

Partnership for DSCSA Governance (PDG) Foundational Blueprint for 2023 Interoperability

Chapter 3: DSCSA TI and TS Exchange Functional Design

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Chapter 3: TI and TS Exchange Functional Design

Sec. 581(26) of the FD&C Act defines the transaction information data elements that must be exchanged between trading partners when the ownership of the product is transferred. Chapter 1 (Requirements-Ser-003 to -024) of this Blueprint provides required and recommended formats for these data elements. This chapter represents the functional design and requirements that must be implemented by trading partners and provides alternatives and examples of exchange scenarios.¹

Purpose of the Document

The TI and TS exchange functional designs in this chapter provide detailed information on *how* the TI and TS Exchange components of the PDG-defined EDDS network will function. This document is created based on the high-level requirements for Serialized TI and TS Data Exchange (Chapter 1) and functional requirements, constraints, and recommendations of PDG. Included in this section are detailed functional requirements including use cases, system inputs and outputs, process flows, diagrams, and sample TI Exchange scenarios.

Terminology

| Term/Acronym | Definition | Notes |
|----------------------------|---|-------|
| Core Interoperability Data | Data elements that are key to the transaction and MUST be standardized . | |
| Contextual Data | Data elements that are provided to add context based on and tied to the NDC or GTIN and are primarily provided through other mechanisms such as contracting, product master data alignment, or synchronization. | |

Standards, Specifications, and Guidelines

The following standards, specifications, and guidelines are pivotal to the proper implementation of product serialization and serialized TI and TS Exchange. Specifically, the HDA “Guidelines for Bar Coding in the Pharmaceutical Supply Chain and the GS1 US “Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability” for using GS1 identifiers (GTIN², GLN³, SSCC⁴), barcoding, and use of GS1.

¹ As new systems and process for serialized TI are implemented in the lead-up to November 27, 2023, it is important to recognize that the lot-level requirements, including exchange of TH, continue through Nov 26, 2023. This may result in the operation of parallel systems and process for a period of time, in which case trading partners should take care to clarify which systems and processes are their designated systems and processes for regulatory compliance.

²GTIN: Global Trade Item Number used for identifying products and encodes the NDC (National Drug Code) for pharmaceuticals sold in the US.

³ GLN: Global Location Number used for identifying companies, locations and functional units within companies.

⁴ SSCC: Serial Shipping Container Code used to identify logistics units such as mixed cases, pallets, and totes.

Table 1 - TI and TS Exchange Reference Documents

| Reference Document | Version | Publisher | Notes |
|---|--|--|---|
| Guidelines for Bar Coding in the Pharmaceutical Supply Chain | April 2022 | Healthcare Distribution Alliance (HDA) | Prerequisite to Serialized TI and TS Exchange |
| Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability | Release 1.2, 2016-11-07 Release 1.3, 2022-12-21 | GS1 US | Chapters 3 – 6 are prerequisite to Serialized TI and TS Exchange. Chapters 7,8 and Part III detail EPCIS use for DSCSA TI and TS Exchange |
| Addendum: Diagrams and XML Examples for Serialized Exceptions Processing | Release 1.2, 2016-11-08 Release 1.3, 2022-12-21 | GS1 US | Details on using EPCIS events to resolve exceptions |
| Serialized Exception Flows | Release 1.2, 2016-11-08 Release 1.3, 2022-12-21 | GS1 US | Diagrams matching the above Addendum |
| Exception Handling Guidelines for the DSCSA | April 2022 | Healthcare Distribution Alliance (HDA) | Guidelines for exceptions involving Manufacturers and Wholesalers |
| EPCIS Standard | Release 1.2 Release 1.3, 2022-12-21 | GS1 | |

TI and TS Exchange Functional Design Overview

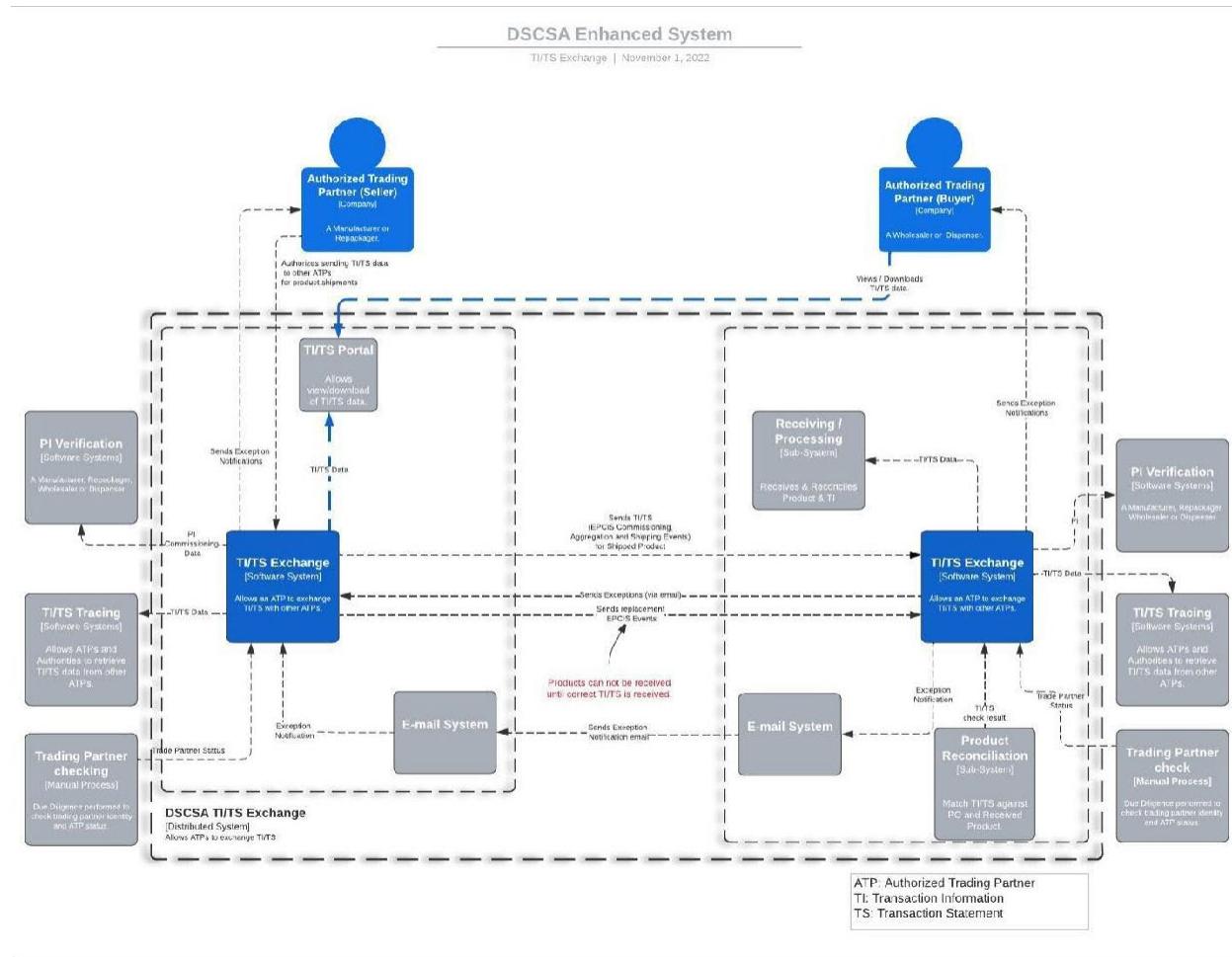


Figure 1 - TI and TS Exchange

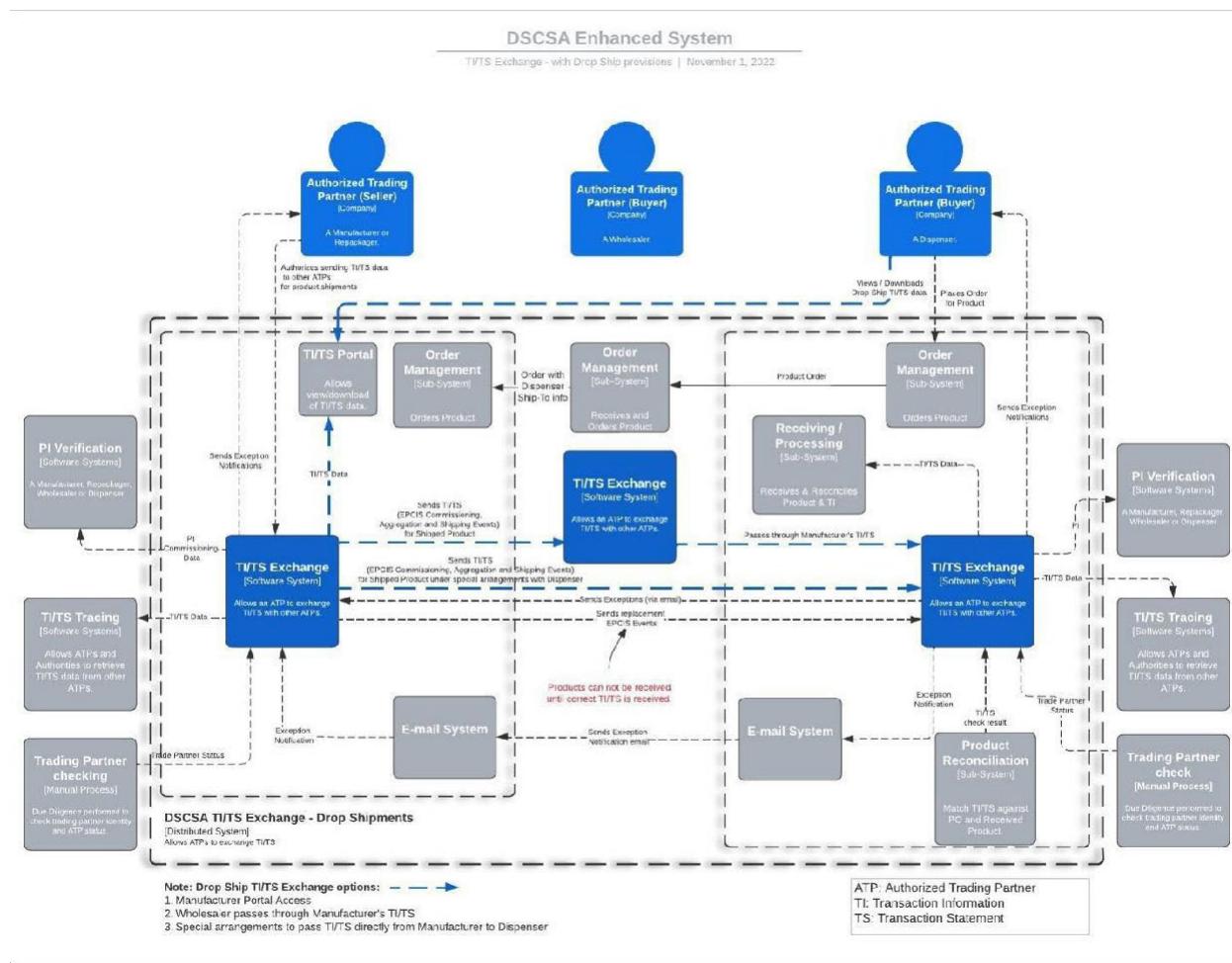


Figure 2 - TI and TS Exchange including Drop Ship Orders

TI and TS Exchange Interactions

TI and TS data is exchanged with, or provided to, customers within an established commercial relationship. That is, we presume both parties have executed their Know Your Customer / Know Your Supplier (KYC/KYS) processes and, for DSCSA purposes, have established each other as being “Authorized” under the DSCSA.

