically transacted such that subsequent trace requests can be accurately responded to.

General Communications practices:

We encourage consultation with the supplier when appropriate. When communicating exceptions to upstream trading partners, the list of data points might include but not be limited to: A standard subject line: Distributor name + Manufacturer name + Exception Category + issue tracking # + . The supplier should respond with the distributor issued tracking # to track & resolve the exception in further electronic communication. The electronic communication should contain as much information as the wholesale distributor can provide. The content will vary depending on the scale of the exception. If the entire shipment is involved, shipment level data is sufficient. For smaller exceptions, more detail may be provided. See Below potential fields to be included:

Issue tracking #(UUID);

PO Number;

Contact info (name/email/phone number; include as three tag elements); exception description;

Sold/Ship-to GLN;

Sold/Ship-from GLNs; Product – Identifier(four elements, parsing recommended);

Product Description;

Delivery number/shipment number/bill of lading/tracking number on partial;

SSCC-18;

# EXCEPTIONS

## Data Issue

**Scenario 1.1: The wholesale distributor was sent the data, but the EPCIS file is not correct in content or format as prescribed in the Gs1 EPCIS implementation guideline.**

* The wholesale distributor discovers upon receipt of the file that a manufacturer has sent an EPCIS file, but it cannot accept the EPCIS file because it is not formatted correctly. There are numerous root causes that result in this sort of exception scenario. Several are cited below.
  1. EPC events out of correct time stamp sequence – aggregation event to the case is time stamped prior to the commission events of the packages going into the case.
  2. Vocabulary Element attribute errors – missing or incorrect product attributes such as dosage form or strength.
  3. Incorrect Gs1 formatted sGLN

**Note:** Wholesale distributors are doing a “handshake” notification today back to the supplier using a feature of the AS2 internet protocol standard used transmit EPCIS files. It is referred to as a Message Disposition Notice(MDN). It is sent back in response to an EPCIS message indicating the file was successfully received & decrypted. It does not however convey that the file was successfully consumed & processed by the recipients EPCIS systems. If a file does fail, ideally a manufacturer would resend prior to the wholesale distributor receiving the shipment. However, if they do, this information will be useful to the manufacturer’s investigation and should be provided. Note that this type of error is not related to a data transmission problem covered elsewhere in this guide. These types of errors would be encountered after the EPCIS message is received, successfully decrypted, and digital signature verified.

**Distributor Action:** The wholesale distributor will notify the manufacturer via email that the file failed based on incorrect formatting. Information provided to manufacturer will differ based on how much of the file is readable but could include, if known, the nature of the format issue such as what’s cited above.

**Manufacturer Action:** If the manufacturer is successful in correcting the file, it should be resent immediately. If efforts to correct & resend the data have failed, product may need to be returned.

**Scenario 1.2: The wholesale distributor receives data, but the Global Company Prefix (GCP), Global Location Number (GLN)/sGLN are not found in the receiver’s master data.**

* A manufacturer sends a distributor an EPCIS file.
* Upon receiving an EPCIS file, the wholesale distributor determines that it does not have a GCP, GLN or sGLN in its system that corresponds to a GLN or sGLN in the EPCIS file the manufacturer sent.

**Distributor Action:** The distributor will notify the manufacturer via email that the file failed based on a GCP, GLN or sGLN master data issue. For more on correct formatting, see [the latest version](https://www.gs1us.org/industries/healthcare/gs1-standards-in-use/pharmaceutical/dscsa-implementation-guideline)  [of the GS1 Implementation Guideline](https://www.gs1us.org/industries/healthcare/gs1-standards-in-use/pharmaceutical/dscsa-implementation-guideline).

* **Manufacturer Action:** The manufacturer will provide updated master data via email and where the file cannot be automatically reprocessed, resend the file after correcting the GCP, GLN or sGLN data issue within the file, ensuring all master data contained within the file have been sent to the wholesale distributor prior to reprocessing.

