EXCEPTIONS HANDLING GUIDELINES FOR THE DSCSA

HDA
Healthcare Distribution Alliance

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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.

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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
- Damaged Product
- Product, No Data
- Data, No Product
- Packaging
- Product Hold

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 2023 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.

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 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.

Manufacturers and distributors have 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 document deviations, 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, even if it did or will create a discrepancy that cannot be resolved. 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 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.

EXCEPTIONS

I. Data Issue

Scenario 1: The wholesale distributor receives data, but the Global Company Prefix (GCP), Global Location Number (GLN)/sGLN is not found in master data (whether incorrect or a format issue; any non-matching GLN will require the same resolution).

- A manufacturer sends a distributor an EPCIS file.
- At receiving, the wholesale distributor determines that it does not have a GCP, GLN or sGLN in its system that corresponds to the manufacturer sending the file.
- The system will indicate an error.
- If the manufacturer has a new or updated GLN, it will need to update the master data provided to the distributor or it will need to update their message with the appropriate GLN and resend the file. The GCP if missing or incorrectly formatted will need to be provided in a correct format.
- In some instances in which the contract manufacturing organization (CMO) GLN read point is inherited from upstream events and passed to the manufacturer or 3PL, the manufacturer should take care to ensure their GLN (and not the CMO's GLN) is embedded in the file.

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 of the GS1 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: Currently, GLNs and GTINs are provided at new item setup. Any future changes could be communicated via new item short form or via another future master data solution. As a best practice, ensure your trading partners have current contact information. One-way companies are handling this is to create DSCSA email box for tracking purposes that is monitored by multiple individuals.

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 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. Note that GS1 1.2 has business location as required, and this will be optional in the future 1.3 guideline.

Scenario 2: The wholesale distributor receives the data, but the GTIN is not found in 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. Either part of the file or the entire file will be rejected based on how wholesale distributor systems are configured.
- The manufacturer will need to update its GTIN master data, send it to the wholesale distributor to update their system, and resend the entire EPCIS file or wait for the file to be reprocessed after the GTIN master data is updated.

Distributor Action: The distributor will notify the manufacturer via email that the file failed based on GTIN master data issue. The distributor will first check internal to ensure that their systems have been updated with master data previously provided by the manufacturer. If the new GTIN has not been provided, it will ask the manufacturer for updated GTIN(s) and update their master data files so that the manufacturer can reprocess/resend the EPCIS file.

Manufacturer Action: The manufacturer will provide updated GTIN master data via email and resend the file or the distributor may automatically reprocess the file. Note that if an EPCIS file contains GTINs below the lowest saleable unit or a convenience bundle pack GTIN (packaging hierarchy between a case and a unit of sale) that have not been provided to the wholesale distributor, it also may lead to a file failure.

Compliance/Best Practice Note: Check your manufacturer change process for product packaging changes and new product launches to ensure changes are communicated prior to sending product to a wholesale distributor. Master data should be sent to downstream trading partners before any product is sent to ensure it can be properly received.

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

5 For FDA requirements regarding when a new NDC is necessary, refer to 21 C.F.R. § 207.35.

Scenario 3: The wholesale distributor was sent the data, but the EPCIS file is not formatted correctly.

- 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.

Note: Wholesale distributors are doing a "handshake" notification today with those that have opted in. If a file does fail, ideally a manufacturer would resend prior to the wholesale distributor receiving the shipment. Often, the wholesale distributor has limited visibility into the reason the file failed or the nature of the format issue. However, if they do, this information will be useful to the manufacturer's investigation and should be provided.

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.

Manufacturer Action: The manufacturer will resend the file in the correct format. This could be either post "handshake" notification or sent after email notification.

Best Practice Note: Manufacturers have the option to opt in to "handshake" notifications today from wholesale distributors where a simple notification acknowledges the message was received. Ideally, if a manufacturer does not receive an acknowledgment that the message was received, a manufacturer can resend the files prior to the shipment arriving at receiving.

Scenario 4: A wholesale distributor receives data, but there is a misalignment between the data received and what is encoded in the 2D bar code.