As TI and TS is exchanged between direct trading partners, trading partners are free to make TI and TS data available in any manner that satisfies DSCSA requirements for exchange, retention, and retrieval to support investigations and TI Requests (see Chapter 5: Tracing). However, PDG has established three methods for the exchange of TI and TS within the PDG-defined EDDS network. These methods support trading partners of varying technical capabilities.

Primary or preferred method: Exchange TI and TS using GS1 EPCIS events⁵ (Commissioning, Aggregation, or Packing and Shipping) as specified in the GS1 US [Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability](#). Figures appearing later in this chapter outline TI and TS exchange using EPCIS

⁵ FDA's July 2022 draft guidance on DSCSA Standards for the interoperable Exchange of Information for Traceability specifies EPCIS as the recommended standard for exchange of electronic data associated with the transaction information and transaction statement between trading partners in the supply chain. Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dscsa-standards-interoperable-exchange-information-tracing-certain-human-finished-prescription-drugs?utm_medium=email&utm_source=govdelivery

events in a number of supply chain scenarios. Examples of delivery methods are AS2, email, and portal download.

Alternate method to serve entities not capable of the primary method: Suppliers serving customers that are not capable of receiving EPCIS events may provide TI and TS through portal access. Suppliers provide access to their portal through their individual onboarding process. Customers who choose to access TI and TS data through portals should develop a strategy for collating data from one or more of these portals for investigations and responding to TI Requests (see Chapter 5, Tracing).

Drop-Ship TI and TS arrangements: Certain Dispenser trading partners receiving drop shipments have the capability and prefer to receive all TI and TS data via the preferred method of EPCIS events. These Dispensers will make arrangements with manufacturers that typically drop ship product(s) to the Dispenser to provide TI and TS via EPCIS events. In this case, these trading partner pairs establish electronic means to securely exchange EPCIS events in the same manner that direct trading partners exchange EPCIS events.

TI and TS Exchange Outside of the PDG-Defined EDDS Network

Outside of the PDG-defined EDDS network, trading partners may have special data format, value, and Exchange needs. By special arrangement, trading partner pairs or solution providers and trading partner pairs may agree to exchange TI data in a format different from EPCIS. Trading partners are cautioned to consider their PI Verification and Tracing responsibilities when engaging in interactions outside of the accepted standard format.

TI Data: Core and Contextual Data Elements

Chapter 1 defines the elements of the TI that are required to be exchanged. Formats and values of certain elements are required; formats and values for certain other elements are recommended, but not mandatory. Recognizing that standard formats for some elements are not universally implemented and some elements may be adjusted to meet individual system field size constraints or customer needs⁶. These elements are seen as contextual in TI exchanges and are primarily sourced through other mechanisms such as product master data management. Individual trading partner pairs may make arrangements to exchange additional data elements (ex: Purchase Order Number). The GS1US Guideline for applying EPCIS documents describes how to provide these elements to EPCIS events.

Core Data Elements

The following data elements are considered core to TI data exchange and are expected to maintain their format and values throughout the product life cycle and at each message exchange event.

- NDC
- GTIN
- Serial Number
- Lot Number
- Expiration Date
- GLN⁷
- Date of Transaction
- Date of Shipment

⁶ ex: Wholesale Distributors may add the manufacturer's name or abbreviated name to product names to differentiate generic products.

⁷ The use of GLN is a Functional Requirement for using EPCIS events as specified in the GS1 EPCIS Standard. It is important to ensure that the TI data retention capability preserves GLNs as it is a requirement for tracing.

- Number of Containers⁸

Contextual Data Elements

The following data elements are included in TI as per the DSCSA; however, values or formats may reasonably vary when comparing one TI exchange dataset to another. Party and product master data management processes are the primary mechanisms for exchanging these elements, and they are included in TI to add context and fulfill the requirements in the statute. Reasonable variance (abbreviations, etc.) in the values of these elements generally is not an indicator of a data error.

- Proprietary Business Name
- Street Address⁹
- Drug Name¹⁰
- Strength
- Dosage Form
- Container Size

Preferred Method of Exchanging TI and TS – GS1 EPCIS

PDG recognizes the GS1 US Implementation Guide: Applying GS1 Standards for DSCSA and Traceability as the preferred method for defining and exchanging TI data. The GS1 US Guideline for using EPCIS includes the use of GS1 standard identifiers, barcoding, and the use of the GS1 EPCIS¹¹ standard and GS1 Core Business Vocabulary standard for exchanging serialized TI data. EPCIS specifies event messages for communication of product exchange and has been augmented with necessary data elements to meet DSCSA “chain of ownership requirements.”

Figure 3 maps TI data elements to the minimum set of EPCIS event messages needed to exchange TI. It also maps the industry requirement¹² for sharing aggregation data needed for trading partners to employ inference in their supply chain processes. Inference allows trading partners to rely on packing¹³ information provided by the entity (manufacturer, repackager, wholesaler) responsible for packing homogeneous cases or mixed totes. Both the shipper and receiver rely on aggregation data to understand and record the individual packages in sealed outer containers. Without the use of packing data and inference practices, sealed cases and totes would be required to be opened to scan individual packages at shipping and receiving, thwarting security mechanisms, introducing additional cost, and increasing risk to the packages within.

Inference-based receiving practices indicate that the outermost container is scanned and thereby the receiving event will be recorded for the scanned outermost container of the hierarchy. Additional receiving events will be recorded for the inferred contents of the outermost container. These will enable the capture of what has been physically scanned and what has been inferred¹⁴.

Notes on *Figure 3*:

⁸ When using EPCIS to transfer TI and TS, the Number of containers is a derived element based on the Shipping event and associated Aggregation (Packing) event to calculate the number of saleable items for a case.

⁹ Extends Chapter 1 list of Contextual TI Elements.

¹⁰ Extends Chapter 1 list of Contextual TI Elements. Drug Names may change as the item moves through the supply chain. Some form of the company name is often prefixed to the Drug Name for generic drugs to provide transparency.

¹¹ Electronic Product Code Information Services.

¹² SER-FR-004 and SER-FR-005.

¹³ Manufacturer or Repackager sealed cases and Wholesaler sealed totes.

¹⁴ In the upcoming GS1 US DSCSA Implementation Guideline R1.3, the disposition of completeness inferred is recommended when receiving inferred products.

1. Transaction Statement applies to all the events in the EPCIS document.
2. Number of Containers is a derived field and can be derived from EPCIS Shipping Event and EPCIS Aggregation Event.

