Partnership for DSCSA Governance (PDG), Healthcare Distribution Alliance (HDA), & GS1 US Exception Handling Workshop Report

On February 6th and 7th, the Partnership for DSCSA Governance (PDG), the Healthcare Distribution Alliance (HDA), and GS1 US joint hosted a two-day workshop (the "Workshop") for industry participants and federal regulators to work through various misalignment exception scenarios —those instances in which DSCSA-required transaction information (TI) is not fully aligned to physical product transacted. This report summarizes the Workshop and captures conclusions and next steps for industry.

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PDG Overview

PDG is an independent, balanced, sector-neutral, nonprofit industry governance body that supports the secure, electronic, interoperable tracing, and verification of prescription drugs in the U.S. supply chain, as required by the Drug Supply Chain Security Act (DSCSA). Through our public-private partnership with FDA, we collaborate to develop, advance, and sustain an effective and efficient model for interoperability.

PDG membership includes leading authorized manufacturers, re-packagers, wholesalers, third-party logistics providers, and dispensers (hospitals and retail and independent pharmacies), as well as leading industry trade associations and technical experts. Together, these members are working to establish a comprehensive vision for industry's implementation of secure, electronic systems and processes for drug traceability in the United States.

For additional information, visit www.DSCSAgovernance.org.

HDA Overview

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.

For additional information, visit www.hda.org.

GS1 US Overview

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely-used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code (EPC®)-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

For more information, visit www.gs1us.org.

Background

The Drug Supply Chain Security Act of 2013 (DSCSA)[1] requires pharmaceutical supply chain trading partners—manufacturers, repackagers, wholesale distributors, and dispensers—to implement interoperable systems and processes to exchange and maintain record of transaction information (TI) for each change in ownership of a prescription pharmaceutical covered by the DSCSA. Trading partners began exchanging lot-level TI in 2015, but enhanced requirements will take effect on November 27, 2023. Specifically, beginning November 27, 2023, TI must be "exchanged in a secure, interoperable, electronic manner"[2] and must include the package-level serial number information.[3] As a result, today's TI, which is comprised of 11 distinct data elements[4] will expand in November 2023 to also include the package-level serial number and expiration date.

The addition of the package-level serial number and expiration date is a dramatic expansion of the granularity at which trading partners handle and manage physical product and the accompanying TI. Trading partners are implementing the required systems and processes to identify and document the specific individual packages—by serial number—being sold and purchased, but when factoring in the reality that approximately 8 to 10 billion package-level transactions occur each year, errors and discrepancies are inevitable. We refer to those instances where the 13 elements of TI do not completely and accurately represent the physical product packages transacted as "misalignment exceptions."

As November 27, 2023 approaches, stakeholders have increasingly identified the volume of anticipated misalignment exceptions and the resource-intensive and collaborative processes needed to management those misalignment exceptions as a risk. HDA worked closely with its members to develop its *HDA Exception Guidelines for the DSCSA*[5] to support manufacturers and wholesalers in their management of misalignment exceptions. PDG, through its *Blueprint*, extended that framework to dispensers. Building on that foundation, GS1 was actively reviewing the ways in which its standard could be applied or extended to support the exception management process. Together, PDG, HDA, and GS1 US designed this Workshop to allow industry participants and regulators to jointly exercise the HDA and PDG work done and explore the ways GS1 standards could support the process.

[1] The Drug Supply Chain Security Act of 2013, 21 U.S.C. § 582 (2013).
[2] § 582(g)(1)(A).
[3] § 582(g)(1)(B).
[4] These are: NDC/GTIN, Serial Number, Lot Number, Expiration Date, GLN, Date of Transaction, Date of Shipment, Number of Containers, Drug Name, Strength, Dosage Form, and Container size.
[5] https://www.hda.org/publications/exceptions-handling-guidelines-for-the-dscsa/.

Goals of the Workshop

The primary goal of the Workshop was to validate and improve the HDA Exception Handling Guidelines and PDG's extension of it to the dispenser community and to provide the foundation for potential standards development by GS1 US to support the exception management process. To meet this goal, participants discussed the contours of the exception scenarios from different perspectives and applied all available standards and guidelines to attempt to resolve the exception and ensure product that is safe to dispense reaches patients without unnecessary delay. Through discussion, participants could determine whether trading partners will be equipped to resolve the exception in the real world or gaps in standards or guidelines remain that prevent resolution.

A full participant list may be found in Appendix A.

Structure of the Workshop

At the start of the Workshop, participants were divided into small groups of four to six people. The Workshop organizers then assigned these groups the role of approaching a scenario as either a manufacturer, a wholesaler, or a distributor. The groups rotated through these roles throughout the Workshop to ensure every participant could look at multiple scenarios from the perspective of a manufacturer, a wholesaler, and a distributor.

For every scenario, the Workshop organizers provided simulated data for the groups to analyze and discuss. During these discussions, the Workshop organizers asked the small groups to identify the business processes they would use to recognize the exception presented and how to resolve the exception through collaboration between trading partners.

Once the small groups finished their discussion, the Workshop organizers expanded the discussion to encompass the entire workshop. Other groups could hear how their peers approached the scenario from different perspectives and different industries.

Framework for Exception Processing

In order to facilitate a more structured discussion format, the Workshop was organized around the three-step process defined in Chapter 1 of the PDG *Blueprint*, which requires trading partners to have systems and process to identify, understand, and resolve misalignment exceptions. These misalignment exceptions occur when there is a discrepancy between the physical supply chain and virtual supply chain.

Identify: Trading partner systems and processes to recognize that a misalignment exception exists..

Understand: Trading partner systems and processes by which the trading partner that identifies the misalignment exception, in coordination with its trading partners, will take various steps to understand

the cause of the misalignment exception, specifically whether the misalignment exception is the result of a data error or reflects the presence of a suspect/illegitimate product.

Resolve: Trading partner systems and processes by which trading partner that identifies the misalignment exception takes steps to address the exception.

Overview of Exception Scenarios

The Workshop explored three general categories of misalignment exceptions: Product, No Data; Data, No Product; and Data Issue.

Product, No Data: Explores different scenarios where a trading partner receives product but does not have complete or accurate data.

Data, No Product: Presents scenarios where a trading partner receives data but does not receive all or some portion of the associated product.

Data Issue: Includes scenarios where the data misalignment comes from other challenges, such as incomplete/inaccurate master data or barcoding issues.

Participants were given variations to each scenario to discuss that provided more factors and perspectives to consider. Each scenario was accompanied by a related HDA exception scenario, which provided some steps to resolve.

These materials are available in Appendix B.

Overall Conclusions and Action Items

Scenario-by-scenarios takeaways are detailed below, but across the workshop, participants reached several overarching conclusions:

1. While the exact number of anticipated exceptions is unknown, exceptions are anticipated to have a significant impact on the supply of medicine, particularly in the first year of the November 27, 2023 requirements. In order to manage quarantine volumes and resource this process effectively, early planning is essential. Increased standardization and systematization in the communication between trading partners working to understand an exception will be valuable.
2. Well-controlled receiving processes play an important role in building confidence in product associated with exceptions identified after receiving. Quantity checks are one important part of a well-controlled receiving process.
3. Exceptions identified during the receiving process will often be easier to understand and resolve than those identified after the product has moved beyond the receiving process. As the exception progresses through the supply chain and involves more trading partners, the complexity of handling the exception increases. The exception handling process is, and must

remain, distinct from the suspect product investigation process. An exception *may* lead to a suspect product investigation, but an exception does not necessarily trigger a suspect product investigation.