- The wholesale distributor returns the product to the manufacturer, and manufacturer quality teams handles according to their internal business processes.

Distributor Action: The wholesale distributor will notify the manufacturer via email that the data received do not match what is encoded in the 2D bar code and that the product will be returned. Note that this will not impact "00" in the date. Also, if there is a partial product identifier match a distributor may note that in the communication back to the manufacturer.

Manufacturer Action: If the product is determined to be suspect product after communication with the manufacturer, then the wholesale distributor will follow its relevant standard operating procedures (SOPs).

The manufacturer will initiate an internal quality review per its existing SOPs.

Note: If a manufacturer's quality review confirms the discrepancy but the manufacturer opts not to remove the product from the marketplace, for example, in the event of an expiration dating extension, the wholesale distributor will record and rely on the manufacturer's instruction. It is important to consider how to communicate information around this product downstream so that downstream partners understand they are not receiving suspect product.

II. Damaged Product

Scenario 1: A wholesale distributor discovers a damaged case or case label at receiving.

- If the eaches are not damaged, the wholesale distributor will receive at the each level.

Distributor Action: The wholesale distributor will receive at the each/lowest saleable unit level if the eaches are not damaged. When the transaction only is transacted at the case (redistribution facility), the wholesale distributor may not be able to receive at the each.

Manufacturer Action: None.

Scenario 2: A wholesale distributor discovers a damaged each, which could be due to either a damaged 2D bar code or human-readable interpretation (HRI) on the label.

- Whether it is discovered at receiving or pick/pack/ship, the product cannot be sold downstream due to the damage. It will be taken out of saleable inventory and returned to the manufacturer.

Distributor Action: These products would be treated as unsaleable under the DSCSA and the product will be returned to the manufacturer. Note that if the product is damaged and discovered at receiving, the product could be returned for credit. If the wholesale distributor damaged the product during the distribution process and it is discovered at pick, pack and ship, then the manufacturer may decide not to allow credit.

Manufacturer Action: The manufacturer will work with the distributor to reconcile the damage claim which could include issuing a call tag to return the damaged product.

III. Product, No Data

Scenario 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.
- A manufacturer will resend the EPCIS file.
- **Note:** Data senders should turn on message disposition notifications (MDNs). If a company is missing a file, it should look at MDNs first to check status of message 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 wholesale distributor will attempt to provide information on the shipment (e.g., PO, delivery number, SSCC, or a serial number from the delivery) to assist the manufacturer in identifying the shipment.

The distributor will set up a process adjacent to receiving to collect product data. The distributor will email the manufacturer with those data and information either in the body of the email or in a file attachment, which will include:

- A standard subject line: Distributor + Manufacturer + UUID + Issue (No EPCIS data).
- The body of the email or attachment should contain as much information as the wholesale distributor can provide, such as:

    UUID (any unique identifier of wholesale distributor's choosing);

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

    Issue (drop down or multiple option types: product no data, receiving, etc.);

    Ship-to GLN;

    Ship-to address;

    GTIN;

    SN;

    LOT;

    Scanned expiry;

    Trade item description; and,

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

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: 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 company is missing a file, it 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 schedule 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.

Scenario 2: A wholesale distributor receives a product, but the serial number is not found within its system, 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 or not the wholesale distributor would refuse the shipment, or create a PO and receive and quarantine the product until EPCIS data could be sent by the manufacturer. It is more likely that a wholesale distributor would keep a smaller mis-shipment versus a larger mis-shipment.

In either instance, the wholesale distributor could provide to the manufacturer information to help the manufacturer identify and investigate the mis-shipment, which potentially includes: the SSCC at the overpack or the pallet level, the PO, SSCC or photographs.

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: 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, manufacturer 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 3: A wholesale distributor receives a shipment in which the serial numbers are not found, either due to the wrong data being sent or because it is an overage. There is a purchase order to reference.

- The wholesale distributor's system will indicate an error at receiving.
- If the product was physically scanned, it will then be quarantined and the wholesale distributor will work with the manufacturer on the missing data.
- The wholesale distributor will monitor daily reconciliation reports to know when the data have been received and the product can be put into saleable inventory.