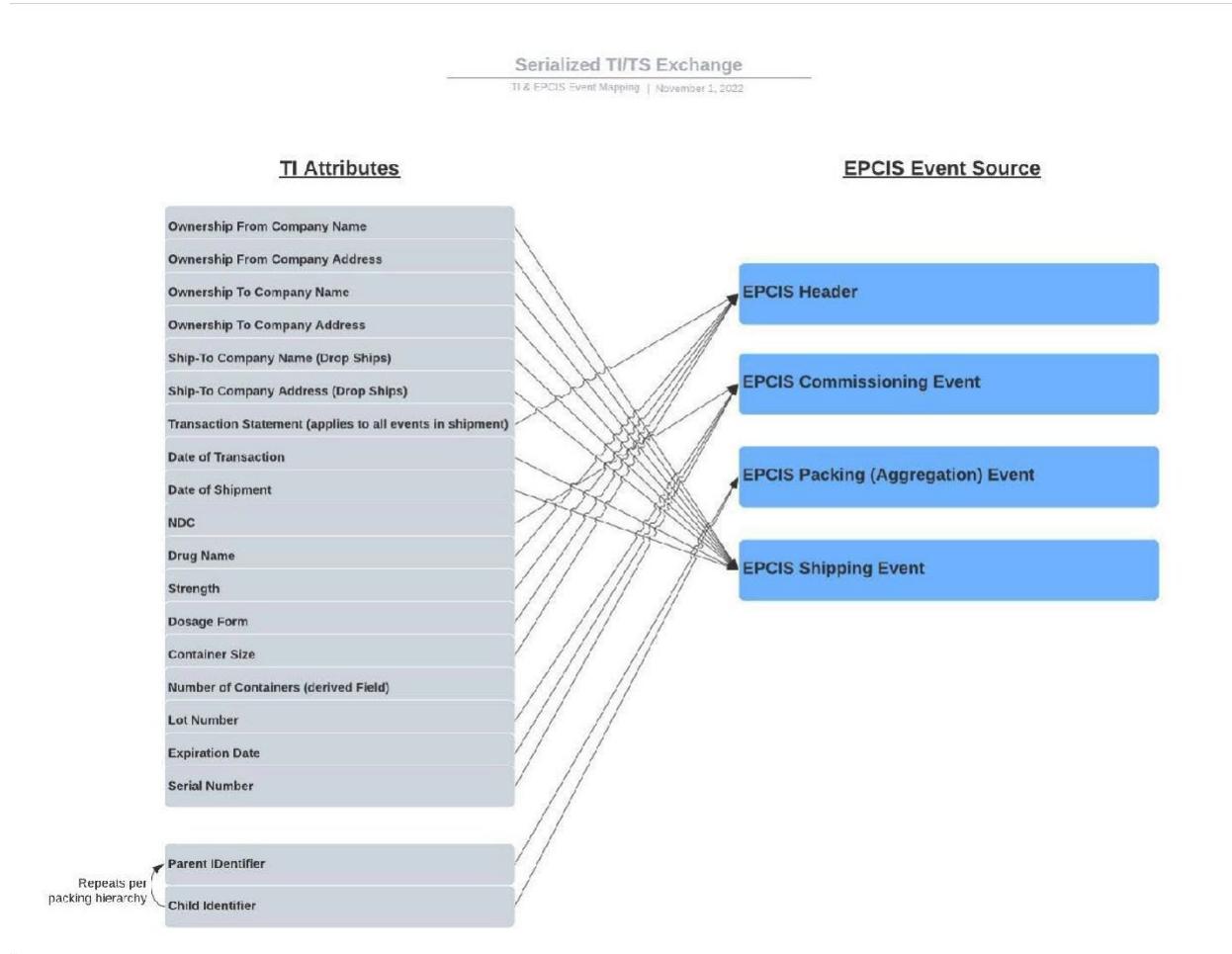


Figure 3 - Mapping TI Attributes to EPCIS Events¹⁵

Minimum Set of EPCIS Events Needed to Exchange TI Data

The GS1 US guideline includes guidance on how to use EPCIS events in multiple situations and to accomplish various goals of product movement, transformation, and exception management between trading partners. *Figure 3* shows the minimum set of EPCIS Events needed (Commissioning and Shipping) to exchange TI data and packing (Aggregation) hierarchy to support inference practices:

- **Commissioning:** Provides attributes defining each package and case in the transaction including the master data elements defining the products¹⁶.
- **Packing (Aggregation):** Provides the hierarchical relationships (i.e., package to case, case to pallet) between objects as they exist at the point of shipping.

Shipping: Provides information and identification of the outermost layer of the packing included in the transfer. The full hierarchy is specified by inference from prior Packing events.

¹⁵ Note: EPCIS events also require GLN for all entities involved.

¹⁶ Mixed cases or pallets will not be product specific.

Additional EPCIS Events Available to Trading Partners

The guideline¹⁷ also defines many events that may be helpful for internal use (receiving, dispensing, etc.) or for use between consenting trading partners engaged in a transaction. It is recommended that each trading partner bear in mind these events considering the data retention, verification, and tracing requirements of DSCSA. For example, receiving, destroying, and other events are not required for the exchange of TI data; however, they may play a role in your ability to respond to verification (manufacturers and repackagers), tracing requests (all Authorized Trading Partners), and exceptions management long after the product has been exchanged.

- **Receiving:** Completing the transfer of a package or case from one trading partner to another.
- **Unpacking:** Removing an object (package or case) from a larger container.
- **Dispensing:** Removing a portion of a product for use while retaining the remainder for subsequent dispensing. The package continues to exist after the Dispensing event.
- **Destroying:** The process of destroying a product so that it no longer exists.
- **Decommissioning:** The end of life for the product identifier. Unlike Destroying, the package may still physically exist.
- **Void Shipping:** Indicating that objects previously recorded in one or more prior Shipping events were, in fact, not shipped.
- **Error Declaration:** In certain error situations, provides a mechanism allowing a previously captured event to be declared erroneous; hence, a new corrective event may be created whose effect is to indicate that a prior event was in error and should be disregarded completely.

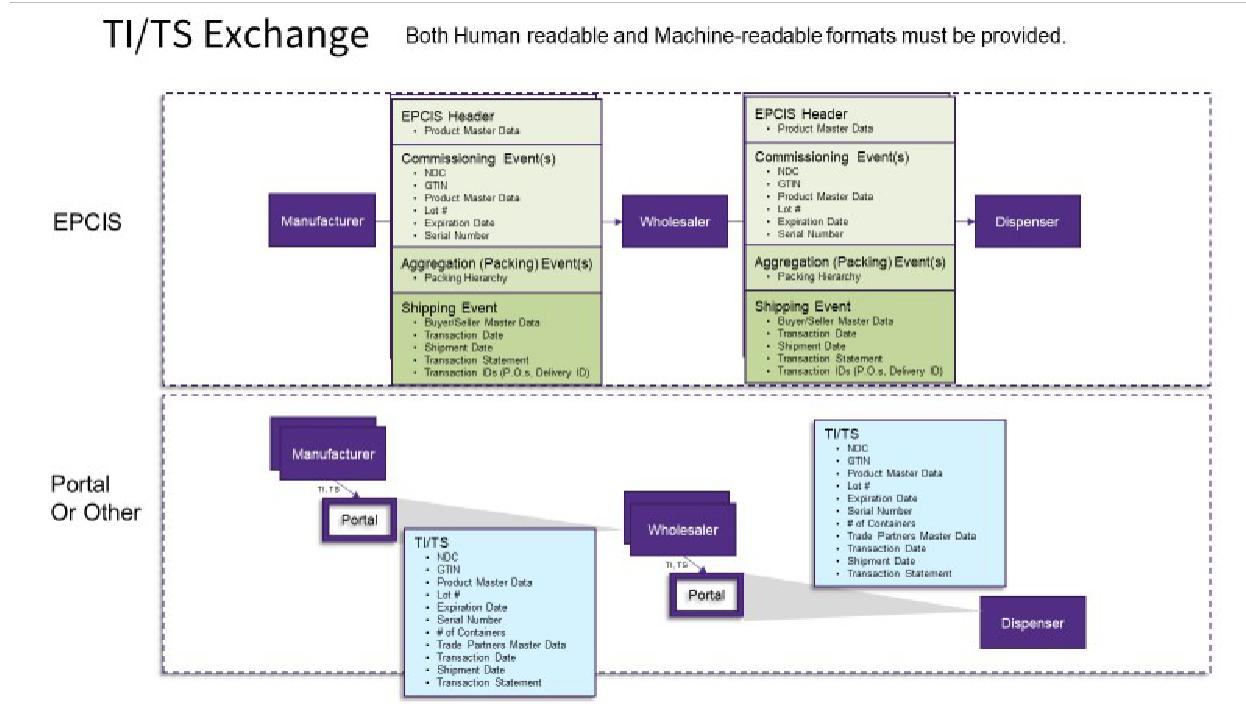


Figure 4 - TI data elements in EPCIS,¹⁸ Portals, and Other Methods

¹⁷ EPCIS Event definitions: [GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability](#).

¹⁸ Note: Transaction Statement is part of the EPCIS document in the EPCIS Header. TS applies to all the events in the EPCIS document.

Record Retention. The DSCSA requires trading partners to retain TI and TS data for six years after the transaction. The DSCSA also requires trading partners to retain investigation data (which may include TI and TS data) for six years after the investigation closes. Therefore, it is possible in some instances to need to retain TI and TS data for twelve years. TI and TS information is the main data relied on for tracing. However, certain movements that do not require the creation, retention, or exchange of TI and TS could leave gaps in the EPCIS record of product exchange. A trading partner may have other data sources that help “tell the chain of ownership” story during a suspect product, illegitimate product, or recalled product investigation or regulator inspection. Information such as returns, dispensing, decommissioning, damage, etc. may be needed to fill in the gaps in the TI and TS data.

Trading partners should prepare to retain TI and TS data along with associated data for these eventualities. Trading partners that rely on multiple sources for their TI and TS data (e.g., portals), should plan on how they will pull this information together to be prepared for tracing requests. Except in the case of wholesaler (seller) and dispenser (buyer) who have entered into an agreement whereby the wholesaler stores the dispenser's TI and TS data, a buyer who retrieves TI and TS data from a portal (due to lack of AS2 delivery method) is responsible to complete the retrieval and should not rely on the seller maintaining the TI and TS on their behalf for 6 years or more. It is recommended that you plan to arrange enough access time on the portal or pull that data into your own systems if you do lose access.

Reconciliation

Figure 5 and *Figure 6* illustrate steps taken to identify misalignment exceptions and steps to reconcile¹⁹ TI received against the product received. Each trading partner determines where in their operation reconciliation takes place. Each trading partner exercises reconciliation steps within their operation taking into consideration factors such as environmental conditions, physical security, case integrity, and other factors.

TI and TS Exchange Illustrations

The following provides insight into TI and TS exchange for several business interaction types. These are illustrative and make use of the minimum set of EPCIS Events. Trading partners are advised to understand situations that may trigger a suspect product or illegitimate product investigation. These illustrations may be helpful in developing internal standard operating procedures to secure product inventories and fulfill reporting and investigation responsibilities.

¹⁹ See Chapter 1: Requirement-Ser-028 and Requirement-Ser-029.

Supplier to Purchaser TI and TS Exchange. *Figure 5* depicts sample processes when receiving TI and TS data prior to receiving the product. Several quality checks can be made at this point in the process and exception and investigative processes can be initiated.