4. Dispensers face particularly difficult decisions when they have limited inventory, an exception occurs, and a patient needs the product. It is important to recognize that the DSCSA does not exist in a vacuum, and trading partners will take many factors into account when deciding whether/how to support patient access.
5. If the trading partners conclude they will continue to distribute the product associated with an exception, correct data must be put in place. It is not sufficient to simply document the exception separate and apart from DSCSA TI data.
    a. For product, no data, supplemental/incremental TI should be issued; sending new complete shipment TI when the entire shipment was not part of the exception would trigger duplicate data challenges. Existing GS1 EPCIS standards generally accommodate this process, but the specific application of those standards merits further work.
    b. For data, no product, further discussion of strategies and options is warranted. Per DSCSA, TI can be sent in advance but the physical product will need to be reconciled to match the data.

HDA Action Items: Guideline Updates

Through discussion of each scenario, the following action items were identified with regard to the HDA Exception Handling Guidelines, and HDA was asked to lead these actions:

1. Explore options for standardizing and systematizing the notification by one trading partner to another that an exception exists. For example, If the manufacturer uploads data when the product ships instead of at commissioning and the buyer does not successfully receive complete and accurate data, verification attempts are likely to fail. As such, reconciliation becomes more difficult and many trading partners will resolve the exception through a return. This may also cause some trading partners to treat the product as suspect, possibly incorrectly, based on the apparent failed verification.

    - There was significant interest in translating the guideline into a standard form.
    - There was support for further exploration of the value of automating/systematizing the communication, may require Standards support.
    - In addition to needing best practices that address what information relating to an exception that trading partners should share, participants agreed that a standardized template would facilitate the sharing of information. Some information that participants discussed sharing via a template includes universally unique identifiers (UUIDs), 4 PIs, and receipt information.

2. Develop a transition process to smooth the change-over from the pre-Nov. 27, 2023 process and post-Nov. 27, 2023 process.
    - Trading partners must continue to exchange DSCSA data. Accordingly, participants recognized a need for an established transition process that provides trading partners with direction on how to use and interact with manual processes until electronic processes are stabilized.
3. Update HDA New Product Form to accommodate identification of waivers, exceptions, and exemptions.

GS1 US Action Items: Standards Updates

Through discussion of each scenario, the following action items were identified with regard to the GS1 standards, and GS1 US was asked to lead these actions:

1. No new Standards were identified to be developed but the application of existing is needed (Addendum to the Implementation Guideline):
    - Best Practice: Which date is to be used for supplemental shipment? (Date of physical shipment, date of exception, transaction date, etc.)
    - Define possible technical transactions, what are required data elements, what are optional data elements, and best practice for all trading partners.
    - Review and update scenarios for addendum (for example include drop shipment).
2. Standards may be defined as necessary based upon the outcome of Guideline updates.
3. Determine the role of GDSN pertaining to master data management.

PDG Action Items: Other Actions

Through discussion of each scenario, the following additional action items were identified, and PDG was asked to lead these actions:

1. Determine whether verification should be part of the buyer's process when they identify an exception.
    a. While trading partners possess the right to submit a verification request when it deems necessary, the Workshop participants were interested in developing direction or best practices for when a verification request should be used in relation to a data exception. The response to a verification request has potential to provide information that can aid inquiry requests and help trading partners resolve data exceptions.

    If verification requests are submitted too frequently, wholesale distributors and manufacturers will likely have challenges managing the volume of requests. To develop

a best practice, participants are interested in further discussion on when to submit a verification request, the goal of a verification request, and the value that would come from the response to a verification request.

2. Discuss whether verification can be used to overcome a misalignment exception in the data.
3. Further highlight the *Blueprint* explanation of what data is considered "core interoperability data" that *must* be standardized.
    a. As trading partners identified the need for standardized master data between sectors, it followed that there must be a clear understanding of what the basic requirements of interoperable data exchange are. Participants believe that consistent TI data elements shared between trading partners is the first step in resolving master data issues before they occur.

       It was noted that the PDG Blueprint addresses this issue, and PDG was tasked with continuing this conversation through its Interoperability Committee and developing a simple, standalone explanation of this notion of core interoperability data versus contextual data.
4. Explore with FDA strategies for balancing patient access and the time needed to resolve exceptions.
5. Discuss strategies/options for resolving data, no product scenarios.

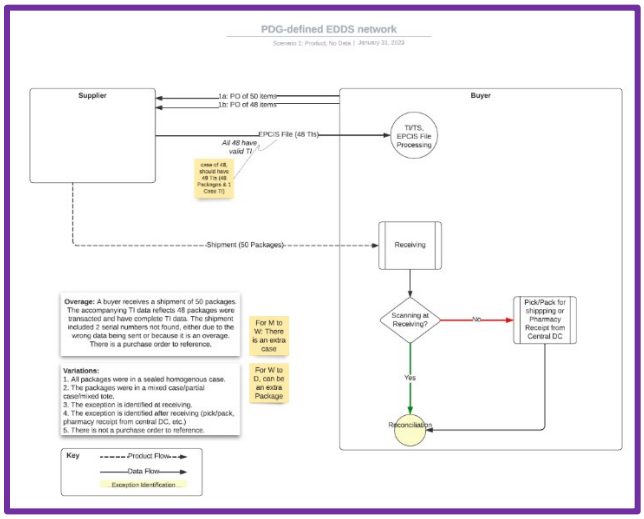
The use of photos in understanding an exception was also identified repeatedly as a point of discussion, but it was decided that alignment will occur between trading partners as part of their commercial relationships.

Exception Scenarios and Variations

Product, No Data

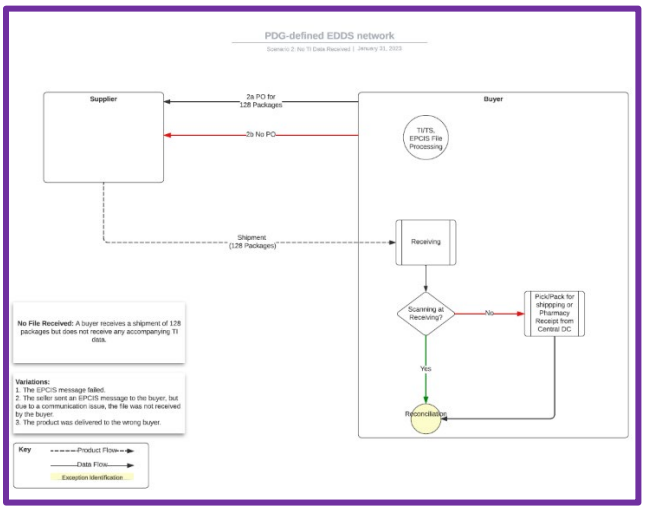
SCENARIO 1: OVERAGE

A buyer orders 46 packages but receives a shipment of 48 packages. The accompanying TI data reflects 46 packages were transacted and have complete TI data. The shipment included two serial numbers not found, either due to the wrong data being sent or because it is an overage.



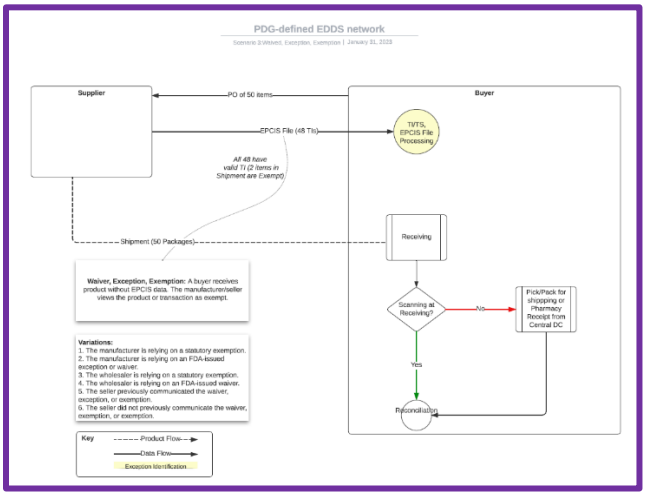
SCENRARIO 2: NO FILE RECEIVED

A buyer receives a shipment of 48 packages but does not receive any of the accompanying TI data.