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.[6] It will provide the PO that is present on the shipment data (and product identifier).

The distributor will set up a process adjacent to receiving to collect product data. The distributor will email the manufacturer with those data and information either in the body of the email or in a file attachment, which will include:

- A standard subject line: Distributor + Manufacturer + UUID + Issue (No EPCIS data).
- The body of the email or attachment should contain as much information as wholesale distributor can provide, such as:

    UUID (any unique identifier of wholesale distributor's choosing);

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

    Issue (drop down or multiple option types: product no data, receiving, etc.);

    Ship-to GLN;

    Ship-to address;

    GTIN;

    SN;

    LOT;

    Scanned expiry;

    Trade item description; and,

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

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.

The wholesale distributor will return the product to inventory once it has received the TI for the missing product identifiers.

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: The manufacturer will conduct an internal investigation to determine (if possible) what purchase order the shipment belongs to and either respond with the missing TI or have the product returned based on manufacturer capability and policy.

The manufacturer will send the recreated TI (commission, aggregation and ship events for missing serial numbers) via EPCIS to the wholesale distributor to accurately reflect what was sold and shipped to the wholesale distributor using the date the exception was discovered.[7] 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.

6 In the future this may be an automated process, but this is unlikely to happen before 2023.
7 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 several days to reconcile and send the TI, the wholesale distributor will likely remove the product from quarantine and return 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 were 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.

Scenario 4: A wholesale distributor receives a product overage with a valid purchase order receipt in which the shipment references the purchase order.

- A wholesale distributor will quarantine the overage product and work with the manufacturer to obtain the missing data. The manufacturer could also request that product be sent back or sent for destruction.
- When a specific PO is referenced, a wholesale distributor has a transaction statement for that product. The wholesale distributor would request an EPCIS message corresponding to the specific serial numbers that it is missing.

Distributor Action: The wholesale distributor discovers upon receipt that it has received a product overage for a specific purchase order. The distributor will quarantine the overage product and notify the manufacturer via email that it is missing data due to a product overage. The wholesale distributor will provide the manufacturer with the PO and product identifier(s) for the overage product(s) and work with the manufacturer to obtain the missing data or return the overage product(s) to the manufacturer.

The distributor will email the manufacturer with that data and information in the body of the email or an attachment, which will include:

- A standard subject line: Distributor + Manufacturer + UUID + Issue (No EPCIS data).
- The body of the email or attachment should contain as much information as the wholesale distributor can provide, such as:

    Ship-to GLN;

    Ship-to address;

    GTIN;

    SN;

    LOT;

    Scanned expiry;

Trade item description; and,

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

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 resend or request return of the overage product.

The manufacturer should send an updated EPCIS file that contains only the missing serial numbers and will need to reference the original PO in the new EPCIS file.

As part of its investigation, the manufacturer should confirm that the serialized data were 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 those serialized data for the overage product to the distributor.

Scenario 5: A delivery was made to the right company, but to the wrong distribution center within that company.

- 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 go back to the manufacturer, a process could be put in place to resolve the PO and execute an intracompany transfer, or the carrier could be redirected to the correct location.
- The wholesale distributor could redirect the shipment to the distribution center it was intended for. If data have been sent, the DC will be able to receive that product, presuming that the data were sent to the correct corporate entity address and not a "sold-to" location.[8]

Distributor Action: If the files post successfully, the wholesale distributor receives the shipment against the data it received from the manufacturer and resolves the PO and executes an intracompany transfer.[9] The wholesale distributor will follow its existing procedures for notification to a manufacturer.

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 centers, some manufacturers may choose to have the product destroyed because they cannot ensure there has not been a temperature excursion or other handling issue.

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

8 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.

9 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 6: A delivery was made to the wrong wholesale distributor.

- The wholesale distributor receiving the product will contact the manufacturer.
- The manufacturer coordinates with the logistics provider/carrier to take it to the correct location.

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.

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.