**Compliance/Best Practice Note:**

* Ensure both trading partners provide the most up-to-date GLN information for each of their facilities respectively. This requires proactively sharing GLNs as new facilities are opened or relocated/repurposed.
* Additionally, a system should interrogate buyer/seller and ship-to/ship-from GLNs as these should be part of master data. However, other read points and bizlocations beyond that should not be interrogated by distributors or other downstream trading partners to prevent failures from GLNs “unknown” to your system, or manufacturers or repackagers may choose to mask those GLNs to prevent the file from failing.
* Every GLN shared in the EPCIS file must have been previously shared with downstream/upstream partners in advance of sending the file. This includes EPCIS tagged “bizLocations” as well as optional elements, such as read-point sGLNs if they are interrogated.

**Scenario 1.3: The wholesale distributor receives the data, but the GTIN is not found in the receiver’s master data.**

* A manufacturer sends a distributor an EPCIS file.
* At receiving, the wholesale distributor determines that it does not have the/one of the GTINs contained within the EPCIS file. The file might be rejected based on how the wholesale distributor’s systems are configured.

**Distributor Action:** The distributor will first check internally to ensure that their systems have been updated with master data previously provided by the manufacturer. If the new GTIN has not been provided, the distributor will ask the manufacturer for updated GTIN(s) and update their master data files so that the file can be reprocessed. The distributor should then reprocess the file.

**Manufacturer Action:** The manufacturer will provide updated GTIN master data.

**Compliance/Best Practice Note:** The distributor should ensure that their new product introduction or package configuration change processes are connected to their data exchange processes so that master data is maintained prior to shipments. The manufacturer should be sure their change process for product packaging changes and new product launches will be communicated prior to sending product to a wholesale distributor. It’s recommended that suppliers make use of the H.D.A product forms as mentioned previously.

Be mindful of where a packaging change requires a new GTIN ([https://www.gs1.org/1/gtinrules/en/](https://www.gs1.org/1/gtinrules/en/healthcare) [healthcare](https://www.gs1.org/1/gtinrules/en/healthcare)) or a new NDC, which will also lead to a new GTIN.5

1. For FDA requirements regarding when a new NDC is necessary, refer to [21 C.F.R. § 207.35](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=207.35).

**Scenario 1.4: A wholesale distributor receives data, but there is a misalignment between the data received and the lot# and/or expiry encoded and successfully scanned in the 2D bar code.**

* Note that the GTIN & serial number on the label match the EPCIS data
* This scenario may result from either an EPCIS data error or a packaging/labeling defect.

**Distributor Action:** The wholesale distributor will quarantine the product and notify the manufacturer via email that the data received do not match what is encoded in the 2D bar code. The wholesaler will coordinate with the manufacturer to further disposition the product. Note that this will not impact “00” in the date. Also, if there is a partial product identifier miss-match a distributor may note that in the communication back to the manufacturer. The e-mail should contain the subject line and body of the email following the communications practices noted above but also include the 2D barcode scan of the product. A snippet of the ECPIS file where the miss-match from the scan occurred might also be helpful.

**Manufacturer Action:** The manufacturer will initiate an internal investigation and work with the distributor to determine further dispositioning of the product.

**Note:** Current systems capabilities may not make it possible to correct lot & expiry on an existing serial number.

**Best Practice Note:** A lot or batch can fail to match because of a special character issue or other upper- and lower-case issues. Each company should ensure that their systems, service providers and labels comply with the special characters and encoding allowed per GS1: [https://www.gs1.org/](https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications) [standards/barcodes-epcrfid-id-keys/gs1-general-specifications](https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications)

## Product, No Data

**Note:** “Product, no data” is a complex exception and trading partners should determine the appropriate action to take and leave it to commercial arrangements to align on practices.