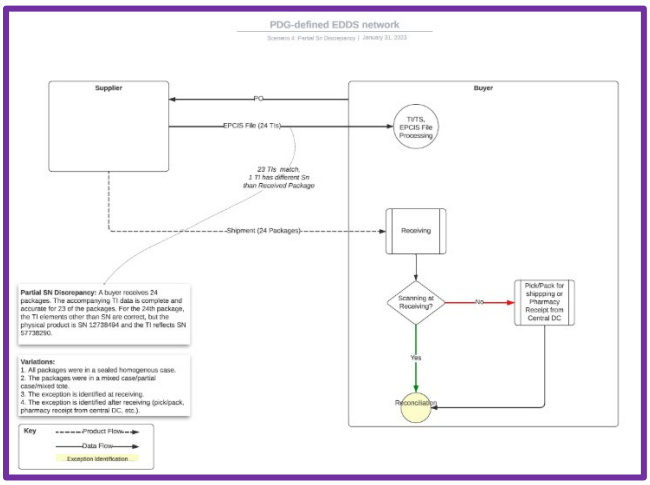
SCENARIO 3: WAVER, EXCEPTION, EXEMPTION

A buyer receives product without EPCIS data. The manufacturer/seller views the product or transaction as exempt.



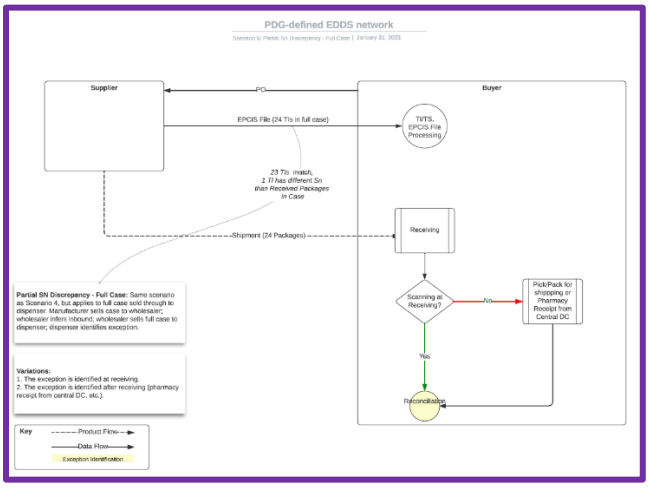
SCENARIO 4: PARTIAL SERIAL NUMBER DISCREPANCY

A buyer receives 24 packages. The accompanying TI data is complete and accurate for 23 of the packages. For the 24th package, the TI elements other than SN are correct, but the physical product is SN 12738494 and the TI reflects SN 57738290.



SCENARIO 5: PARTIAL SERIAL NUMBER DISCREPANCY – FULL CASE

A manufacturer sells a case to a wholesale distributor. The wholesale distributor relies on inference for the inbound and sells the full case to a dispenser. The dispenser identifies that the TI data for one package within the case has an incorrect serial number. The physical product is SN 12738494 and the TI reflects SN 57738290.



Product, No Data: Overall Takeaways

- Identifying the Exception
    - The robustness of a receiving process will ultimately impact later decisions about whether an exception received after receiving can be confidently treated as non-suspect/legitimate product. Quantity checks are one important part of such receiving processes.

- The later in the distribution process (especially the longer since a case was opened), the more difficult it is to understand whether the exception reflects a suspect product or a legitimate product.
- The HDA New Product Form is a good mechanism to convey a product is exempt and also the time period and context of the exemption.
- Template to standardize the information to be shared would be valuable (UUID, 4 PIs, receipt information, etc.)

- **Understanding the Exception**
  - Stakeholders should prepare for the potential volume exceptions and how that will impact staffing, quarantine availability, etc.
  - Collaboration and coordination between trading partners is essential.
  - There is an important distinction between exceptions that can be definitively understood and those that cannot.
    - *E.g.*, If the file fails because the GTIN was not in the recipient's master data, the cause of the file failure—and therefore, the legitimacy of the product—may be definitively determined.
    - *E.g.*, If an exception was, in actuality, caused by a picking error, it may not be possible to definitively determine the cause of that individual exception later in the distribution process.
  - Stakeholders should be educated on the impact of whether VRS data is upload at production versus shipment.

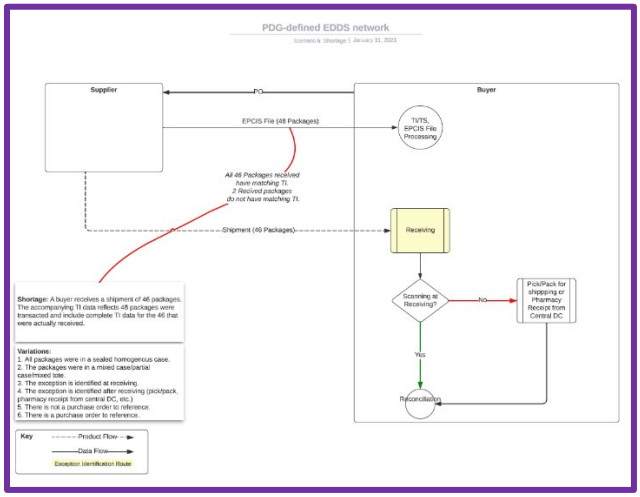
- **Resolving the Exception:**
  - Understanding when/whether a change of ownership has occurred is an important factor in understanding the exception and what resolutions are available.
  - Best Practice: Which date is to be used for supplemental shipment? (Date of physical shipment, date of exception, transaction date, etc.)
  - Existing GS1 standards generally support the resolution process, including the standards for Error Declaration, Void Shipment, and No Ship Events.
  - Dispensers face particularly difficult circumstances when they have limited inventory, and exception will take days to resolve, and a patient needs a medication for which all factors other than the TI exception suggest is legitimate product. These decisions will be based on numerous factors:
    - Quality relationship between a Seller and a Buyer
    - Quality agreements

- Ability to physically verify
- Need of supply
- Historical performance
- Etc.

Data, No Product

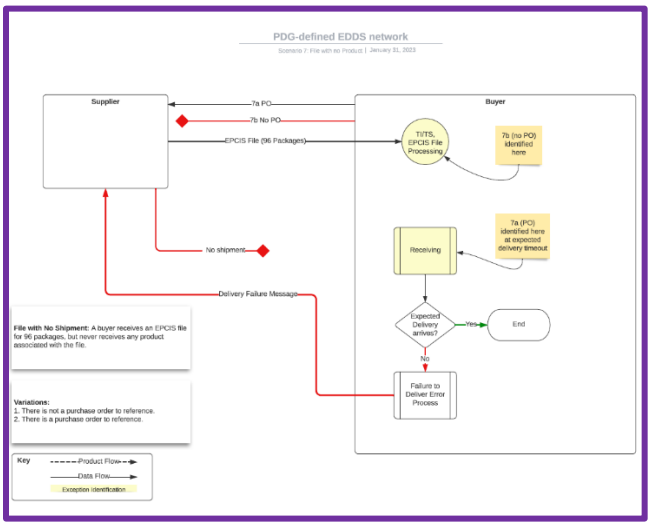
SCENARIO 6: SHORTAGE

A buyer receives a shipment of 46 packages. The accompanying TI data reflects 48 packages were transacted and include complete TI data for the 46 packages actually received.



SCENARIO 7: FILE WITH NO SHIPMENT

A buyer receives TI data for 96 packages but never receives any product associated with the file.



