DSCSA EXCEPTIONS HANDLING COMMUNICATION GUIDE

HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

DSCSA EXCEPTIONS HANDLING COMMUNICATION GUIDE

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

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INTRODUCTION

The DSCSA Exceptions Communication Guide was prepared by the Healthcare Distribution Alliance's (HDA) Exceptions Handling Work Group. This document was developed to standardize communication between trade partners to more quickly and efficiently resolve exceptions. This is an addendum to the *Exceptions Handling Guidelines for the DSCSA* and represents the updated recommendations for communicating with trading partners.

This communication guide is voluntary and based on an evolving understanding of DSCSA requirements. It does not constitute and is not intended to represent legal advice. Accordingly, these recommendations may change as the FDA issues/finalizes guidance documents or releases other regulations. Each company must make its own business decisions about how it will procedurally handle trade partner communications. Companies should consult with its own legal counsel, regulatory compliance specialists and trading partners for further implementation guidance.

General Recommendations

At this time, the Work Group believes that exceptions handling will largely be a manual process, conducted through email exchanges between trading partners. The Work Group makes the following general recommendations:

- During EPCIS onboarding, trading partners should exchange group emails monitored by a team qualified to address exceptions as appropriate and updated as staffing changes occur.

- Shipments from upstream trade partners should include PO and shipment number clearly labeled and appearing near the top of bill of lading and pack slip documents

- The trading partner discovering an exception should provide notice to the other trading partner as soon as possible and provide a unique issue tracking number. Ongoing communications between trade partners should use this issue tracking number.

- The initiator's exception notice should contain as much information as possible so the responder can triage and work the exception. The content will vary depending on the type, scale and detail of the exception. If an entire shipment is involved, shipment level data is generally sufficient. For exceptions involving smaller quantities (such as package, carton, case), more detail may be necessary.

- The trading partner receiving an exception notice should respond back to the initiating trade partner as soon as possible and begin working to resolve it.

> **Note:** A barcode scan is preferred for product, no data incidents. In lieu of a scan, a photo is preferred over hand keying for GTIN, serial number, lot, expiry or SSCC number. For data, no product incidents, provide data from the EPCIS file if available.

Recommendations for the Exception Notice

The Work Group recommends that the exception notice should include, as applicable, the information identified below. Receiving this information in this standard order and format will help the responding trading partner to investigate and resolve the exception promptly.

- **A standard subject line:** trading partners involved + Exception Category + issue tracking #

- **A brief narration of the exception:** Be as brief as possible in explaining the incident, refraining from stating any pieces of information already specified in the field list below.

- **Fields in the body of the email:** The responding trading partner will typically need the following information (where applicable:).

    - PO Number:

    - Delivery #/Shipment ID/DESADV:

    - NDC(s) involved in the exception:

    - 2D Barcode scan:

        – For product, no data exceptions where output of the scan cannot be provided, a photo of the 2D data matrix barcode inclusive the human readable [i.e. (GTIN (01), Serial # (21), batch/lot#(10), expiry(17)] adjacent to the 2D barcode.

        – For data no product exception where there is no physical product to scan, capture the GTIN, Serial number, batch and expiry from the incoming file.

    - SSCC-18 (00) as applicable

    - Exception category (Product and No Data, Data and no product)

    - Where/when the exception occurred (e.g., receiving, outbound picking, returns processing),

    - Scope of exception (e.g., entire shipment, pallet, case, inner pack, package, etc.)

    - Product description (Drug/Biologic Name)

    - Source owning/location GLNs

    - Destination owning/location GLNs or ship-to address if GLN is not known

    - Carrier tracking number

    - Contact info (name/email/phone)

Sample Messages

The following message is directed to a supplier for an exception covering an entire shipment:

Subject: Acme Distribution + New Horizon Pharma + Product-No Data + #1234567

Attention trade partner, your shipment has arrived in our warehouse and has been quarantined due to a DSCSA exception. Please send missing EPCIS data so we can keep the product or provide instructions on dispositioning.