**Scenario 2.1: A manufacturer sends an EPCIS file for a shipment, but there was a communication issue, and the file was not received by the wholesale distributor.**

* A distributor will send a message that it received product and no corresponding data.
* If needed, a manufacturer will resend the EPCIS file.

**Distributor Action:** A wholesale distributor will conduct internal checks to confirm the distributor’s system is not “down,” then email the manufacturer that it received product but not the corresponding EPCIS file for that shipment. The distributor will email the manufacturer according to the best communications practices noted above. If the distributor has the EPCIS message in their queue and can reprocess it, they should do so.

**Manufacturer Action:** The manufacturer may know that there was a connection issue due to their system notifying them and resend the file proactively. If a wholesaler notifies a manufacturer after receiving product without a corresponding EPCIS file, the manufacturer will investigate to determine the root cause of the failure and resend the EPCIS file.

**Best Practice Notes:** Data senders should turn on MDNs. If a receiving company is missing a file, the sender should look at MDNs first to check status of message file. Additionally, it is recommended that data senders do not use once a day or once a night batch scheduling to send data. It is better to send data during working hours well ahead of receipt of product.

Technical teams may also monitor outbound file failures and look at logs daily to ensure files are sent regularly.

**Note:** Wholesale distributors are doing a “handshake” notification today back to the supplier using a feature of the AS2 internet protocol standard used transmit EPCIS files. It is referred to as a Message Disposition Notice(MDN). It is sent back in response to an EPCIS message indicating the file was successfully received & decrypted. The B2B systems using the AS2 protocol can provide for resending files that encountered problems getting sent. If a file does fail after AS2 processing, ideally a manufacturer would resend prior to the wholesale distributor receiving the shipment. However, if they do, this information will be useful to the manufacturer’s investigation and should be provided.

**Scenario 2.2: A wholesale distributor receives a product, but the serial number is not found within any EPCIS file delivered and there is no purchase order or delivery number to reference.**

* The wholesale distributor’s system will indicate an error at receiving. This scenario could arise when an unexpected shipment arrives as a mis-shipment or has come with smaller, direct shipments from a manufacturer.
* The wholesale distributor will work with the manufacturer on the “surprise” shipment and resolution steps.

**Distributor Action:** The wholesale distributor will notify the manufacturer that they received a product and that there is no associated purchase order for the product. The size of the shipment will impact the resolution and whether the wholesale distributor would be able to refuse the shipment if the carrier has not left or create a PO to receive and quarantine the product until EPCIS data could be sent by the manufacturer. If the carrier has left and the distributor does not wish to keep the product, they should work with the manufacturer to further disposition the product.

In any instance, the wholesale distributor could provide to the manufacturer information to help the manufacturer identify and investigate the potential miss-shipment.

**Manufacturer Action:** The manufacturer will need to determine if this was a mis-shipment and if the product needs to be returned or sent to another location. The manufacturer would open an investigation. If the wholesale distributor does not refuse the shipment, the manufacturer will

request confirmation of what serial numbers/product identifiers the wholesale distributor has in its possession to send corresponding data. As part of its investigation, the manufacturer will need to confirm that the serialized data was not already provided to another distributor. If so, manufacturers will have to reconcile the data within their system before providing it to the distributor.

If the manufacturer determines there has been a pallet switch, it may be easy to identify and rectify. Each manufacturer will need to identify what their preferred process is in these various scenarios.

**Scenario 2.3: A wholesale distributor receives a shipment in which the serial numbers are not found due to the wrong data being sent. There is a valid purchase order number to reference.**

* The wholesale distributor’s system will indicate an error at receiving.
* This scenario assumes some data was received for the shipment and that this appears to be as serial number miss-match.
* This could also exist as a data, no product scenario elsewhere.

**Distributor Action:** The wholesale distributor’s system will notify upon receipt that there is an error, and the product will be quarantined. The wholesale distributor will notify the manufacturer via email that it has product and no data. Following best communication practices, the distributor should list the ECPs they have scanned that there is no data for. The wholesale distributor will return the product to inventory once it has received the TI for the missing product identifiers.