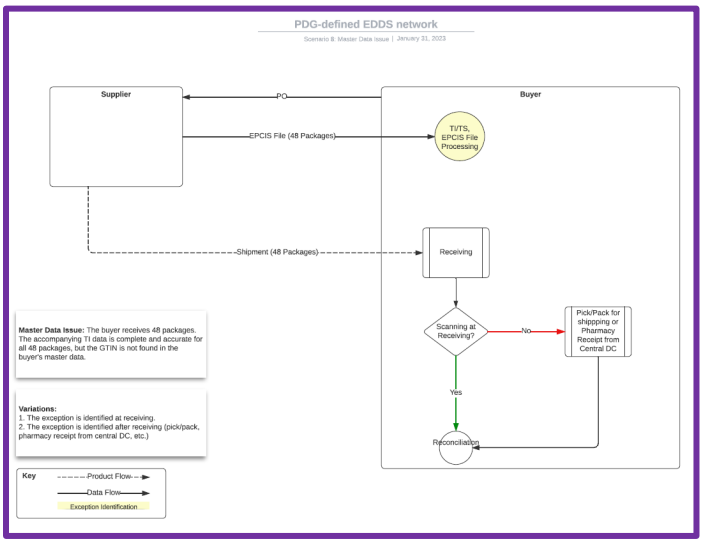
Data, No Product: Overall Takeaways

- Shortages and other "data, no product" exceptions are often much more difficult to detect than "product, no data" once they pass the receiving process. "Product, no data" exceptions are most often found after receiving through outbound reconciliation processes, and there in "data, no product" situations, there is no product to trigger that reconciliation.
- Data that reflect product being received by not shipped for very long periods of time can be identified, but when managing and handling large volumes of product, it is very difficult to confirm the product is *not* in inventory.

Data Issue

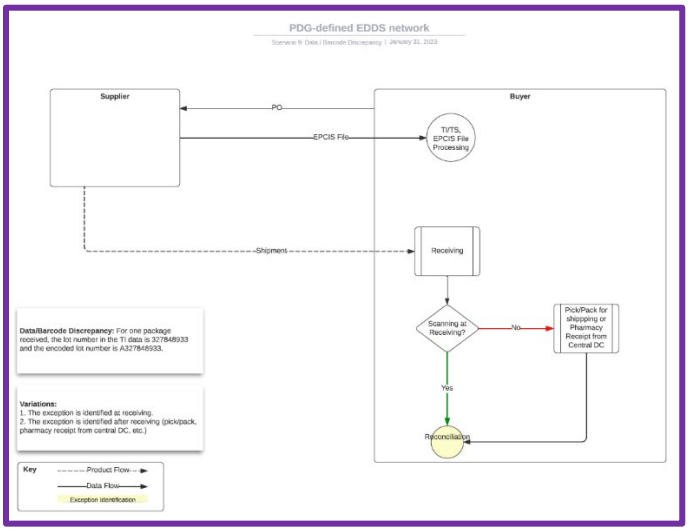
SCENARIO 8: MASTER DATA ISSUE

The buyer receives 48 packages. The accompanying TI data is complete and accurate for all 48 packages, but the GTIN is not found in the buyer's master data.



SCENARIO 9: DATA/BARCODE DISCREPANCY

The lot number in the TI data is 327848933 and the encoded lot number is A327848933.



Data, No Product: Overall Takeaways

- Certain elements of TI (core interoperability data) are essential to interoperability and must be standardized.
- GS1 US will evaluate the role of GDSN for master data management of trading partners.
- Supplemental/incremental TI is an important mechanism to resolve exceptions. A second TI file can trigger problematic duplicates.

Resolutions

As part of the scenario simulations, participants were tasked with resolving the misalignment exception to the extent possible. Participants fully recognized that, in practice resolution of misalignment exceptions will be a business decision based on circumstances related to specific instances of each misalignment exceptions; but participants were encouraged to work toward a hypothetical solution as part of the exercise. Most importantly, any resolution to a misalignment exception must remain in compliance with the DSCSA and all other relevant laws and regulations.

Over the course of the Workshop, participants identified a limited number of possible resolutions that trading partners could employ. The DSCSA requires trading partners to quarantine and investigate suspect product.[6] However, participants at the Workshop agreed and emphasized that a misalignment exception is not necessarily ground for declaring a product suspect. Some misalignment exceptions, through the course of inquiry, may rise to the level of suspect product, but that is expected to a very small portion of the misalignment exceptions that occur.

Below is a description of each potential resolution and what factors should be taken into account when employing each.

Return the Product

One simple solution many trading partners employed during the workshop was to return the extra, or unknown product to the trading partner from which it received the product.

Factors to Consider:

- Can the selling trading partner actually receive the product back from the purchasing company? There may be no formal transaction to tie receipt of the product to.
- Does the selling trading partner want the product back?
- Does the purchasing company want the product? It is possible the purchasing company may want to keep the product and purchase it.
- Do you know which trading partner actually sent the product to the purchasing company?
- How confident are you that the product is not a suspect product based on your company's analysis?
- If the product is returned to a wholesaler, they need a code to tie it to a specific shipment error.

Differing perspectives

[6] § 582(b)(4)(A)(i)(I).

- Some trading partners will have a higher risk tolerance than others when it comes to wanting to keep extra or product for when it cannot be definitively determined that a misalignment was caused by a data error.

Issue New or Supplemental TI

Issuing new or supplemental TI is one solution available to the selling trading partner. If product has been sent without TI or incomplete TI, the seller may want to issue new or supplemental TI corresponding to the product that lacked complete TI.

Factors to Consider:

- What will be provided to the purchasing company so that the TI data is complete, and how is that connected to the initial TI, if needed?
- Documentation of why product was retained is critical if new TI will be provided.

Differing Perspectives

- It may be practically difficult to generate and provide supplemental TI and there is sometimes not enough information to do so, or the resources needed to do so may outweigh the value of the product.

Destruction of the Product

In some circumstances, a trading partner may receive a product and determine it cannot return it to the selling trading partner, receive new data, or use the product in some other way. In this case, the trading partner may have to destroy the product rather than allow it to remain in the pharmaceutical supply chain.

Factors to Consider:

- Can the selling trading receive the product back from your company? There may be no formal transaction to tie receipt of the product to, or the product may not be able to be returned safely to the selling trading partner.
- How long has your company been in possession of the product?

Differing Perspectives:

- Some trading partners will have a higher risk tolerance than others when it comes to wanting to destroy extra, or unknown product, versus others.

The Role of Documentation

Documentation is a critical aspect of solving problems that arise from exceptions. Often a lack of documentation or incorrect documentation is what causes an exception to arise in the first place.

Factors to Consider:

- What document tracing techniques and technologies does your company emphasize?
- How is documentation used to determine exceptions and errors and how is documentation used to create/inform potential solutions?

Differing Perspectives:

- Some trading partners may value certain forms of documentation over others. For example, manufacturers expressed greater interest in photo verification than wholesalers and distributors.

The Role of Verification

Participants at the workshop discussed whether verification should be part of the buyer's process when they identify an exception. They also discussed whether verification can be used to overcome a misalignment exception in the data.

Factors to Consider:

- There should be general discretion applied to whether the verification is needed and will satisfy the ultimate need of dispensing the product.
- There is likely a greater need for verification among dispensers.
- Some parts of the dispensing community do not fully understand what verification means. Information on the purpose of verifications should be shared with dispensers.

Differing Perspectives:

- Some trading partners may see the role of verification as less important than others, especially if they are not as aware of how to conduct product verification.