Scenario 7: A serial number is not found either due to wrong data or an overage while a wholesale distributor is trying to pick, pack and ship.

- This could be an overage or an aggregation error. The wholesale distributor will quarantine the product and work with the manufacturer to obtain missing data.

Distributor Action: The wholesale distributor discovers at pick, pack and ship it has product without the corresponding serialized data. The distributor will quarantine the product and reach out to the manufacturer via email, include the product identifier(s) and include:

- A standard subject line: Distributor + Manufacturer + UUID + Issue (No EPCIS data).
- The body of the email or file attached should contain as much information as the wholesale distributor can provide, such as:

  Ship-to GLN;

  Ship-to address;

  GTIN;

  SN;

  LOT;

  Scanned expiry; and,

  Trade item description.

The wholesale distributor will return the product to inventory once it has received the TI for the missing product identifier(s). Note: If data are resent for the entire delivery, the file will fail. Only missing data should be sent. Additionally, if it takes days to reconcile and send the TI, the wholesale distributor will likely return as an overage and not continue to quarantine the product. Suitable timeframes will be determined in business discussions between trading partners.

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: 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 could request the product back from the wholesale distributor or provide the TI for the product to the wholesale distributor.

If the manufacturer elects to provide TI to the wholesale distributor, it will send recreated TI for that specific product identifier, including TS and a commissioning statement via EPCIS to the wholesale distributor to accurately reflect what was sold and shipped to the wholesale distributor using the date the exception was discovered as the transaction date. Note that this will likely be a manual process at the manufacturer prior to sending missing TI, and that ONLY the missing product identifiers can be contained in the new EPCIS message, or the file will be rejected. If the data for the full shipment data are resent, the file will fail.

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.

IV. Data, No Product

Scenario 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 reconciliation processes.
- The wholesale distributor will notify the manufacturer promptly upon learning that they have data, no product. The meaning of "promptly" will be determined by trading partners in their commercial arrangements.

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.

10 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, at some later point, does a reconciliation for financial purposes or to check inventory, it may then identify the exception and choose to notify a manufacturer. The primary way a data overage will be discovered is because it will be realized as a product overage correction reported elsewhere to the manufacturer. A wholesale distributor will notify a manufacturer promptly. What promptly means will be determined by trading partners in their commercial arrangements.

The wholesale distributor will notify a manufacturer promptly (with each company determining what promptly means) upon learning that they have data, but no product.

Manufacturer Action: A manufacturer will investigate and do a data correction on their side. It is likely that a manufacturer will discover that data have been sent to the wrong place because of a product overage elsewhere. Therefore, data will be corrected in their systems to reflect where product was sent, and an investigation will be conducted per their SOPs.

Manufacturers are not expected to send error declarations (such as "void shipment" events) via EPCIS when excess or incorrect data are sent.

Scenario 2: A manufacturer sends data that is received by the distributor, but later the manufacturer changes or cancels the shipment quantity.

- Manufacturer customer service contacts a wholesale distributor to cancel or change and 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. However, if the data were already sent, a manufacturer will need to work on how to pull back the data. The data should reflect what was sent by the manufacturer (either no products or the correct product identifiers for the shipment).

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 overage or 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. At onboarding trading partners should identify a point of contact to notify in the event this occurs.

Scenario 3: A manufacturer sends data that are received by the wholesale distributor, but the shipment is refused or undeliverable at the wholesale distributor.

- A wholesale distributor might refuse delivery of a shipment, or the carrier may be unable to deliver 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
- Cancellation of a shipment should occur prior to product send. If the product and data are sent, but the product is refused then then trading partners may resolve utilizing the process below.

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. The wholesale distributor will notify the manufacturer through the customer operations group after a minimum of seven business days to rule out partial or split shipments that they received data with no product. 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.

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 and were returned. If the wholesale distributor agrees to accept redelivery, the manufacturer will need to work with the wholesale distributor to make sure that the second delivery does not fail due to the wholesale distributor receiving duplicate transaction data.

The manufacturer and wholesale distributor also will need to work together to determine why the rejection or delivery failure occurred.