**Note:** If this is a large shipment, it may be a scan of product identifier at a higher level of packaging, such as a case or a pallet. The resolution will vary on the scale of the issue.

**Manufacturer Action:** The manufacturer will conduct an internal investigation and either respond with the missing TI or have the product dispositioned based on manufacturer capability and policy. Refer to data remediation practices for missing TI noted above.

**Scenario 2.4: A wholesale distributor receives a product overage with a valid purchase order receipt in which the shipment references the purchase order.**

* This scenario covers either an insufficient number of EPCs or no EPCs for a given NDC.

**Distributor Action:** The wholesale distributor’s system will notify upon receipt that there is an error, and the product will be quarantined. The wholesale distributor will notify the manufacturer via email that it has product and no data. Following best communication practices, the distributor should list the ECPs they have scanned that there is no data for. The wholesale distributor will return the product to inventory once it has received the TI for the missing product identifiers.

**Manufacturer Action:** The manufacturer will conduct an internal investigation and send incremental ECPIS data to cover the overage or arrange for dispositioning of the product for which no product identifiers were provided.

**Scenario 2.5: A delivery was made to the right company, but to the wrong distribution center within that company.**

* Note this is not a DSCSA compliance issue. Because the delivery was made to the right company but the wrong facility within that company, the decision as to how to handle this scenario should consider other regulatory, statutory, or business requirements.

**Distributor Action:** Each company will handle this differently. A first step will be to communicate with your trading partner to determine the appropriate resolution. The product could be returned back to the manufacturer, a process could be put in place to resolve the PO, keep the product in the DC it was delivered to, or execute an intracompany transfer, or the carrier could be redirected to the correct location. A distributor could also elect to keep the product in the . Tim to revise.

**Manufacturer Action:** The manufacturer works with the carrier and wholesale distributor to redirect the product to the correct DC in instances where the distributor does not elect to keep the delivery (if data for the associated delivery are aligned with the data received from the manufacturer).

If product is requested to be rerouted to another of the wholesale distributor’s distribution center, some manufacturers may choose to have the product destroyed because they cannot ensure there has not been a temperature excursion or other handling issues.

The manufacturer may initiate an internal quality investigation to determine why the mis-shipment occurred.

1. The DSCSA [§ 581(I) and (J)] specifies that the business name and address of the person from whom ownership is being transferred and to whom ownership is being transferred are to be included in TI, not ship-from/ship-to locations.
2. The DSCSA [§ 581(24)(B)(1)] excludes intracompany transfers between affiliates from the definition of “transaction.” Assuming that a wholesale distributor’s two distribution centers are under the control of the same corporate entity (§ 581(1), this type of intracompany company is not a transaction and TI and TS would not have to be provided.

**Scenario 2.6: A delivery was made to the wrong wholesale distributor.**

* Unlike scenario 2.5, this is a DSCSA compliance issue.
* Product was miss-delivered to a trading partner that did not order the product and the shipment paperwork may confirms this. The person receiving the product often will not recognize the PO number with the paperwork.

**Distributor Action:** The wholesale distributor will reject the shipment and reach out to the manufacturer by email to let them know a delivery was made to the wrong wholesale distributor. They will share the PO that is listed on the manifest/pallet label with the manufacturer. Refer to the General Communications practices section for other key data points the distributor should share with the manufacturer.

**Manufacturer Action:** The manufacturer will work with their logistics provider/carrier to reroute the shipment to the correct wholesaler. In some instances, the manufacturer may route it for destruction if they cannot ensure product has been stored/handled appropriately. The manufacturer should also confirm that the data associated with the rerouted delivery was sent to the correct distributor. The manufacturer may initiate an internal quality investigation to determine why the mis-shipment occurred.