PO Number: 89101234

Delivery #/Shipment ID/DESADV: 123456

NDC(s) involved in the exception: N/A

Batch/Lot number(10): N/A

GTIN (01) and Serial # (21): N/A

SSCC-18 (00): N/A

Exception Category: Product-No data

Where exception occurred: receiving

Scope of exception: entire shipment

Product description (Drug/Biologic Name): N/A

Source owning/location GLNs: 1234567890120/1234567890131

Destination owning/location GLNs: 1234567890133/1234567890144

Carrier tracking number: Tracking_1234

Contact Info: John Doe; john_Doe@horizon_Distribution.com; 555-123-4567

The following message is directed to the supplier for an exception covering an overage of two sealed cases discovered during receiving:

Subject: Acme Distribution + New Horizon Pharma + Product-No Data + #1234567

Attention trade partner, your shipment arrived in our warehouse and a portion was quarantined due to a DSCSA exception. Please send the missing EPCIS data so we can keep the product or provide instructions on dispositioning.

PO Number: 89101235

Delivery #/Shipment ID/DESADV: 12345678

NDC(s) involved in the exception: 12345-0678-10

Batch/Lot number (10): ABC1234

2D Barcode scan(s):   010503002569140141726083110PL0335~2113799999952240

010503002569140141726083110PL0335~2113799999952241

SSCC-18 (00): N/A

Exception Category: Product-No data

Where exception occurred: receiving

Scope of exception: case

Product description (Drug/Biologic Name): Ibuprofen

Source owning/location GLNs: 1234567890120/1234567890131

Destination owning/location GLNs: 1234567890133/1234567890144

Carrier tracking number: UPS123456789

Contact Info: John Doe; john_Doe@horizon_Distribution.com; 555-123-4567

The following message is directed to a supplier for an exception discovered during outbound order picking:

Subject: Acme Distribution + New Horizon Pharma + Product-No Data + #1234567

Attention trade partner, we discovered missing package level data during dispenser order picking that was product previously received from your company. This product was quarantined due to this DSCSA exception. Please send the missing EPCIS data so we can keep the product or provide instructions on dispositioning.

PO Number: 89101234

Delivery #/Shipment ID/DESADV: 123456

NDC(s) involved in the exception: 12345-0678-10

Batch/Lot number (10): ABC1234

2D Barcode scan(s): 0150300256914014172608311OPL0335~2113799999952245

SSCC-18 (00): N/A

Exception Category: Product-No data

Where exception occurred: outbound order picking

Scope of exception: partial outbound shipment

Product description(Drug/Biologic Name): Ibuprofen

Source owning/location GLNs: 1234567890120/1234567890131

Destination owning/location GLNs: N/A

Carrier tracking number: N/A

Contact Info: John Doe; john_Doe@horizon_Distribution.com; 555-123-4567

The following message is directed to a supplier for a shortage exception discovered during receiving:

Subject: Acme Distribution + New Horizon Pharma + Product-No Data + #1234567

Attention trade partner, we discovered a shortage in a shipment received from your company.

PO Number: 89101234

Delivery #/Shipment ID/DESADV: 123456

NDC(s) involved in the exception: 0001-0123-45

Batch/Lot number (10): ABC1234

Expiration Date(17): 01/31/2024

sGTIN(s) of product not received: urn:epc:id:sgtin:030001.0012345.100123456789

SSCC-18 (00): 123456789012345678

Exception Category: Data, No product

Where exception occurred: receiving

Scope of exception: partial shipment

Product description (Drug/Biologic Name): Ibuprofen

Source owning/location GLNs: 1234567890120/1234567890131

Destination owning/location GLNs: 1234567890123/1234567890144

Carrier tracking number: N/A

Contact Info: John Doe; john_Doe@horizon_Distribution.com; 555-123-4567

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