Follow-Up Discussion:

PDG was tasked with further discussing the role of verification in the process of understanding an exception and whether verification can be used to "overcome" and exception. The PDG Verification Work Group discussed these issues further and recognized:

- Verification is not a mandatory step in a company's "understand" process. Verification is a tool available to each trading partner, and whether and when a trading partner utilizes that tool as part of its "understand" process is a business decision that will often be made on a fact-specific basis.

- Each trading partner will ultimately make its own business decision as to whether it will continue to distribute product that it determines to be legitimate (*i.e.*, not suspect or illegitimate). Verification may be one valuable input to that business decision, but it will be a business decision based on multiple factors.

The Role of Photographs

Many participants at the exception workshop expressed interest in some type of photo verification process. Photos would allow the selling trading partners more information to determine exactly what has gone wrong and what exception the product issue should fall into. Conversely, photos are difficult to incorporate into systems and are difficult to manage in large volumes.

Factors to Consider:

- May not be a routine or standard solution for every trading partner to consider.
- Manufacturers often need pictures to determine what has caused the exception to occur.
- Taking photos for every exception would be difficult for the workflow of both wholesalers and dispensers.

Differing Perspectives:

- Workshop participants determined the consensus view was to use photos when requested, but there are differing perspectives as to how often photo requests should be made and what volumes are reasonable.

Conclusion

Throughout the Workshop, industry participants demonstrated a commitment to working collaboratively to resolve anticipated data exception challenges. This level of collaboration will be necessary once the final DSCSA deadline arrives on November 27, 2023. While the Workshop identified areas of continued work, the members of PDG, HDA, GS1 US, and industry participants across all sectors will continue to discuss, explore, and respond to the various challenges that occurring while preparing to successfully implement all requirements of the DSCSA.

Appendix A: Participants

Government Representatives

Connie Jung, FDA
Abha Kundi, FDA

Manufacturers

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Nirmal Annamreddy, Genentech
Harini Sundar, Gilead Sciences
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Lee Murtagh, Hikma Pharmaceuticals
Manish Garg, Hikma Pharmaceuticals
April Sese, Johnson & Johnson
Sharon Webster, Novartis/Sandoz
Cathy Barbic, Novo Nordisk
Mike Mazur, Pfizer
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Murali Kandulapati, Viatris

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Kelly Lacy, ABC
Maryann Nelson, Cardinal Health
Liberty Dewey, Cardinal Health
Shela Trinidad, Hercules Pharmaceuticals
Pam Forster, Inmar
Bruce Harold, KeySource Acquisition
Scott Mooney, McKesson
Matthew Price, Medline Industries
Vanessa Moore, R&S Northeast
Jake Beck, Reliance Wholesale
Julie Malone, Value Drug Company
Craig Little, Value Drug Company

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TJ Garrigan, CVS Health
Chris Chandler, FMOLHS
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Tony Newberg, Publix Super Markets
Jessica Nix, UNC Health
Max Peoples, Uptown Pharmacy
Melissa Wilkins, VA
David G. Brown, Walgreens
Melva Chavoya, Walgreens

Technology & Solution Providers

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Christopher Stickel, Excellis Health Solutions
Gary Lerner, Gateway Checker
Feliz Malanpitan, KPMG
Ben Taylor, LedgerDomain
Riya Cao, LSPedia
Feliz Malapitan, KPMG
Lloyd Mager, Med
Mark Karhoff, NABP
Anil Suresh, SAP
Steve Tallent, Systech
Elizabeth Waldorf, TraceLink
Greg Makin, Two Labs Pharma Services

Product, No Data: Case Example #1 – Overage

A buyer orders 48 packages but receives a shipment of 50 packages. The accompanying TI data reflects 48 packages were transacted and have complete TI data. The shipment included 2 serial numbers not found, either due to the wrong data being sent or because it is an overage.

Discussion Variations

Table 1 & 2: The transaction was between a manufacturer and a wholesaler. All packages were in a sealed homogenous case [case SGTIN], and the exception was identified at receiving at the wholesaler at the time the case was opened. The two serial numbers not found were [SN] and [SN]. There is a PO to reference [PO#].

Table 3 & 4: The transaction was between a manufacturer and a wholesaler. All packages were in a sealed homogenous case [case SGTIN], and the exception was identified later in the process after the case was opened and the packages were placed into inventory. The two serial numbers not found were [SN] and [SN]. There is a PO to reference [PO#].

Table 5 & 6: The transaction was between a manufacturer and a wholesaler. All packages were in a mixed/non-homogenous case, and the exception was identified at receiving at the wholesaler. The two serial numbers not found were [SN] and [SN]. There is a PO to reference [PO#].

Table 7 & 8: The transaction was between a wholesaler and a dispenser. All packages were in a mixed/non-homogenous case, and the exception was identified at receiving at the dispenser. The two serial numbers not found were [SN] and [SN]. There is a PO to reference [PO#].

Table 9: The transaction was between a wholesaler and a dispenser. All packages were in a mixed/non-homogenous case, and the exception was identified later in the process after the mixed case was opened and put into inventory at receiving. The two serial numbers not found were [SN] and [SN]. There is a PO to reference [PO#].

Applicable HDA Scenarios

HDA Scenario 3: A Buyer 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 Buyer's system will indicate an error at receiving.
- If the product was physically scanned, it will then be quarantined and the Buyer will work with the Seller on the missing data.

- The Buyer will monitor daily reconciliation reports to know when the data have been received and the product can be put into saleable inventory.

Buyer Action: The Buyer's system will notify upon receipt that there is an error, and the product will be quarantined. The Buyer will notify the Seller 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 Buyer will set up a process adjacent to receiving to collect product data. The Buyer will email the Seller with those data and information either in the body of the email or in a file attachment, which will include:

- A standard subject line: Buyer + Seller + UUID + Issue (No EPCIS data).
- The body of the email or attachment should contain as much information as Buyer can provide, such as:
    - UUID (any unique identifier of Buyer'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 Buyer 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 Seller, then the Buyer will follow its relevant SOPs.

Seller Action: The Seller 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 Seller capability and policy.

The Seller will send the recreated TI (commission, aggregation and ship events for missing serial numbers) via EPCIS to the Buyer to accurately reflect what was sold and shipped to the Buyer 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 is resent, the file will fail.

Additionally, if it takes several days to reconcile and send the TI, the Buyer 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 Seller will need to reference the original PO in the new EPCIS file with the missing serial numbers. In some instances, Sellers 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 Seller should confirm that the serialized data was not already provided to another Buyer. If so, the Seller 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 Buyer.

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

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

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

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

- A standard subject line: Buyer + Seller + UUID + Issue (No EPCIS data).
- The body of the email or attachment should contain as much information as the Buyer 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 Seller, then the Buyer will follow its relevant SOPs.

Seller Action: The Seller will conduct an internal investigation and resend or request return of the overage product.

The Seller 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 Seller should confirm that the serialized data was not already provided to another Buyer. If so, the Seller 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 Buyer.

Product, No Data: Case Example #2 – No File Received

A buyer receives a shipment of 128 packages but does not receive any of the accompanying TI data.

Discussion Variations

Table 1 & 2: The transaction was between a manufacturer and a wholesaler. All packages were in a sealed homogenous case [case SGTIN], and the exception was identified at receiving at the wholesaler. There is a PO to reference [PO#]. The manufacturer's system indicates an EPCIS message for the case was sent to the wholesaler, but the wholesaler never received an EPCIS message for the case.

Table 3 & 4: The transaction was between a manufacturer and a wholesaler. All packages were in a sealed homogenous case [case SGTIN], and the exception was identified at receiving at the wholesaler. There is not a PO to reference, nor any other indication the product was ordered by the wholesaler.