Note: Both parties may decide that the distributor will keep the miss-routed product. Data remediation steps would need to be taken for the distributor to keep the product.

**Scenario 2.7: A serial number is not found while a wholesale distributor is trying to pick, pack and ship.**

* This signals the serial number was not sent in an EPCIS file from the manufacturer. This could be an aggregation error, or it could also indicate a miss-pick of physical product the manufacture shipped.
* It’s important to note this was discovered during pick pack & ship so the wholesaler may not have much to provide other than the PI not found in their systems.

**Distributor Action:** The wholesale distributor discovers at pick, pack, and ship it has product without the corresponding serialized data. If the distributor discovers this is transitional inventory, it does not need to be handled as an exception since the product was purchased under lot level requirements. The distributor will need to capture the PI and send out TI containing it. If necessary, the wholesale distributor will quarantine the product and work with the manufacturer to obtain missing data or further disposition the product in the event data cannot be obtained. Product cannot be further distributed without data resolution. The distributor will reach out to the manufacturer and follow General Communications practices in communicating this exception.

The wholesale distributor will return the product to inventory once it has received the TI for the missing product identifier(s). Additionally, if agreed it takes days to reconcile and send the TI, the wholesale distributor will likely request further dispositioning of the product and not continue to quarantine it. Suitable timeframes for resolving this incident will be determined in business discussions between trading partners.

**Manufacturer Action:** The manufacturer will conduct an internal investigation and make an appropriate business determination on how to move forward, which may depend upon the status of the data for that product in their system. The manufacturer will provide the needed TI or provide further instructions on dispositioning of the product.

## Data, No Product

**Scenario 3.1: A shortage occurs, and the manufacturer sends data that includes product that a wholesale distributor did not receive.**

* The wholesale distributor will discover that it has been sent data but is missing product via internal receiving reconciliation processes. The ASN & packing list confirm this a true shipment shortage.
* This may also include product lost in transit.

**Distributor Action:** If a wholesale distributor process allows them to determine at receiving that data have been received without product, a wholesale distributor will share the discrepancy at that time with the manufacturer. However, at receiving, most wholesale distributors only do quantity checks today to ensure that there is enough data to support the shipment. A detailed reconciliation generally is not done at the serial number level and is impractical due to the impact to operations.10 Consequently, having data but no product will likely be discovered later.

1. As of the publishing of these guidelines, the EDDS Draft Guidance has created ambiguity regarding reconciliation. On the one hand, the EDDS Draft Guidance recognizes and supports the use of aggregation and inference as commercially and operationally necessary. However, the EDDS Draft Guidance also can be interpreted as expecting a purchasing trading partner to check that all electronic transaction data received reflects the product that was physically shipped. This step cannot be accomplished if trading

partners are transacting in sealed cases and totes as it suggests that every package the purchasing trading partner receives must be “checked,” that is, removed from the larger container, and scanned in order to be “properly associated” with the data received from the selling trading partner. The provisions on aggregation and inference in the EDDS Draft Guidance specifically state that the contents of sealed cases may be inferred and that they do not have to be (and, for security and operational reasons should not be) opened. HDA and other stakeholders have asked that the EDDS Draft Guidance positions on reconciliation and use of aggregation and inference be aligned.

If a wholesale distributor reports a shortage on an invoice, it will then identify the exception and notify the manufacturer. The wholesaler should correct their data according to Gs1 recommendations if warranted.

**Manufacturer Action:** A manufacturer will investigate and determine if data correction per Gs1 instructions is warranted. This could also result from a manufacturer discovering that data has been sent to the wrong place because of product overage elsewhere. Therefore, an investigation will be conducted per their SOPs.