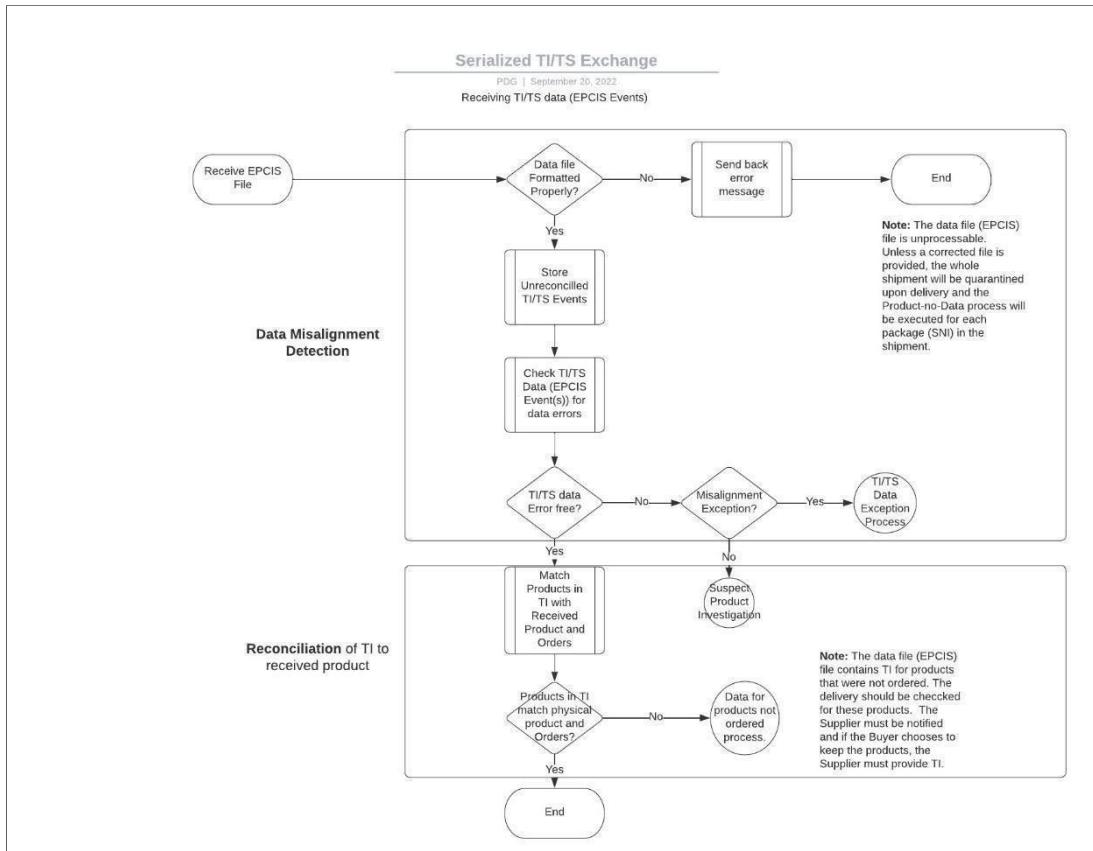


Figure 5 - Receiving TI and TS Data (EPCIS Events)

Figure 5 depicts receiving the product. Note that scanning individual packages may take place when the trading partner's internal process makes those packages available for scanning. Industry practice is to keep products in the sealed manufacturer or repackager cases when possible and infer individual packages in those cases using the supplier-provided packing data given the added security sealed cases provided.

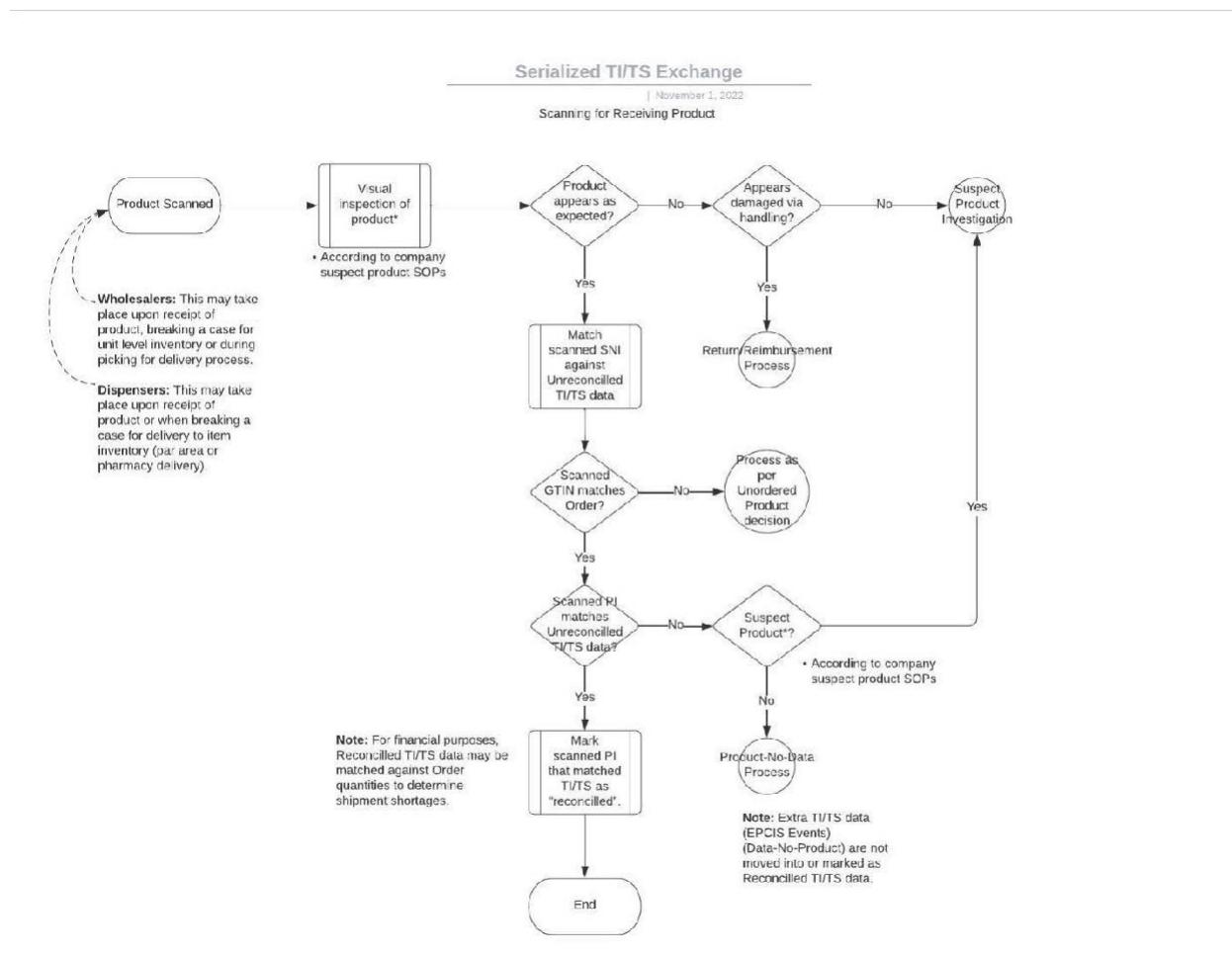


Figure 6 - Receiving Product: Scanning²⁰

Drop Shipments and TI and TS Exchange

Drop shipments provide a unique challenge to the exchange of serialized TI data because the ownership path of the product (which is traced under the DSCSA) diverges from the possession path for the product (which is not traced under the DSCSA). A drop shipment typically occurs when a dispenser orders a product from a wholesaler and the wholesaler orders the product from the manufacturer to be shipped directly to the dispenser. The shipment triggers a change of ownership from the manufacturer (or repackager) to the wholesaler. A later transaction indicates a change of ownership between the wholesaler and dispenser. Unlike typical supplier/buyer transactions, the TI and TS data supporting the transfer of ownership between the manufacturer (or repackager) to the wholesaler is provided to the drop ship customer (dispenser).

In the case of drop shipments, the PDG-designed architecture relies on the manufacturer's TI which includes the wholesaler as the buyer and the dispenser as the ship-to entity, as permitted under 582(f).

To provide the dispenser with the TI data, the dispenser needs to receive, reconcile, inventory, and dispense the product, three options have been recognized (see *Figure 6*). As depicted for options 2 & 3,

²⁰ Reconciliation of electronic TI and TS with an order will likely require matching the PO # from the Shipment with the PO in the order. Note that PO is a business transaction document number required by the business rather than regulatory compliance.

the TI and TS may be sent directly to the drop-ship customer. The manufacturer or repackager relies on the wholesaler's KYC process for dispenser identity and ATP status.

1. Wholesaler agrees to pass through the unedited manufacturer's TI and TS to the dispenser²¹
2. The manufacturer provides TI and TS via a portal and provides portal access information to the dispenser in shipping documents.
3. In cases where the manufacturer and dispenser have or establish an electronic data exchange connection to provide TI and TS data, the manufacturer sends TI and TS directly to the dispenser.

In all cases, in the EPCIS Shipping Event, the trading parties SHALL be identified as

- Manufacturer is identified as the transfer-from party
- Wholesaler is identified as the transfer-to party
- Dispenser is identified as the ship-to party

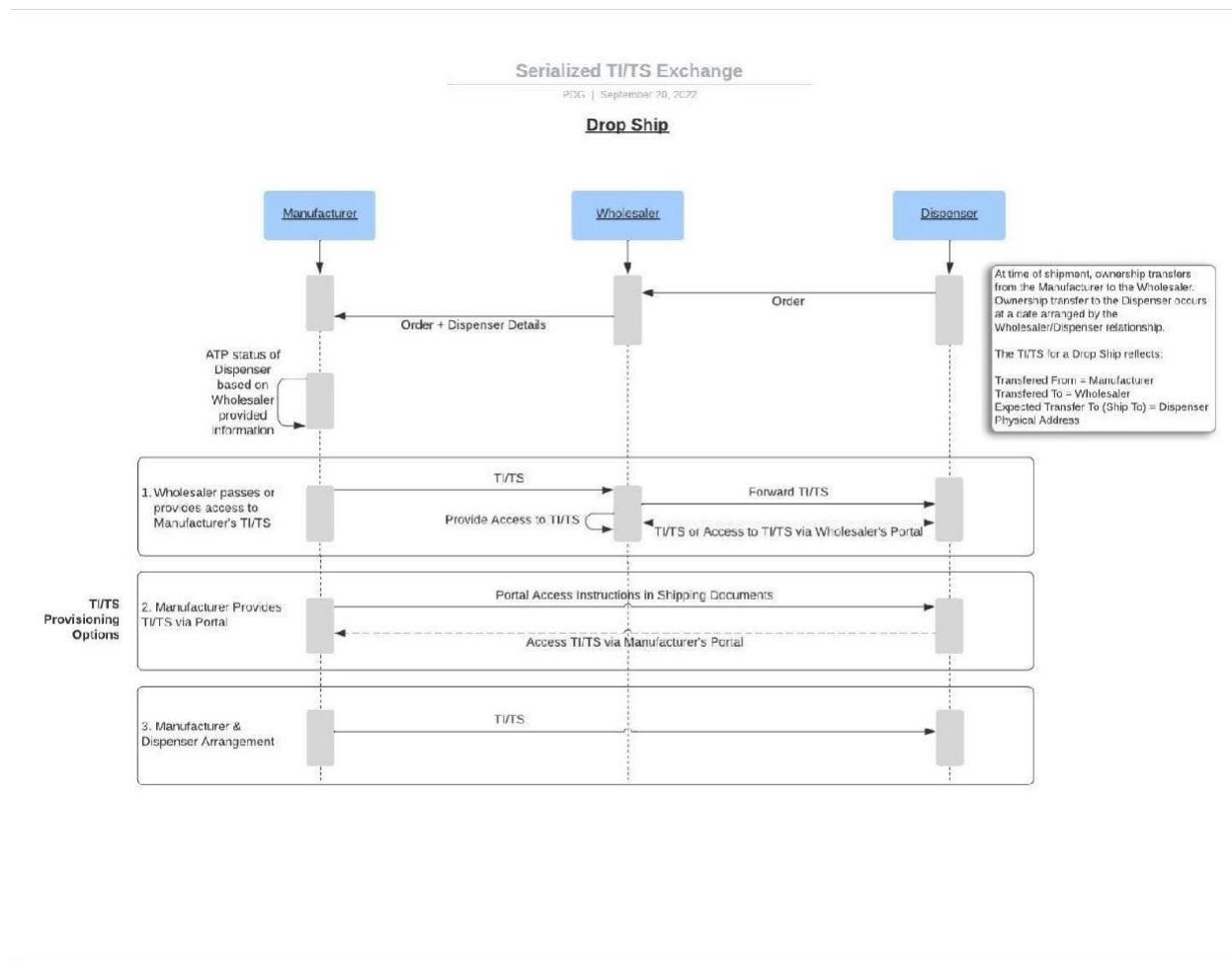


Figure 7 - TI and TS Exchange: Drop Shipment

²¹ In doing so, the Manufacturer or Repackager is leveraging the exception in 582(f).