Table 5 & 6: The transaction was between a wholesaler and a dispenser. All packages were in a sealed homogenous case [case SGTIN], and the exception was identified at receiving at the dispenser's central warehouse. There is a PO to reference [PO#]. The wholesaler's system indicates an EPCIS message for the case was sent to the dispenser, but the dispenser never received an EPCIS message for the case.

Table 7 & 8: The transaction was between a wholesaler and a dispenser. All packages were in a sealed homogenous case [case SGTIN], and the exception was identified at receiving at the dispenser's central warehouse. There is not a PO to reference, nor any other indication the product was ordered by the dispenser.

Table 9: The transaction was between a manufacturer and a dispenser. All packages were in a sealed homogenous case [case SGTIN], and the exception was identified at receiving at the dispenser's central warehouse. There is a PO to reference [PO#]. The manufacturer's system indicates an EPCIS message for the case was sent to the dispenser, but the dispenser never received an EPCIS message for the case.

Applicable HDA Scenarios

HDA Scenario 1: A Seller sends an EPCIS file for a shipment, but there was a communication issue, and the file was not received by the buyer.

- A buyer will send a message that it received product and no corresponding data.
- A seller will resend the EPCIS file.
- Note: Data senders should turn on messaging disposition notifications (MDNs). If a company is missing a file, it should look at MDNs first to check status of message files.

Buyer Action: A buyer will conduct internal checks to confirm the buyer's system is not "down," then email the Seller that it received product but not the corresponding EPCIS file for that shipment. The buyer will attempt to provide information on the shipment (e.g., PO, delivery number, SSCC, or a serial number from the delivery) to assist the Seller in identifying the shipment.

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

- A standard subject line: Buyer + Seller + UUID + Issue (No EPCIS data).
- The body of the email or attachment should contain as much information as the buyer can provide, such as:
    - UUID (any unique identifier of buyer'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 Seller, then the buyer will follow its relevant SOPs.

Seller Action: The Seller may know that there was a connection issue due to their system notifying them and resend the file proactively. If a wholesaler notifies a Seller after receiving product without a corresponding EPCIS file, the Seller 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.

HDA Scenario 6: A delivery was made to the wrong buyer.

- The buyer receiving the product will contract the Seller.
- The seller coordinates with the logistics provider/carrier to take the product to the correct location.

Buyer Action: The buyer will reject the shipment and reach out to the seller by email to let them know a delivery was made to the wrong buyer. They will share the PO that is listed on the manifest/pallet label with the seller.

Seller Action: The Seller will work with their logistics provider/carrier to reroute the shipment to the correct wholesaler. In some instances, the Seller may route it for destruction if they cannot ensure product has been stored/handled appropriately.

The Seller should also confirm that the data associated with the rerouted delivery was sent to the correct buyer.

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

Product, No Data: Case Example #3 – Waiver, Exception, Exemption

A buyer receives product without EPCIS data. The manufacturer/seller views the product or transaction as exempt.

Discussion Variations

Table 1 & 2: The transaction was between a manufacturer and a wholesaler. The transaction included 3 cases of Product A [case sGTIN], which was accompanied by complete and accurate TI data and 1 case of Product B [case sGTIN], which had no accompanying TI data. The manufacturer previously obtained an exception for Product B because the package was too small to accommodate a product identifier, but the wholesaler has no prior knowledge of that exception. The exception was identified at receiving at the wholesaler. There is a PO to reference [PO#].

Table 3 & 4: The transaction was between a wholesaler and a retail dispenser. The transaction included 6 packages of Product A [GTIN], which was accompanied by complete and accurate TI data and 4 packages of Product B [GTIN], which had no accompanying TI data. The manufacturer previously obtained an exception for Product B because the package was too small to accommodate a product

identifier, but the dispenser has no prior knowledge of that exception. The exception was identified at receiving at the retail pharmacy. There is a PO to reference [PO#].

Table 5 & 6: The transaction was between a manufacturer and a wholesaler. The transaction included 2 cases of Drug A [case sGTINs], which the manufacturer considers to be an imaging drug (and therefore does not meet the statutory definition of a product). There is no accompanying TI data. This is the first time the parties have transacted Drug A, and the manufacturer's classification of Drug A as an imaging drug was not previously communicated to the wholesaler. The exception was identified at receiving at the wholesaler. There is a PO to reference [PO#].

Table 7, 8, & 9: The transaction was between a wholesaler and a hospital pharmacy. The transaction included 2 cases of Drug A [case sGTINs], which the manufacturer considers to be an imaging drug (and therefore does not meet the statutory definition of a product). There is no accompanying TI data. This is the first time the parties have transacted Drug A, and the manufacturer's classification of Drug A as an imaging drug was not previously communicated to the pharmacy by the wholesaler. The exception was identified at receiving at the hospital pharmacy. There is a PO to reference [PO#].

Product, No Data: Case Example #4 – Partial SN Discrepancy

A buyer receives 24 packages. The accompanying TI data is complete and accurate for 23 of the packages. For the 24th package, the TI elements other than SN are correct, but the physical product is SN 12738494 and the TI reflects SN 57738290.

Discussion Variations

Table 1 & 2: The transaction was between a manufacturer and a wholesaler. All packages were in a single sealed homogenous case [case SGTIN], and the exception was identified at receiving at the wholesaler at the time the case was opened. The accompanying TI data is complete and accurate for 23 of the packages. For the 24th package, the TI elements other than SN are correct, but the physical product is SN [12738494] and the TI reflects SN [57738290]. There is a PO to reference [PO#].

Table 3 & 4: The transaction was between a manufacturer and a wholesaler. All packages were in a single sealed homogenous case [case SGTIN]. The wholesaler relies on inference at receiving and the exception is identified in the picking process several days after the case was opened. The accompanying TI data was complete and accurate for 23 of the packages. For the 24th package, the TI elements other than SN were correct, but the physical product is SN [12738494] and the TI reflects SN [57738290]. There is a PO to reference [PO#].

Table 5 & 6: The transaction was between a wholesaler and a retail pharmacy. All packages were in a mixed tote, and the exception was identified at receiving at the pharmacy at the time the tote was opened. The accompanying TI data is complete and accurate for 23 of the packages. For the 24th

package, the TI elements other than SN are correct, but the physical product is SN [12738494] and the TI reflects SN [57738290]. There is a PO to reference [PO#].

Table 7 & 8: The transaction was between a wholesaler and a retail pharmacy. All packages were in a mixed tote, and the exception was identified several days after receiving at the pharmacy. The accompanying TI data was complete and accurate for 23 of the packages. For the 24th package, the TI elements other than SN were correct, but the physical product is SN [12738494] and the TI reflects SN [57738290]. There is a PO to reference [PO#].

Table 9: The transaction was between a manufacturer and a wholesaler. All packages were in a partial/non-sealed case, and the exception was identified at receiving at the wholesaler at the time the case was opened. The accompanying TI data is complete and accurate for 23 of the packages. For the 24th package, the TI elements other than SN are correct, but the physical product is SN [12738494] and the TI reflects SN [57738290]. There is a PO to reference [PO#].

Applicable HDA Scenarios

HDA Scenario 2: A buyer receives a product, but the serial number is not found within the system, and there is no purchase order or delivery number to reference

- The buyer'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 seller.
- The buyer will work with the seller on the "surprise" shipment and resolution steps.

Buyer Action: The buyer will notify the seller 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 buyer would refuse the shipment, or create a PO and receive and quarantine the product until EPCIS data could be sent by the seller. It is more likely that a buyer would keep a smaller mis-shipment versus a larger mis-shipment.

In either instance, the buyer could provide to the seller information to help the seller 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 seller, then the buyer will follow its relevant SOPs.