**Scenario 3.2: A manufacturer sends data that is received by the distributor, but later the manufacturer cancels the full/partial shipment or carrier fails to deliver sellable product.**

* Manufacturer customer service contacts a wholesale distributor to cancel or change an order quantity. Note: If a cancellation occurs, it should be prior to a manufacturer shipping the product.
* ~~The wholesale distributor would confirm that it does have data for the changed quantity amount that it has received.~~

**Distributor Action:** A wholesale distributor receives a phone call/email from a manufacturer notifying them of a shipment cancellation or change to order quantity. ~~If the cancellation or change occurs prior to a manufacturer shipping the product, then the data should also not have been sent.~~ ~~The data should reflect what was sent by the manufacturer (either no products or the correct product identifiers for the shipment).~~ *Note: Data should be corrected to only reflect data that will be or is received.*

~~If quantity changes, but the data has already been sent then the distributor would have to notify the manufacturer of what products (by identifiers) it did receive and what data it received to identify and reconcile the shortage.~~

**Manufacturer Action:** A manufacturer will investigate and explain to the wholesale distributor what the error was. A manufacturer will notify the wholesale distributor when they are aware that data were sent, but the product that corresponds to the data was pulled from the shipment and is still in their control. However, since the data were already sent, a manufacturer will need to either correct the data and not send product or send product that is covered by the data. **At onboarding trading partners should identify a point of contact to notify in the event this occurs (Add to best practices section).**

**Scenario 3.3: A manufacturer sends data that are received by the wholesale distributor, but the shipment is refused because product is deemed non-sellable.**

* ~~A wholesale distributor might refuse delivery of a shipment, or the carrier may be unable to deliver the shipment.~~
* Refusal examples could be damages to product or temperature excursion.

**Distributor Action:** ~~When a wholesale distributor rejects a shipment, or the carrier is unable to make delivery, the carrier should return the product to the manufacturer. If the wholesale distributor refused the shipment, it will need to update its systems to indicate that, though it received data for a shipment, it did not take delivery of any of the products in the shipment. In instances where part of or the entirety of the shipment is refused, there should be a way to note which serial numbers are not received.~~

Wholesale distributors should contact the manufacturer and let them know what product is being refused by communicating exactly what was refused or what was received or that the whole shipment was refused. Wholesale distributors should correct the data.

**Manufacturer Action:** The manufacturer will be contacted by the wholesale distributor’s customer operations group. The manufacturer will need to update the serialized data in its system to reflect that the products were not accepted. The manufacturer and wholesale distributor will also need to work together to determine why the rejection occurred.

**Scenario 3.4: A manufacturer sends data that are received by the wholesale distributor, but the shipment is refused even though it is sellable.**

* Sellable product refused due to cancelled or expired order.

**Distributor Action:** ~~When a wholesale distributor rejects a shipment or the carrier is unable to make delivery, the carrier should return the product to the manufacturer. If the wholesale distributor refused the shipment, it will need to update its systems to indicate that, though it received data for a shipment, it did not take delivery of any of the products in the shipment. In instances where part of or the entirety of the shipment is refused, there should be a way to note which serial numbers are not received.~~

Wholesale distributors should contact the manufacturer and let them know what product is being refused by communicating exactly what was refused or what was received or that the whole shipment was refused. Wholesale distributors should correct the data in their EPCIS systems in case the same product is received in the future.

**Manufacturer Action:** The manufacturer will be contacted by the wholesale distributor’s customer operations group. The manufacturer and wholesale distributor will also need to work together to determine why the rejection occurred. The manufacturer will provide further instructions on dispositioning of the product, if appropriate, and update the serialized data in its system to reflect that the products were not accepted.

**Scenario 3.5: A manufacturer sends data for a shipment that is to be received by a wholesale distributor, but the shipment or partial shipment is stolen.**

* A trading partner discovers the shipment is stolen in transit.
* Wholesale distributor may observe tampered parcels/pallets.

**Distributor Action:** If the wholesale distributor receives only a partial shipment or no shipment at all, it will notify the manufacturer. The wholesale distributor will work with the manufacturer on the manufacturer’s investigation and will provide the serial numbers of the product that it has received to help the manufacturer identify what product identifiers are missing.