Consignment Shipments and TI and TS Exchange

When a product is consigned, the product is shipped to and possessed by the consignee, but the consignee does not take ownership of that product until the consignee uses the product. Consignment product is typically considered the property of the consigning supplier (typically the manufacturer, repackager, or wholesaler) until the product is used by the consignee (typically the dispenser). This poses a challenge to the trading partners in providing TI and TS to the consignee in a timely manner that allows them to use (dispense) the product when needed and stay within the DSCSA requirements for receiving TI and TS. The PDG-defined EDDS network recognizes this challenge and agrees that the consigning **supplier will** provide TI and TS at the time of shipment of the consignment product. This allows the consignee time to pre-check the TI and TS data and perform reconciliation prior to using the product.

In all cases, in the EPCIS shipping event, the transaction date (and ship date) are based on the date the product was shipped and not the date the inventory transitioned from consignment.

Alternately, for consignment, upon the consignment supplier receiving consignment usage from the dispenser, it is possible (not required) to send an EPCIS transaction event (which captures the transfer of ownership information including ownership transfer date).

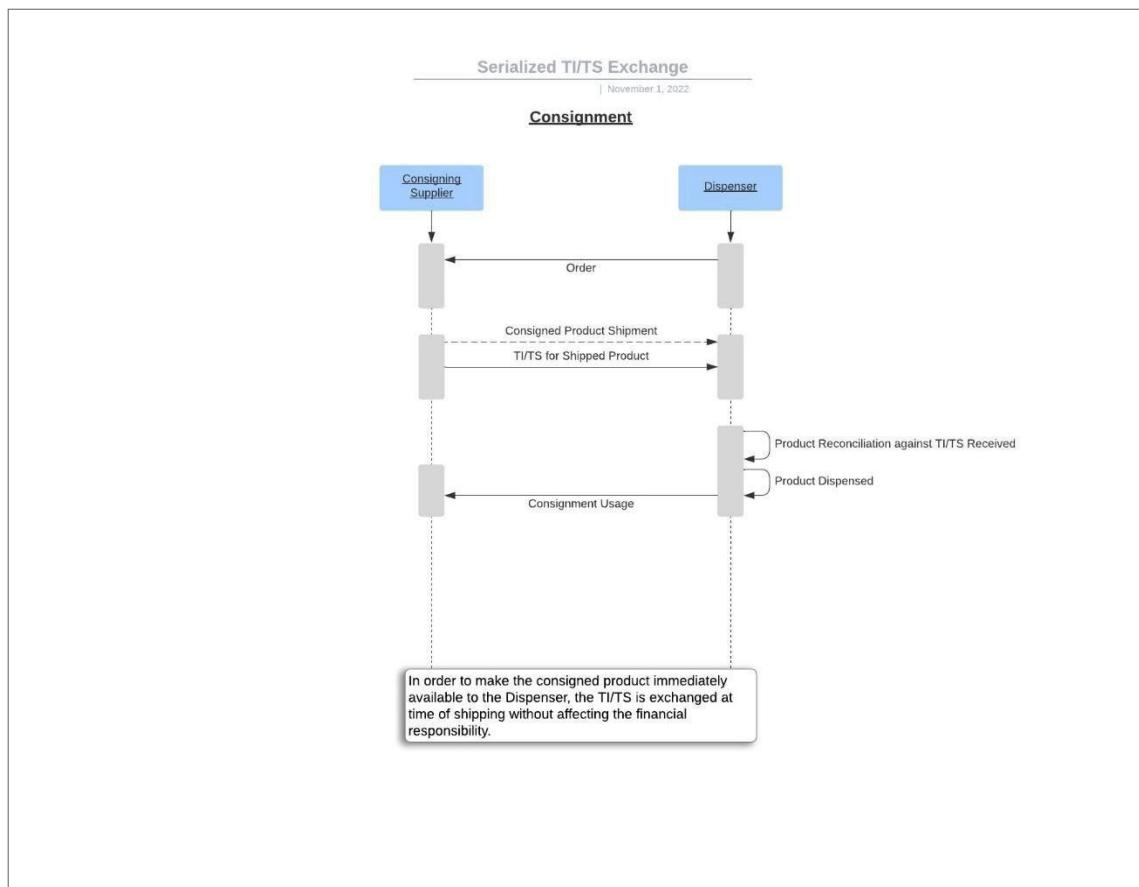


Figure 8 – TI and TS Exchange: Consignment Shipment

Replacement Shipments and TI and TS Exchange

A replacement order from a manufacturer perspective is a free-of-charge order shipped by the manufacturer to the wholesaler's customer (not the manufacturer's direct customer).

In instances where a dispenser determines there is an issue with a product that they purchased through a wholesaler, the dispenser may work directly with the manufacturer or repackager to resolve the issue. The resolution may take the form of the manufacturer or repackager providing replacement product directly to the dispenser. As the wholesaler is not part of this replacement transaction, the manufacturer or repackager provides TI and TS directly to the dispenser either directly (establish a relationship, develop digital connections, etc.) or through a portal.

In all cases, in the EPCIS Shipping Event, the trading parties SHALL be identified as

- Manufacturer is identified as the transfer-from party
- Dispenser is identified as the transfer-to party
- Dispenser is identified as the ship-to party

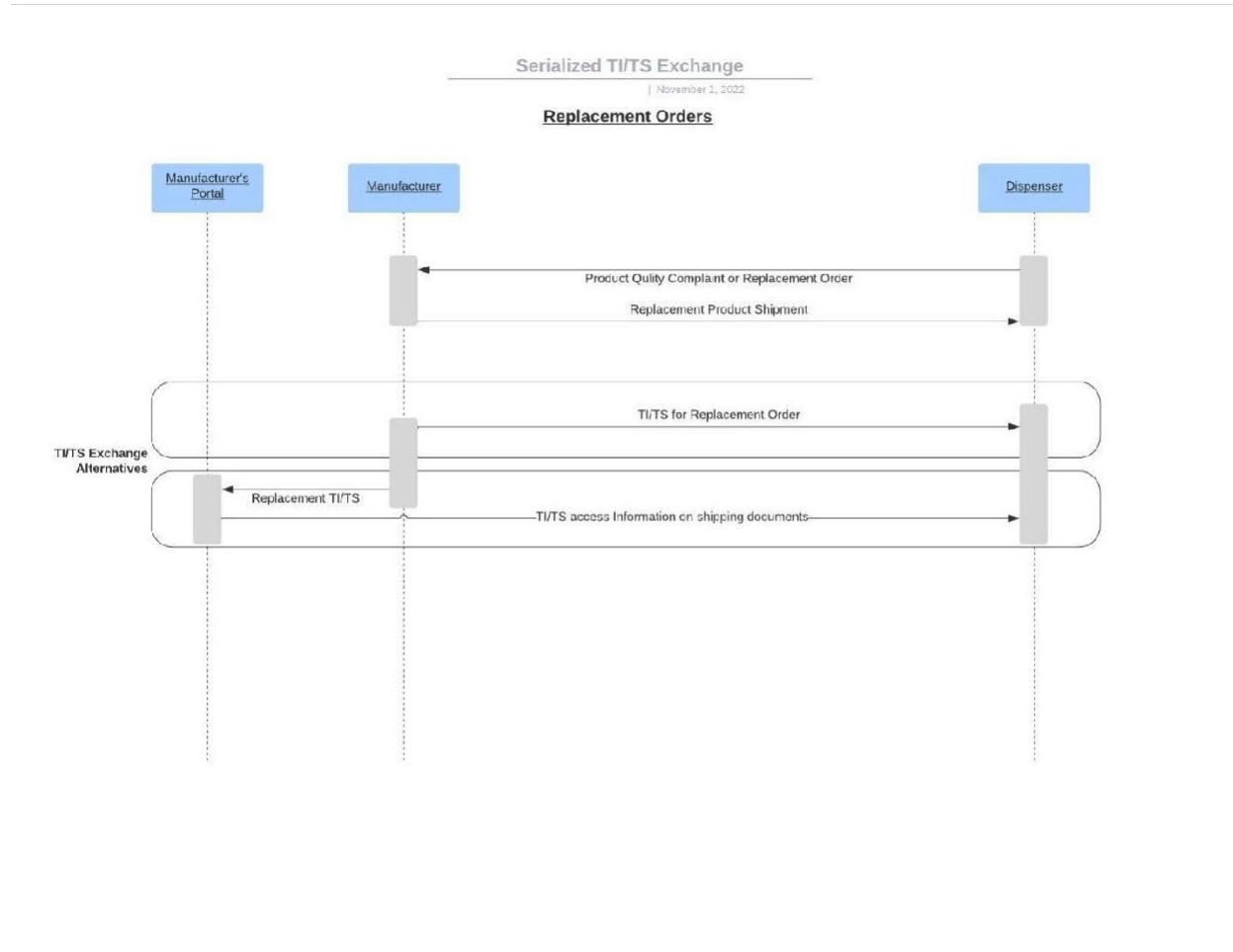


Figure 9 - TI and TS Exchange: Replacement Shipment

340B²² Shipments and TI and TS Exchange

Similar to drop shipments, 340B transactions present complications because the path of possession and ownership diverge. The complicating factor is that the TI and TS compliance exchange occurs between the transfer-from-party (wholesaler) and the 340B covered entity (transfer-to party). For 340B shipments, the example in *Figure 10*, illustrates that the EPCIS shipping event SHALL identify the parties as;