Seller Action: The seller will need to determine if this was a mis-shipment and if the product needs to be returned or sent to another location. The seller would open an investigation. If the buyer does not refuse the shipment, the seller will request confirmation of what serial numbers/product identifiers the buyer has in its possession to send corresponding data. As part of its investigation, the seller will need to confirm that the serialized data was not already provided to another buyer. If so, the seller will have to reconcile the data within their system before providing it to the buyer.

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

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

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

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

- A standard subject line: Buyer + Seller + UUID + Issue (No EPCIS Data)
- The body of the email or file attached should contain as much information as the buyer can provide, such as:
    - Ship-to GLN;
    - Ship-to address;
    - GTIN;
    - SN;
    - LOT;
    - Scanned expiry; and
    - Trade item description.

The buyer 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 buyer 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 seller, then the buyer will follow its relevant SOPs.

Seller Action: The seller 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 seller could request the product back from the buyer or provide the TI for the product to the buyer.

If the seller elects to provide TI to the buyer, it will send recreated TI for that specific product identifier, including TS and a commissioning statement via EPCIS to the buyer to accurately reflect what was sold and shipped to the buyer using the date the exception was discovered as the transaction date. Note that this will likely be a manual process at the seller 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.

Product, No Data: Case Example #5 – Partial SN Discrepancy – Full Case

A manufacturer sells a case to a wholesale distributor. The wholesale distributor relies on inference for the inbound and sells the full case to a dispenser. The dispenser identifies that the TI data for one package within the case has an incorrect serial number. The physical product is SN 12738494 and the TI reflects SN 57738290.

Discussion Variations

Table 1, 2, 3, 4, & 5: Transactions of a full sealed homogenous case occurred between a manufacturer and a wholesaler and between the wholesaler and a chain pharmacy. All packages were in a single sealed homogenous case [case SGTIN]. The wholesaler relies on inference at receiving and shipping and sells the full sealed case to the chain pharmacy. The chain pharmacy identifies the exception at receiving at the time the case is opened. For both transactions, the accompanying TI data is complete and accurate for 23 of the packages. For the 24th package, the TI elements other than SN are correct, but the physical product is SN [12738494] and the TI reflects SN [57738290]. There is a PO to reference for both transactions [PO#].

Table 6, 7, 8, & 9: Transactions of a full sealed homogenous case occurred between a manufacturer and a wholesaler and between the wholesaler and a chain pharmacy. All packages were in a single sealed homogenous case [case SGTIN]. The wholesaler relies on inference at receiving and shipping and sells the full sealed case to the chain pharmacy. The chain pharmacy relies on inference at receiving and identifies the exception during distribution to a retail location several days after the case is opened. For both transactions, the accompanying TI data is complete and accurate for 23 of the packages. For the 24th package, the TI elements other than SN are correct, but the physical product is SN [12738494] and the TI reflects SN [57738290]. There is a PO to reference for both transactions [PO#].

Applicable HDA Scenarios

HDA Scenario 2: A buyer receives a product, but the serial number is not found within the system, and there is no purchase order or delivery number to reference

- The buyer'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 seller.
- The buyer will work with the seller on the "surprise" shipment and resolution steps.

Buyer Action: The buyer will notify the seller 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 buyer would refuse the shipment, or create a PO and receive and quarantine the product until EPCIS data could be sent by the seller. It is more likely that a buyer would keep a smaller mis-shipment versus a larger mis-shipment.

In either instance, the buyer could provide to the seller information to help the seller 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 seller, then the buyer will follow its relevant SOPs.

Seller Action: The seller will need to determine if this was a mis-shipment and if the product needs to be returned or sent to another location. The seller would open an investigation. If the buyer does not refuse the shipment, the seller will request confirmation of what serial numbers/product identifiers the buyer has in its possession to send corresponding data. As part of its investigation, the seller will need to confirm that the serialized data was not already provided to another buyer. If so, the seller will have to reconcile the data within their system before providing it to the buyer.

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

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

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

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

- A standard subject line: Buyer + Seller + UUID + Issue (No EPCIS Data)
- The body of the email or file attached should contain as much information as the buyer can provide, such as:
    - Ship-to GLN;
    - Ship-to address;
    - GTIN;
    - SN;
    - LOT;
    - Scanned expiry; and
    - Trade item description.

The buyer 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 buyer 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 seller, then the buyer will follow its relevant SOPs.

Seller Action: The seller 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 seller could request the product back from the buyer or provide the TI for the product to the buyer.

If the seller elects to provide TI to the buyer, it will send recreated TI for that specific product identifier, including TS and a commissioning statement via EPCIS to the buyer to accurately reflect what was sold and shipped to the buyer using the date the exception was discovered as the transaction date. Note that this will likely be a manual process at the seller 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.

Data, No Product: Case Example #6 – Shortage

A buyer receives a shipment of 46 packages. The accompanying TI data reflects 48 packages were transacted and include complete TI data for the 46 packages actually received.

Discussion Variations

Table 1 & 2: The transaction was between a manufacturer and a wholesaler. All packages were in a sealed homogenous case [case SGTIN], and the exception was identified at receiving at the wholesaler at the time the case was opened. The two serial numbers reflected in TI, but not in the physical inventory were [SN] and [SN]. There is a PO to reference [PO#].

Table 3 & 4: The transaction was between a manufacturer and a wholesaler. All packages were in a sealed homogenous case [case SGTIN], and the exception was identified later in the process after the case was opened and the packages were placed into inventory. The two serial numbers reflected in TI, but not in the physical inventory were [SN] and [SN]. There is a PO to reference [PO#].

Table 5 & 6: The transaction was between a manufacturer and a wholesaler. All packages were in a mixed/non-homogenous case, and the exception was identified at receiving at the wholesaler. The two serial numbers reflected in TI, but not in the physical inventory were [SN] and [SN]. There is a PO to reference [PO#].

Table 7 & 8: The transaction was between a wholesaler and a dispenser. All packages were in a mixed/non-homogenous case, and the exception was identified at receiving at the dispenser. The two serial numbers reflected in TI, but not in the physical inventory were [SN] and [SN]. There is a PO to reference [PO#].

Table 9: The transaction was between a wholesaler and a dispenser. All packages were in a mixed/non-homogenous case, and the exception was identified later in the process after the mixed case was opened and put into inventory at receiving. The two serial numbers reflected in TI, but not in the physical inventory were [SN] and [SN]. There is a PO to reference [PO#].

Applicable HDA Scenarios

HDA Scenario 1: A shortage occurs and the seller send data that includes product that buyer did not receive.

- The buyer will discover that it has been sent data but is missing product via internal reconciliation processes.
- The buyer will notify the seller promptly upon learning that they have data, no product. The meaning of "promptly" will be determined by trading partners in their commercial arrangements.

Buyer Action: If a buyer process allows them to determine at receiving that data have been received without product, a buyer will share the discrepancy at that time with the seller. 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. Consequently, having data but no product will likely be discovered later.

If a buyer, 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 seller. The primary way a data overage will be discovered is because it will be realized as a product overage correction reported elsewhere to the seller. A buyer will notify a seller promptly. What promptly means will be determined by trading partners in their commercial arrangements.

The buyer will notify a seller promptly (with each company determining what promptly means) upon learning that they data, but no product.

Seller Action: A seller will investigate and do a data correction on their side. It is likely that a seller 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.

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

Data, No Product: Case Example #7 – File with No Shipment

A buyer receives TI data for 96 packages but never receives any product associated with the file.

Discussion Variations

Table 1 & 2: The data transaction was between a manufacturer and a wholesaler. TI for the 96 packages was received as an EPCIS message. There is a PO to reference [PO#].

Table 3 & 4: The data transaction was between a manufacturer and a wholesaler. TI for the 96 packages was received as an EPCIS message. There is not a PO to reference, nor any other indication the product was ordered by the wholesaler.