Given that deliveries can be delayed due to transit issues, splitting of shipments and other ordinary reasons, the wholesale distributor may wait several days before it notifies the manufacturer that it appears the shipment may be stolen.

~~If the product is determined to be suspect product after communication with the manufacturer, then the wholesale distributor will follow its relevant SOPs.~~

**Manufacturer Action:** After receiving tracking notification or communication from the wholesale distributor that it believes all or part of a shipment was stolen, the manufacturer will conduct an investigation. If the investigation confirms the product was stolen, the manufacturer will proceed per its relevant SOPs. ~~A lost or stolen shipment would trigger an investigation by the manufacturer. With the wholesale distributor’s assistance in the investigation, the manufacturer should be able to identify which product and, if applicable, case identifiers are missing. If the wholesale distributor received part, but not all, of a missing shipment, the wholesale distributor would be able to share, by identifier, the product(s)/case(s) that were received.~~

The manufacturer and the wholesale distributor will follow their relevant SOPs for stolen items and determine any legal and compliance obligations such as whether to submit a Form 3911 notification to FDA.

## Packaging and Labeling

**Scenario 4.1: A wholesale distributor scans a product when receiving or preparing it for shipping that results in a mismatch between product and transaction data that the manufacturer determines is a labeling issue.**

* The wholesale distributor scans a product at receiving, revealing a mismatch between the bar code and the data. This scenario is related to section 1, scenario 4. \* does this combine with 1.4?

**Distributor Action:** A wholesale distributor discovers ~~on receipt~~ that the labeling on a product does not match the EPCIS data. ,. The wholesale distributor will quarantine the product and will reach out to the manufacturer to notify them of the issue. Issue details could include results of the product scan to show the manufacturer what the wholesale distributor has discovered. After investigating the manufacturer determines it is a labeling issue and responds to the wholesale distributor.. The wholesale distributor could use the product if a lower level package label is correct , or they should work with the manufacturer to further disposition the product .

~~If the product is determined to be suspect after communication with the manufacturer, then the wholesale distributor will follow its relevant SOPs.~~

**Manufacturer Action:** The manufacturer will conduct an internal investigation and will communicate to the wholesale distributor that it is a labeling issue and provide further instructions on dispositioning of the product. The manufacturer also will work with their internal teams to understand the issue and correct in the future based on the returned product.

**Best Practice Note:** A lot or batch can fail to match because of a special character issue or other upper- and lower-case issues. Each company should ensure that their systems, service providers and labels comply with the special characters and encoding allowed per GS1: [https://www.gs1.org/](https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications) [standards/barcodes-epcrfid-id-keys/gs1-general-specifications](https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications)

**Scenario 4.2: A wholesale distributor discovers when receiving a product or preparing it for shipping that it has no HRI of the GTIN, serial number, lot, or expiry on the label.**

* ~~The wholesale distributor will quarantine this product.~~ This product does not comply with the DSCSAand is unsaleable product. ~~that will go to the wholesale distributor’s reclamation/ morgue and be processed in accordance with the manufacturer’s instructions (return to manufacturer/provide to returns processor for disposition).~~
* **Note:** This scenario assumes product is covered under the DSCSA, is not grandfathered and is not the subject of a temporary or permanent waiver, exception or exemption.

**Distributor Action:** The wholesale distributor discovers that the product is missing some or all HRI on the product. The wholesale distributor will reach out to the manufacturer to notify them of the issue. They should work with the manufacturer to further disposition the product.

**Manufacturer Action:** The manufacturer will conduct an internal investigation with their teams to understand the issue and correct it in the future. They will also provide further instructions on dispositioning of the product.