Manufacturers are not expected to send error declarations (such as "void shipment" events) via EPCIS when excess or incorrect data are sent.

Scenario 4: A manufacturer sends data for a shipment that is received by a wholesale distributor, but the shipment or partial shipment is lost or stolen.

- A trading partner discovers the shipment is lost or stolen in transit and the products cannot be returned.
- 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 and determine any legal and compliance obligations such as whether to submit a Form 3911 notification to FDA.

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 and, if applicable, case 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 for up to 10 business days before it notifies the manufacturer that it appears the shipment was lost or 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 notification from the wholesale distributor that it believes all or part of a shipment is lost or stolen, the manufacturer will conduct an investigation. If the investigation confirms the product was stolen, the manufacturer will proceed per its relevant SOPs. In the case that a partial shipment is missing, the wholesale distributor will provide the identifiers of the products it did receive so a manufacturer can determine what is missing.

The manufacturer will determine if a notification must be made to FDA on a Form 3911. That submission would include, among other things, the identifiers for the missing products and cases, if known.

The manufacturer also will work with its quality team to determine if any serial numbers should be decommissioned and may place alerts in its systems if those numbers reappear in commerce.

V. Packaging and Labeling

Scenario 1: A wholesale distributor scans a product on receiving that results in a mismatch between product and data that the manufacturer determines is a batch labeling issue.

- The wholesale distributor scans a product at receiving, revealing a mismatch between the bar code and the data.
- The wholesale distributor will reach out to the manufacturer, sharing the scanned data so that it can investigate.
- The manufacturer will start an investigation and determine that there is a mismatch between the batch/lot on the package and the batch/lot in the data. This could be a mislabeling issue, the result of special characters, or other issue.

Distributor Action: A wholesale distributor discovers on receipt that the batch labeling on a product is incorrect. The wholesale distributor will quarantine the product and will reach out to the manufacturer to notify them of the issue via a phone call. The phone call could be followed up with an email with the results of the product scan to show the manufacturer what the wholesale distributor is "seeing." The manufacturer will need to investigate and respond to the wholesale distributor with a determination. Once a determination is made, the issue will either be resolved, or product would be returned to the manufacturer because of a mismatch between the product

label and data. If there is an issue in which the lot in the bar code differs from what is on the product label, a notification may be made through a wholesale distributor's product integrity or suspect product team.

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: The manufacturer will conduct an internal investigation after the wholesale distributor notifies them of the product and data mismatch. Once the investigation is completed, the manufacturer will communicate the determination back to the wholesale distributor with instructions. 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/standards/barcodes-epcrfid-id-keys/gs1-general-specifications

Scenario 2: A wholesale distributor discovers on receiving a product that it has no HRI of the serial number on the label.

- The wholesale distributor will quarantine this product. This product does not comply with the DSCSA. It becomes 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 a covered product 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 on receipt that the product has no HRI of the serial number on the product. The wholesale distributor will reach out to the manufacturer to notify them of the issue. The product is unsaleable per DSCSA unless grandfathered or subject to a waiver, exception or exemption that permits it to exclude the HRI.

If the product is determined to be suspect product after communication with the manufacturer, then the wholesale distributor will follow the relevant SOPs it has in place.

Manufacturer Action: The manufacturer will conduct an internal investigation with their teams to understand the issue and correct in the future.

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. If grandfathered or subject to one of these exclusions, waivers, exceptions or exemptions, the product may be sold.

Scenario 3: A wholesale distributor discovers on receiving that the Serialized Shipping Container Code (SSCC) is damaged or unusable.

- The wholesale distributor will receive at the case or each level if those product labels are intact and compliant.

Distributor Action: The wholesale distributor discovers on receipt that the product's SSCC is damaged or unusable. The wholesale distributor will receive the product at the case or each level, whichever the highest level of packaging is, if those labels are compliant and not damaged. 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: A wholesale distributor receives a product 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 case level, a wholesale distributor may choose to check if the each bar codes are readable and receive at the each level.
- If bar codes are unreadable at the each level, the product will likely be placed in the morgue. For high-value products, if the HRI is readable some distributors may choose to manually enter the sGTIN.
- Note that there are several possible approaches to addressing this exception.