Table 5 & 6: The data transaction was between a wholesaler and a dispenser. TI for the 96 packages was received as an EPCIS message. There is a PO to reference [PO#].

Table 7 & 8: The data transaction was between a wholesaler and a dispenser. TI for the 96 packages was made available to the dispenser via the wholesaler's web portal. There is not a PO to reference, nor any other indication the product was ordered by the dispenser.

Table 9: The data transaction was between a manufacturer and a dispenser. TI for the 96 packages was received as an EPCIS message. There is not a PO to reference, nor any other indication the product was ordered by the dispenser.

Applicable HDA Scenarios

HDA Scenario 4: A seller sends data for a shipment that is received by a buyer, 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 seller.
- With the buyer's assistance in the investigation, the seller should be able to identify which product and, if applicable, case identifiers are missing. If the buyer received part, but not all, of a missing shipment, the buyer would be able to share, by identifier, the product(s)/case(s) that were received.
- The seller and buyer will follow their relevant SOPs and determine any legal and compliance obligations such as whether to submit a Form 3911 notification to FDA.

Buyer Action: If the buyer receives only a partial shipment or no shipment at all, it will notify the seller. The buyer will work with the seller on the seller's investigation and will provide the serial numbers of the product that it has received to help the seller 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 buyer may wait for up to 10 business days before it notifies the seller that it appears the shipment was lost or stolen.

If the product is determined to be suspect product after communication with the seller, then the buyer will follow its relevant SOPs.

Seller Action: After receiving notification from the buyer that it believes all or part of a shipment is lost or stolen, the seller will conduct an investigation. If the investigation confirms the product was stolen, the seller will proceed per its relevant SOPs. In the case that a partial shipment is missing, the buyer will provide the identifiers of the products it did receive so a seller can determine what is missing.

The seller 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 seller 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.

HDA 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 seller, 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 buyer 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.

Buyer Action: If the files post successfully, the buyer receives the shipment against the data it received from the seller and resolves the PO and executes an intracompany transfer. The buyer will follow its existing procedures for notification to a seller.

Seller Action: The seller works with the carrier and buyer 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 seller).

If product is requested to be rerouted to another of the buyer's distribution centers, some sellers may choose to have the product destroyed because they cannot ensure there has not been a temperature excursion or other handling issue.

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

HDA Scenario 6: A delivery was made to the wrong buyer.

- The buyer receiving the product will contact the seller.
- The seller coordinates with the logistics provider/carrier to take it to the correct location.

Buyer Action: The buyer will reject the shipment and reach out to the seller by email to let them know a delivery was made to the wrong buyer. They will share the PO that is listed on the manifest/pallet label with the seller.

Seller Action: The seller will work with their logistics provider/carrier to reroute the shipment to the correct wholesaler. In some instances, the seller may route it for destruction if they cannot ensure product has been stored/handled appropriately.

The seller should also confirm that the data associated with the rerouted delivery was sent to the correct distributor.

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

Data Issue: Case Example #8 – Master Data Issue

The buyer receives 48 packages. The accompanying TI data is complete and accurate for all 48 packages, but the GTIN is not found in the buyer's mater data.

Discussion Variations

Table 1 & 2: The transaction was between a manufacturer and a wholesaler. All packages were in a sealed homogenous case [case sGTIN]. While the manufacturer's TI data is complete and accurate, the EPCIS file failed because the package GTIN was not found in the wholesaler's master data. There is a PO to reference [PO#].

Table 3 & 4: The transaction was between a manufacturer and a wholesaler. All packages were in a sealed homogenous case [case sGTIN]. While the manufacturer's TI data is complete and accurate, the EPCIS file failed because the case GTIN was not found in the wholesaler's master data. There is a PO to reference [PO#].

Table 5 & 6: The transaction was between a wholesaler and a dispenser. The packages were in a mixed case. While the wholesaler's TI data is complete and accurate, the EPCIS file failed because the package GTIN was not found in the dispenser's master data. There is a PO to reference [PO#].

Table 7, 8, & 9: The transaction was between a manufacturer and a dispenser. All packages were in a sealed homogenous case [case sGTIN]. While the manufacturer's TI data is complete and accurate, the file failed because the case GTIN was not found in the dispenser's master data. There is a PO to reference [PO#].

Applicable HDA Scenarios

HDA Scenario 2: The buyer receives the data, but the GTIN is not found in master data.

- A seller sends a distributor an EPCIS file.
- At receiving, the buyer 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 buyer systems are configured.
- The seller will need to update its GTIN master data, send it to the buyer 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 seller 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 seller. If the new GTIN has not been provided, it will ask the seller for updated GTIN(s) and update their master data files so that the seller can reprocess/resend the EPCIS file.

Seller Action: The seller 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 buyer, it also may lead to a file failure.

Compliance/Best Practice Note: Check your seller change process for product packaging changes and new product launches to ensure changes are communicated prior to sending product to a buyer. 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.

Data Issue: Case Example #9 – Data/Barcode Discrepancy

The lot number in the TI data is 327848933 and the encoded lot number is A327848933.

Discussion Variations

Table 1 & 2: The transaction was between a manufacturer and a wholesaler. The lot number in the TI data is 327848933 and the encoded lot number is A327848933. All impacted packages were in a sealed homogenous case [case SGTIN], and the exception was identified at receiving at the wholesaler at the time the case was opened. There is a PO to reference [PO#].

Table 3 & 4: The transaction was between a manufacturer and a wholesaler. The lot number in the TI data is 327848933 and the encoded lot number is A327848933. All impacted packages were in a sealed

homogenous case [case SGTIN], and the exception was identified later in the process after the case was opened and the packages were placed into inventory. There is a PO to reference [PO#].

Table 5 & 6: The transaction was between a manufacturer and a wholesaler. The lot number in the TI data is 327848933 and the encoded lot number is A327848933. All impacted packages were in a mixed/non-homogenous case, and the exception was identified at receiving at the wholesaler. There is a PO to reference [PO#].

Table 7 & 8: The transaction was between a wholesaler and a dispenser. The lot number in the TI data is 327848933 and the encoded lot number is A327848933. All packages impacted were in a mixed/non-homogenous case, and the exception was identified at receiving at the dispenser. There is a PO to reference [PO#].

Table 9: The transaction was between a wholesaler and a dispenser. The lot number in the TI data is 327848933 and the encoded lot number is A327848933. All packages were in a mixed/non-homogenous case, and the exception was identified later in the process after the mixed case was opened and put into inventory at receiving. There is a PO to reference [PO#].

Applicable HDA Scenarios

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

- The buyer returns the product to the seller, and seller quality teams handles according to their internal business processes

Distributor Action: The buyer will notify the seller 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 seller.

Seller Action: If the product is determined to be suspect product after communication with the seller, then the buyer will follow its relevant standard operating procedures (SOPs).

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

Note: If a seller's quality review confirms the discrepancy but the seller opts not to remove the product from the marketplace, for example, in the event of an expiration dating extension, the buyer will record and rely on the seller'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.

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

- The buyer scans a product at receiving, revealing a mismatch between the bar code and the data.
- The buyer will reach out to the seller, sharing the scanned data so that it can investigate.
- The seller 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 buyer discovers on receipt that the batch labeling on a product is incorrect. The buyer will quarantine the product and will reach out to the seller 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 seller what the buyer is "seeing." The seller will need to investigate and respond to the buyer with a determination. Once a determination is made, the issue will either be resolved, or product would be returned to the seller 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 buyer's product integrity or suspect product team.

If the product is determined to be suspect product after communication with the seller, then the buyer will follow its relevant SOPs.

Seller Action: The seller will conduct an internal investigation after the buyer notifies them of the product and data mismatch. Once the investigation is completed, the seller will communicate the determination back to the buyer with instructions. The seller 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-specification.