**Best Practice Note:** If the product does not contain a serial number because it is not covered by the DSCSA or is the subject of a waiver, exception or exemption, then the manufacturer should notify the wholesale distributor.  ~~via a letter or by noting this on the [HDA new product form](https://www.hda.org/resources/hda-standard-rx-product-and-medical-device-info-form). If grandfathered or subject to one of these exclusions, waivers, exceptions or exemptions, the product may be sold.~~

**Scenario 4.3: A wholesale distributor discovers during their operations that the Serialized Shipping Container Code (SSCC), is damaged, unusable, or missing.**

**Distributor Action:** The wholesale distributor discovers that the logistical container labeling is damaged, unusable, or missing. The wholesale distributor may handle the product at the case or next lower level or manage as per business processes. Note that it is unlikely that the manufacturer will be notified unless this is an ongoing problem.

**Manufacturer Action:** The manufacturer will conduct an internal investigation if notified by a wholesale distributor to determine what happened and assess labeling practices.

**Best Practice Note:** To avoid damage to SSCC labels, it is suggested that companies place the SSCC label on the pallet or logistics unit and then clear wrap over it so that the SSCC is visible and readable through the wrap and less likely to be damaged in transport.

**Scenario 4.4: A wholesale distributor receives a product or is preparing to ship it and is unable to read the 2D bar code, because it will not scan, is encoded incorrectly, or has incomplete elements.**

* Whether this problem with the 2D bar code is discovered at receiving or pick, pack and ship the process is the same.
* If a bar code is unreadable at the initially scanned packaging level, the barcode at the next lower package level may be readable.

**Distributor Action:** If the wholesale distributor cannot read the bar code on a case, it should first eliminate scanner and user error as the reason (e.g., confirm that scanner is in good working order, that scanner has been updated with latest software, that user has been instructed properly). If the 2D bar code on the each/lowest saleable unit still cannot be scanned and read, the product will be quarantined, and the manufacturer will be notified. They should work with the manufacturer to further disposition the product.

~~° If the product is brought into inventory and then quarantined, it is likely that the product will move through the normal morgue/reclamation process and be processed~~

~~in accordance with the manufacturer’s instructions (return to manufacturer/provide to returns processor for disposition).~~

**Manufacturer Action:** A manufacturer will conduct an investigation to determine why the bar code is improperly encoded, incomplete, or unscannable and work with their quality teams to rectify the issue going forward. Once the investigation is completed, the manufacturer will communicate the determination back to the wholesale distributor. They will also provide further instructions on dispositioning of the product.

* **Scenario 4.5: A wholesale distributor discovers it has an aggregation error in the EPCIS data it received from the manufacturer.** This might be discovered during receiving or inventory spot checking.
* This might be discovered during picking when a package is already shown to have been shipped because the case the package was aggregated to has already shipped

**Distributor Action:** The distributor will reach out to the manufacturer and follow General Communications practices in communicating this exception. Further handling of this exception will be based on SOPs.

**Manufacturer Action:** The manufacturer will investigate the exception based on data provided from the wholesaler based on its SOPs.

## Unavailable for Distribution - Product Indicated to be recalled, suspect or illegitimate.

**Scenario 5.1: A wholesale distributor discovers a serial number or lot number is unavailable** **for distribution due to being recalled, suspect or illegitimate.**

**Distributor Action:** The wholesale distributor discovers the serial number status that is unavailable for distribution due to being recalled, suspect, or illegitimate. The wholesale distributor will quarantine the product and follow their recall or suspect/illegitimate product processes, whichever is applicable. In the event of a suspect or illegitimate product situation, the wholesale distributor would notify the manufacturer in accordance with its SOPs.

**Manufacturer Action:** The manufacturer will work with the distributor on the investigation after being contacted following guidance: Verification Systems Under the Drug Supply Chain Security Act: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies







#### 901 North Glebe Road, Suite 1000

#### Arlington, VA 22203

#### (703) 787-0000

### [www.hda.org](http://www.hda.org/)