- Wholesaler is identified as the transfer-from party
- Covered Entity is identified as the transfer-to party
- Contracted Dispenser is identified as the ship-to party

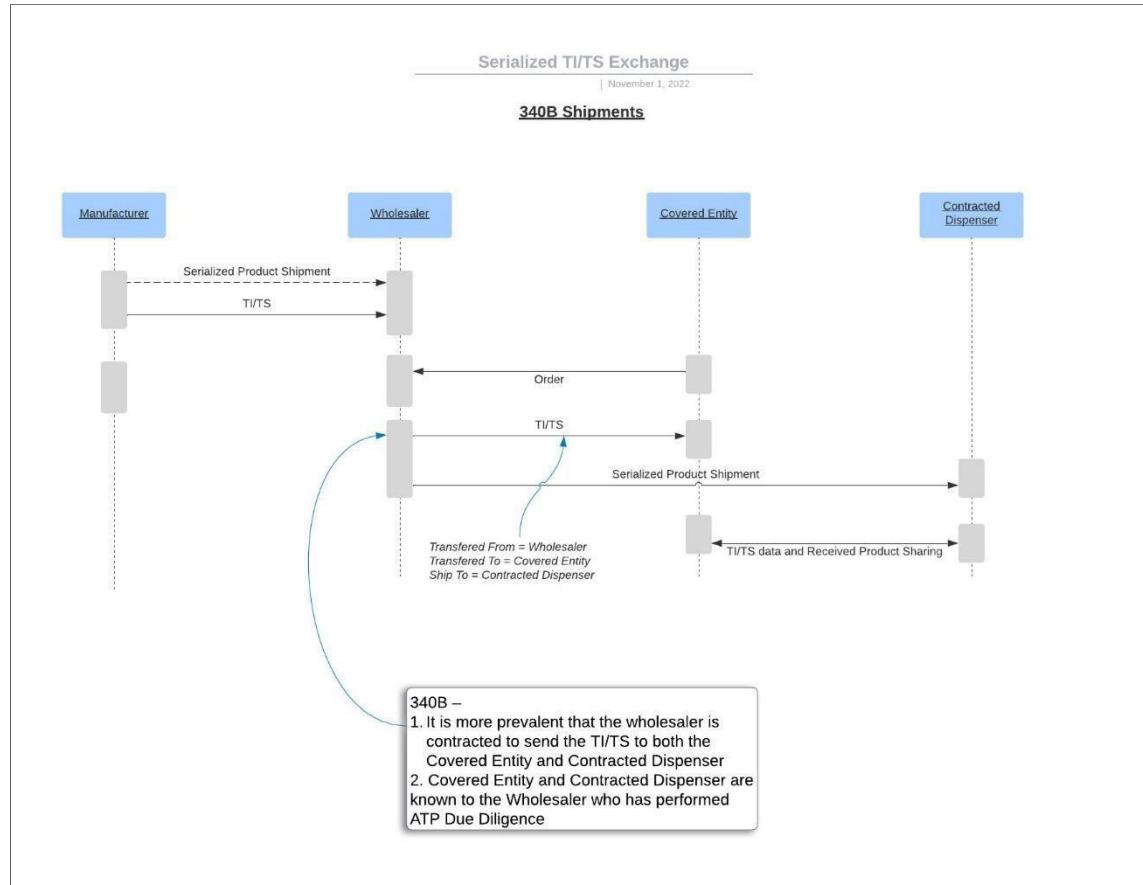


Figure 10 – TI and TS Exchange: 340B Shipment

²² The 340B Drug Pricing Program is a [US federal government](#) program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. The intent of the program is to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."^{[1][2][3]} Maintaining services and lowering medication costs for patients is consistent with the purpose of the program, which is named for the section authorizing it in the [Public Health Service Act](#) (PHSA).

Misalignment Exception Processing

The following misalignment exceptions conform with the HDA Exceptions Handling Guideline for DSCSA which addressed exception scenarios between Manufacturers and Wholesalers. PDG has extended the scope to include dispenser trading partners.

Misalignment exception resolution may result in replacing previously exchanged TI and TS data. Table 1 references the GS1 US guideline titled “the GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability”, which specifies how to use the GS1 EPCIS Standard to exchange DSCSA TI and TS data between trading partners.

The PDG-defined EDDS Network design utilizes email as the delivery mechanism for misalignment exception notifications. As the industry gains experience with misalignment exceptions and resolutions, PDG may later seek standardization of exception alerts.

If at any time during the exceptions process, the buyer or seller determines the product is suspect or determines that the product is illegitimate, the trading partner will initiate the appropriate suspect or illegitimate product investigation.

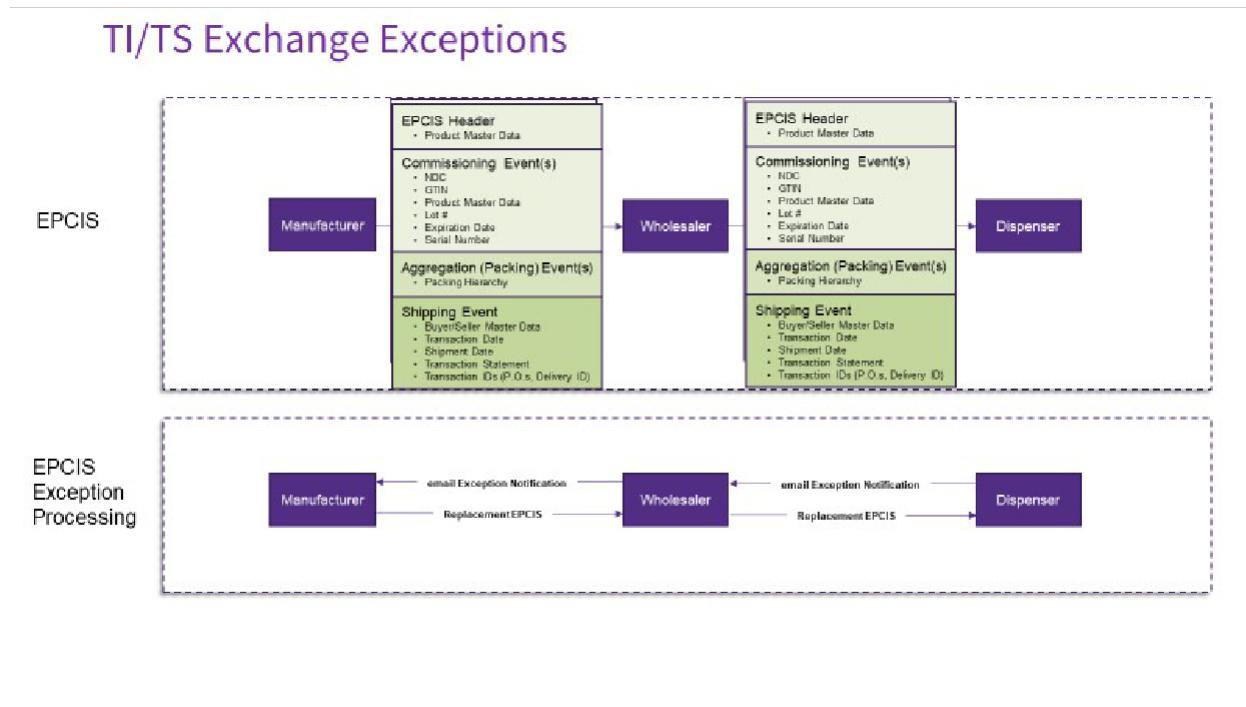


Figure 11 - Exception Process

Misalignment Exception Types

PDG recognizes misalignment exceptions fall into five categories that trading partners must work through together. The following is the PDG recommendation for exception processes for all trading partner types. For trading partners that exchange TI and TS via the primary recommended format of EPCIS events, the sending trading partner MUST replace EPCIS events with corrected ones. For trading partners that are exchanging TI and TS via an alternate method (e.g., supplier portal), the supplying trading partner must replace the TI and TS data in error with corrected TI and TS. It is acknowledged that when a TI and TS exception occurs, trading partners should communicate and mutually agree on the corrective action to be taken to ensure that corrected TI and TS issued by the selling trading partner are processed by the buying trader partner.

PDG-Defined EDDS Network Exceptions

These are exceptions that occur within the TI and TS exchange functionality of the PDG-defined EDDS network. [TI and TS Data Issues](#)

Master Data Issues: Upon receiving TI and TS data, the buyer determines that the seller or product master data does not exist in their system. This may be a GLN (seller's, buyer's, or ship-to in the case of a drop shipment) or GTIN.

Resolution: The buyer notifies the seller (via email) of the master data issue and the seller provides the correct master data. Buyer is able to process the TI and TS.

Product Quarantine: Yes, any product received affected by this exception must be quarantined until the exception is resolved.

EPCIS file not formatted properly: Upon receiving TI and TS data via the EPCIS file, the buyer determines that the file cannot be processed.

Resolution: Buyer notifies seller (via email) of the file error. The seller will correct the error and resend the EPCIS file.

Product Quarantine: Yes, any product received affected by this exception must be quarantined until the exception is resolved.

Extended Expiration Dates: Upon receiving TI and TS data via the EPCIS file, the buyer determines that the expiration date for an item(s) has passed. Upon notifying the seller of the issue, the seller provides information that the manufacturer has extended the expiration date. Note that the expiration date in the TI and TS data corresponds to the product expiration date encoded in the serialized product barcode. Therefore, no correction is needed on the supporting TI and TS data when the manufacturer has extended the expiration date.

Resolution: If the seller is the manufacturer, the buyer will record and rely on the manufacturer's instructions. If the Seller is not the manufacturer, the buyer will perform a verification²³ with the manufacturer to verify that an extended expiration is in effect. The buyer will also contact the manufacturer to determine the extended expiration date value.

Product Quarantine: Yes, any product received affected by this exception must be quarantined until the exception is resolved. Until the product is determined to have an extended expiration date, the product is considered expired.