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.

If the product is quarantined at receiving because it does not scan and therefore does not meet DSCSA requirements, the wholesale distributor will likely return the product to the manufacturer at that point.

    - 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).

If the product is determined to be suspect after communicating with the manufacturer, then the wholesale distributor will follow the relevant SOPs it has in place.

Manufacturer Action: A manufacturer will conduct an investigation to determine why the bar code is improperly encoded or incomplete 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 with instructions.

Scenario 5: A wholesale distributor discovers at pick, pack and ship that there is no HRI serial number on the label.

- The wholesale distributor will quarantine the product. By 2023, wholesale distributors are not anticipating to receive non-serialized, grandfathered product. It could be that the product is not subject to the DSCSA at all, or is subject to a waiver, exemption or exception.
- If the product is labeled incorrectly and missing required information, such as the serial number, it could also be a product quality problem and not be compliant with the DSCSA.
- If the product is not a covered product under the DSCSA; is not subject to a waiver, exemption or exception; and is not grandfathered it will be considered suspect product.
- The wholesale distributor will work through its suspect product processes.

Distributor Action: If the product does not contain an HRI serial number on the label, the wholesale distributor will notify the manufacturer via a product complaint to determine whether or not the product is exempt from DSCSA labeling requirements, is subject to a waiver, exemption or exception, or is grandfathered. If grandfathered or subject to one of this exclusions, waivers, exceptions, or exemptions, the product may be sold. If the product is not grandfathered and not subject to an applicable exclusion, exemption, exception or waiver, it may not be sold. Such product is unlawful under the DSCSA and should be returned to the manufacturer or otherwise dispositioned in accordance with the manufacturer's instructions.

If the product is considered suspect, the wholesale distributor will notify the manufacturer per their suspect product process.

Manufacturer Action: If the product is not exempt from DSCSA labeling requirements, is not subject to a waiver, exemption or exception, and is not grandfathered, the manufacturer will have to investigate to determine the cause of the issue and work with their quality teams to rectify the problem. The manufacturer may need to treat the product as suspect and follow its suspect product process.

VI. Product Hold

Scenario 1: A wholesale distributor receives EPCIS file events of out sequence, and they do not match the status of the product.

- EPCIS file events should be in order (commission, pack, ship) for a wholesale distributor to be able to receive them from the manufacturer. If sent out of sequence, the system will indicate an error when the product is scanned at receiving.
- The error will indicate that a wholesale distributor does not have the serial number. Ideally, this sequence error should be rectified prior to receiving. If it is not, the product must be held until the error is resolved and the wholesale distributor can receive the product.
- The wholesale distributor would send a request back to the manufacturer that the files be sent in the correct order.

Distributor Action: The wholesale distributor will notify the manufacturer that the EPCIS files do not have the proper sequencing, and the manufacturer will resend the files with the correct sequencing so that it can receive the files. Some wholesale distributors have automatic electronic notifications back to a manufacturer if a file that was sent cannot be read and a manufacturer will be prompted to resend.

Manufacturer Action: The manufacturer will resend EPCIS files for the entire shipment with the correct sequencing (commission, pack, ship).

Best Practice Note: EPCIS files should be sent to downstream trading partners in a timely manner so that a wholesale distributor can react to any issues prior to the product arriving.

Scenario 2: A wholesale distributor, when trying to pick, pack and ship, discovers a serial number in HOLD status due to being recalled, suspect or illegitimate.

- If the product is recalled, the wholesale distributor will follow their recall protocols and the product will be quarantined.
- If the product is shown as a "HOLD" because it is suspect or illegitimate (either because it has been noted by the distributor since the product has been received or a manufacturer has pushed a status update to a distributor) the product will be quarantined and a wholesale distributor will follow its suspect and illegitimate product procedures.

Distributor Action: The wholesale distributor at pick, pack and ship discovers the serial number status that is in "HOLD" due to being recalled or 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.

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