²³ [Release 1.3 \(and re-titled\) of the GS1 US Implementation Guideline: Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Product Identifiers.](#)

Product, No/Incomplete TI and TS Data

The buyer receives the product and has not received complete TI and TS data to match the product. This could apply to a whole shipment, partial shipment, or package(s) inside of cases or totes.

Resolution: The buyer should check:

- that their EPCIS system is operating,
- that they have a purchase order that matches the GTINs received.

The buyer will contact the seller and either arrange to return the whole shipment, process and receive products with TI and TS and return those without TI and TS or have the seller send the missing TI and TS.

Product Quarantine: Yes, any product received affected by this exception must be quarantined until the exception is resolved.

TI AND TS Data, No Product

Through internal reconciliation processes, the seller or buyer may determine that TI and TS data was sent or received, and the associated product was not shipped or received. Either trading partner may notify the other of the issue to start the exception process.

Pre-shipment scenario: The seller sent TI and TS to the buyer and prior to shipping the product, and the seller makes a change to the shipment quantity.

Resolution: Seller notifies the buyer of the exception and sends replacement TI and TS. Assuming the buyer has not yet processed the original TI and TS data into their system, the buyer disregards the original TI and TS and processes the replacement TI and TS. In the case where the buyer has already processed the original TI and TS, the buyer indicates in their system that the original TI and TS is replaced with the replacement TI and TS.

Product Quarantine: There is no physical product to quarantine.

Shortage: Upon receiving a shipment, the buyer discovers that the seller sent TI and TS for additional items.

Resolution: Buyer may receive the product that was delivered that has a matching TI and TS. Buyer notifies the seller for extra TI and TS without matching physical product.

Product Quarantine: If the seller determines the shortage was caused by an operations error, the product with matching TI and TS data can be received and processed. If the buyer and/or the seller determine the shortage was due to in-transit theft, the buyer may decide to quarantine the remaining product received for the shipment until a determination can be made that it has not also been tampered with.

Shipment refused: Upon delivery, the buyer refuses the entire shipment.

Resolution: Buyer will disregard or mark the sent TI and TS as rejected and unprocessed such that it is not included in future TI traces. The seller will examine the refused product and either process it back into inventory or process it as a destruction of the product. When refused product is returned into seller's inventory and subsequently shipped to the buyer with supporting TI and TS data, the buyer will need to ensure it can process the supporting TI and TS data and not treat it as duplicate.

Product Quarantine: No, the shipment is refused and returned to the seller. Based on the refusal circumstances, the seller may quarantine the product until a determination is made.

Operational Exceptions

These are situations that do not directly cause a misalignment exception but disrupt the normal systems and processes implemented.

Damaged Product

Damaged case: Upon receiving a shipment, the buyer discovers a damaged case or case label.

Resolution: The buyer will receive the individual packages within the case. If unable to receive the packages individually, the buyer may return the damaged case. If the buyer discovers damaged packages within the case(s), they may receive the undamaged packages or return the case. The buyer should ensure that the TI and TS data received for cases or packages that are not received are marked as not received or not included in the buyer's TI and TS records used for tracing.

Product Quarantine: Yes, any product received affected by this exception must be quarantined until the exception is resolved.

Unreadable PI or 2D barcode: Upon discovering an unreadable label (human-readable interpretation or human-readable identifier) or an unscannable 2D barcode.

Resolution: The product is considered unsellable and will be taken out of inventory and returned to the seller. An exception to this is the case of a dispenser, which may need the product for patient use. The dispenser may be able to capture the product identifier information visually from the label or 2D scan. Upon reading or scanning, the dispenser may verify the product with the manufacturer as an extra precaution. In case where product is re-labeled such that the same sGTIN is used and product is returned into seller's inventory and subsequently shipped to the buyer with supporting TI and TS data, the buyer will need to ensure it can process the supporting TI and TS data and not reject it as duplicate TI and TS data.

Product Quarantine: Yes, any product received affected by this exception must be quarantined until the exception is resolved.

Packaging and Labeling

Lot Number mismatch: Upon scanning a product, the buyer discovers that the GTIN and serial number do not match the human-readable on the label. A lot number can fail because of a special character issue or upper/lower case issue.

Resolution: The buyer contacts the seller to resolve or return the product. If the buyer suspects the product, the buyer may contact the manufacturer and/or perform verification on the product identifier.

Product Quarantine: Yes, any product received affected by this exception must be quarantined until the exception is resolved.

Exception Notifications

PDG recognizes that system-to-system notifications may be needed as the industry gains experience with exception handling. For the near future, however, the following information²⁴ is recommended for email notifications.

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 buyer or seller can provide, such as

 UUID (any unique identifier of trading partner'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;

²⁴ From the HDA "Exception Handling Guidelines for the DSCSA."

Ship-to address;
GTIN;
SN;
LOT;
Scanned expiry;
Trade item description; and,
Delivery number/shipment number/bill of lading/tracking number on partial.

Exception Notification Recommendation

As the first step toward a standardized exception notification that will reduce data transcription errors. PDG recommends a trial JSON file schema be developed to provide an interim solution for trading partners with the desire and capability to process this format. A schema includes foundational data attribute formatting, content rules, and cardinality rules. A standardized format will reduce data transcription errors and allow for the notifier to test their data against a recognized schema prior to transmission.

Exception Processing Illustrations

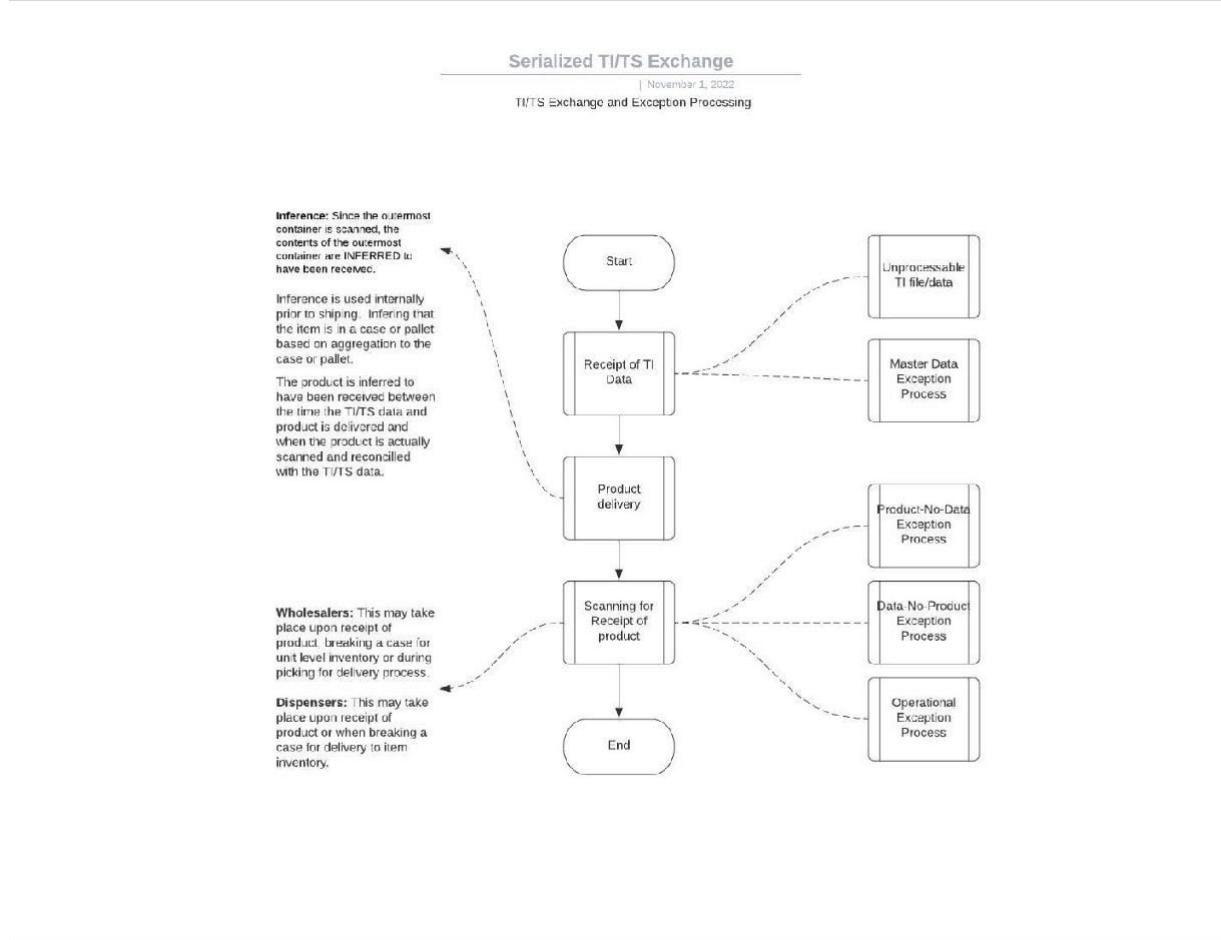


Figure 12 - TI and TS Exchange and Exception High-Level

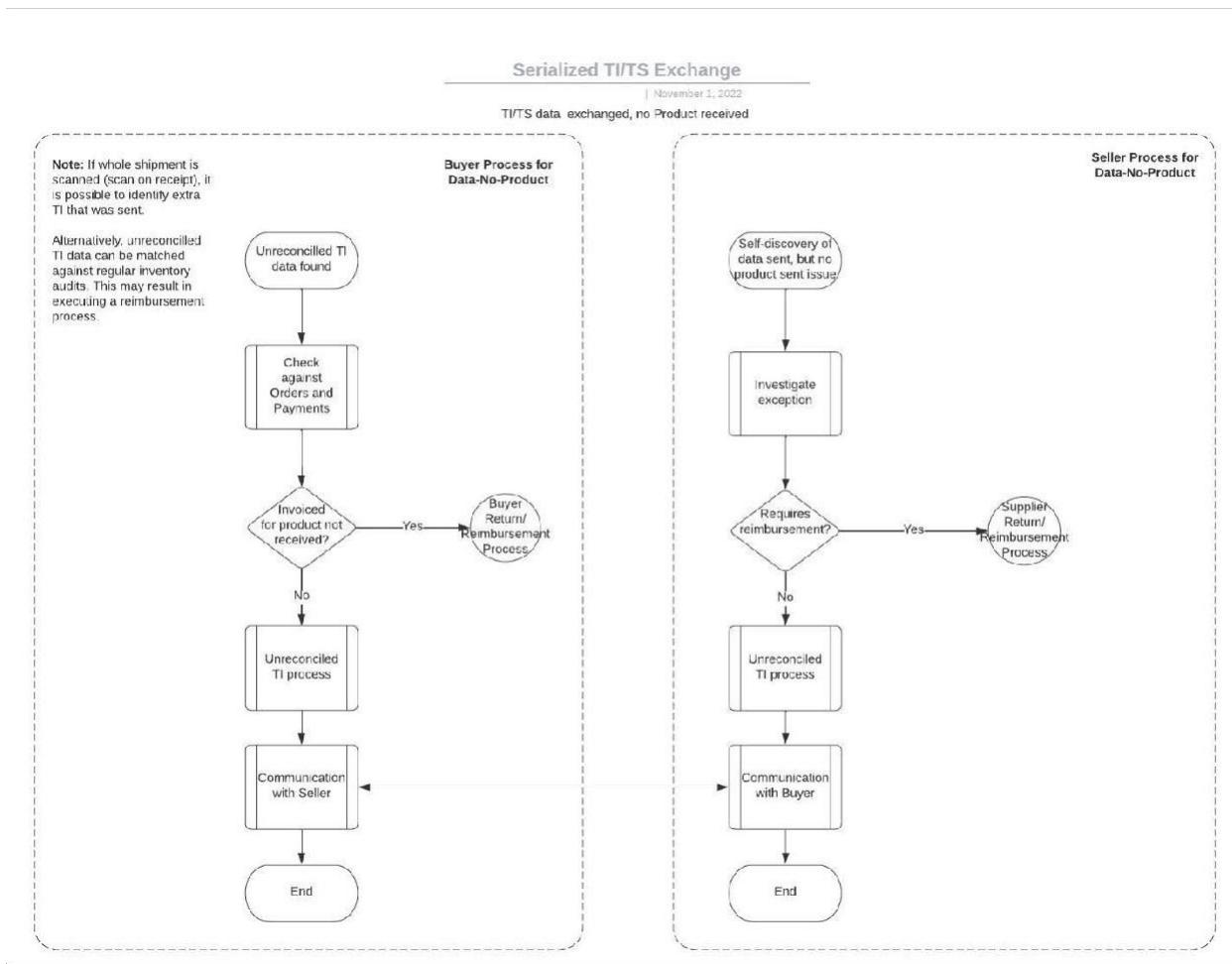


Figure 13 - TI and TS Exchange Exception: Product, No Data

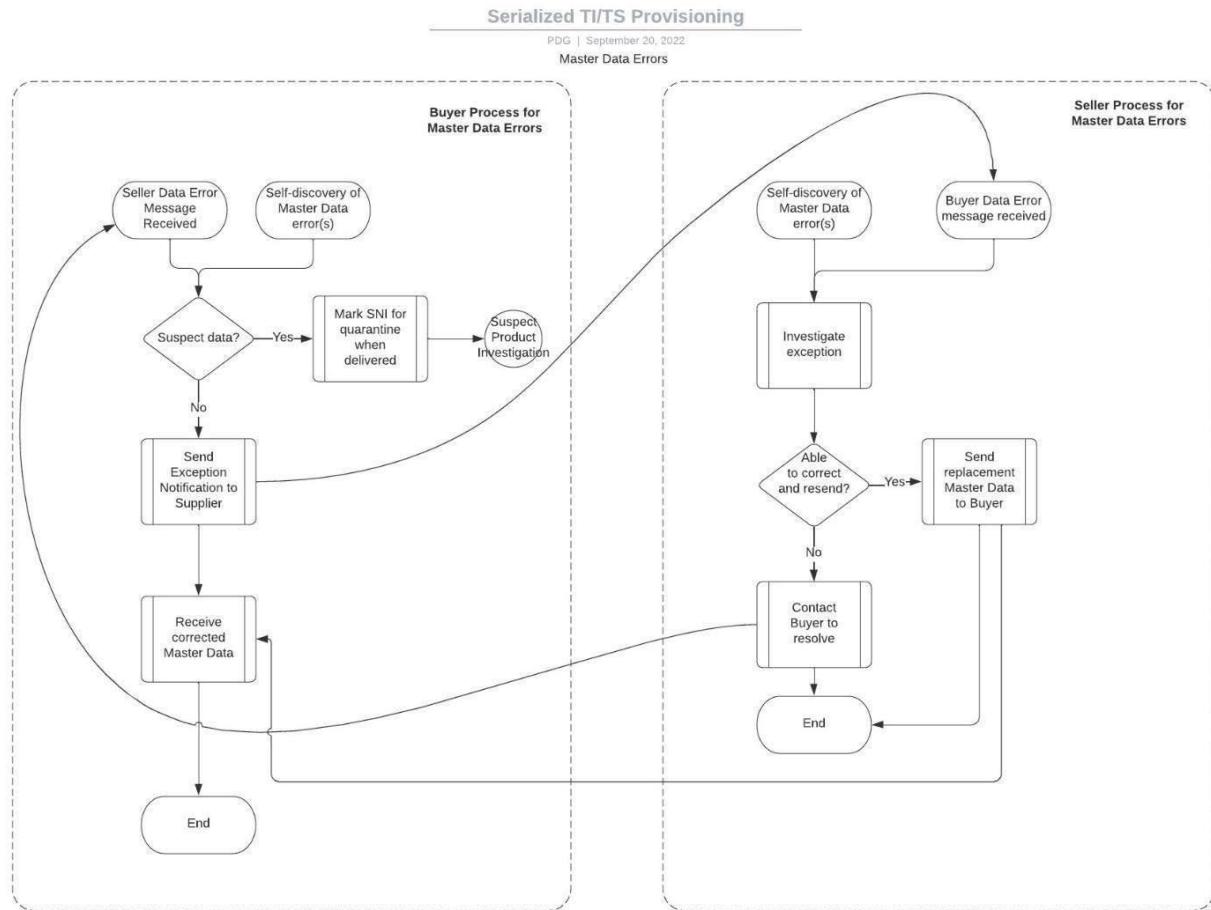


Figure 14 - Master Data Errors

Technical Requirements

| ID | Functional Requirements ²⁵ |
|------------|--|
| Ser-FR-001 | Sellers and their solutions SHALL provide TI and TS push capability (e.g. via B2B connection) in GS1 EPCIS format and May provide TI and TS Portal access. |
| Ser-FR-002 | Sellers using Portals may provide TI and TS download, which SHALL use standard attribute formats. ²⁶ |
| Ser-FR-003 | Sellers and their solutions SHALL provide TI and TS push capability (e.g. via B2B connection) in GS1 EPCIS format and May provide TI AND TS Portal access. |
| Ser-FR-004 | When using portals, suppliers SHALL provide aggregation data to purchasers in a mutually agreed manner. |
| Ser-FR-005 | Trading partners SHALL use the GS1 GLN to identify sellers, buyers, and drop ship customers (in drop ship transactions). |
| Ser-FR-006 | When using EPCIS to transfer TI and TS, the number of containers is calculated from the shipping event and associated aggregation (packing) event to calculate the number of saleable items for a case. Individual saleable items (packages) always hold a number of containers of “1.” |
| Ser-FR-007 | For consignment transactions: the EPCIS shipping event, the transaction date (and ship date) are based on the date the product was shipped and not the date financial responsibility is required. |
| Ser-FR-008 | <p>For Drop Shipment transactions:</p> <p>In all cases, in the EPCIS shipping event, the trading parties SHALL be identified as</p> <ul style="list-style-type: none"> • Manufacturer is identified as the transfer-from party • Wholesaler is identified as the transfer-to party • Dispenser is identified as the ship-to party |
| Ser-FR-009 | <p>For replacement of product transactions:</p> <p>In the EPCIS shipping event, the trading parties are identified as</p> <ul style="list-style-type: none"> • Manufacturer is identified as the transfer-from party • Dispenser is identified as the transfer-to party • Dispenser is identified as the ship-to party |
| Ser-FR-010 | <p>For 340B transactions:</p> <p>In the EPCIS shipping event, the trading parties are identified as</p> <ul style="list-style-type: none"> • Supplier is identified as the transfer-from party • Covered entity is identified as the transfer-to party |

²⁵ This section illustrates identified functional requirements, however, the chapter sections provide additional requirements and rules.

²⁶ See Chapter 1 requirements for TI and TS data attribute formats.

| ID | Functional Requirements ²⁵ |
|------------|---|
| | <ul style="list-style-type: none"> Contract dispenser is identified as the ship-to party |
| Ser-FR-011 | Buyers shall receive TI and TS data and retain it directly or via a third party. |

Non-Functional Requirements

| ID | Non-Functional Requirements |
|-------------|-----------------------------|
| Ser-NFR-001 | None |

Considerations and Challenges

TI and TS exchanged between trading partners represents the data upon which PI Verifications and TI Tracing functions and requirements are based on. The requirements for TI and TS exchange provide a record of products exchanged between trading partners using EPCIS “Commissioning”, “Packing” and “Shipping”. However, they do not provide a record of product movement within an organization or other manipulations of the product (e.g., unpacking, transforming for repackaging) that a trading partner may need to connect inbound product to outbound product. A trading partner should consider using other EPCIS events found in the GS1 Guideline such as “Unpacking, Transforming, Dispensing, Destroying, and Decommissioning.

Open Issues

| ID | Issues |
|---------------|--|
| Ser-Issue-001 | Exceptions are managed through email. To achieve a higher level of automation, exception processing needs to be supported by EPCIS-level messaging and resolution. |

Change Control

| Date of Change | Section | Description of Change | Approved By |
|----------------|--------------------|---|------------------------|
| Version 1.2 | | | |
| 2/21/2023 | Ch. 3 | Inclusion of the GS1 US DSCSA Implementation Guideline R1.3 | PDG General Membership |
| 2/21/2023 | Ch. 3 FN23 | Removed “Returned,” consistent with R1.3 | PDG General Membership |
| 2/24/2023 | Ch. 3 Introduction | Added footnote 1 | PDG General Membership |
| Version 1.3 | | | |
| 8/28/2023 | Ch. 3 | Changed TI/TS to TI and TS | PDG Board of Directors |
| Version 1.4 | | | |
| | | No changes from prior version | |
| Version 1.5 | | | |
| | | No changes from prior version | |