Verification of Saleable Returns under the DSCSA

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35th Global GS1 Healthcare Conference
Thursday, March 28, 2019
The DSCSA Path

- 3PL & Wholesale Distributor reporting to FDA 2014-2015
- Product Tracing & Verification
  - Authorized Trading Partners 2015
  - Product Identification (Serialization) 2017-2018
  - BEGIN AFFIXING
- Product Verification (down to package level) 2019+
  - RETURNS
- Electronic, Interoperable System (product tracing down to package level) 2023
- Licensure standards for 3PLs and wholesale distributors
2017/2018 Requirements
Underway:
Product Marking
DSCSA 2018 Labeling Requirements

2017/2018 is all about labeling product and NOT passing serialized data.
Product Labeling Guidances Issued

- Product marked with a 2D bar code containing:
  - GTIN/NDC, Serial, Lot, Expiry

- Manufacturers received Enforcement Discretion allowing them to delay until Nov 2018 to begin affixing new 2D bar codes

- Manufacturers and repackagers received Grandfathering Guidance allowing them to continue to sell unserialized product packaged before Nov 2018
2019 Requirements under Development: Returns Verification
NEW Returns Requirements

1) Distributors must associate the original Transaction Information, Transaction History and Transactional Statement with a saleable return.

2) Verify that the product identifier affixed to the product corresponds with the data the manufacturer assigned.
   • Manufacturers can send serialized data for their shipments to their trading partners to be used for verification of future saleable returns
     --- OR ---
   • Manufacturers can make serial data available for query using a Verification Router Service requesting data for the distributors

Annual saleable returns in US estimated at 60 million pieces across the industry

McKesson saleable returns approximately 19 Million per year
Returns Verification

Initial successful pilot conducted in 2016 and follow up pilots ongoing at present time

Must query manufacturer when internally data not present

If serial data exists in ATTP ten responds to query

Serialized product that cannot be verified must be quarantined and investigated
DSCSA Verification Router Service

Needed for 2019

Requestor sends GTIN, Serial, Lot and Expiry

Responder sends Y or N and optionally a comment

Solution Provider

Manufacturer

Manufacturer

VRS

VRS

Distributor

Distributor
DSCSA Verification Router Service

Needed for 2019

How do we do this with standards? ... enter GS1
Journey to Verification Messaging Standard

Collaboration between GS1 Global, GS1 US & HDA VRS Taskforce

Dec 21, 2018
Ratification of GS1 Standard

Dec 12, 2018
Draft standard approval

Aug 16, 2018
BRD approval

May 21, 2018
GSMP workgroup launch

Mar 2, 2018
WR entry
GS1 Verification Messaging Standard
Designed for global cross sector use

- Driven by urgent (Nov 2019) DSCSA deadlines, but developed as a **generic lightweight framework** that will support use and extension by other sectors (e.g. food, technical industries) in distinct regulatory jurisdictions

- Specifies a standardised, *simple* (“lightweight”) messaging framework that foresees:
  - verification request and response
  - provision of actionable information that enables the requestor to determine whether to accept, reject, or quarantine the product
GS1 Verification Messaging Standard
Positioning within GS1 Architecture

- Verification Message as new addition to the 'Share' layer

- First ever GS1 “Share” standard to...
  - leverage the new GS1 Digital Link standard (verification request syntax)
  - include JSON as a message response syntax (verification response syntax)
GS1 Verification Messaging Standard

What is GS1 Digital Link?

GS1 Digital Link provides a Web-friendly way to express any GS1 identifier (including compound keys) and associated data attributes as a Web URI that works on the Web and enables retrieval of associated information through a straightforward Web request (HTTP GET)

(01)00361414567894(10)400806(21)1908642E(17)170728

translation

https://id.gs1.org/01/00361414567894/10/400806/21/1908642E?17=170728
https://id.gs1.org/gtin/00361414567894/lot/400806/ser/1908642E?exp=170728
https://example.com/gtin/00361414567894/lot/400806/ser/1908642E?exp=170728
GS1 Verification Messaging Standard
Redirection of GS1 Digital Links

https://id.gs1.org/gtin/00361414567894/lot/400806/ser/1908642E?exp=170728

Make a Web request (HTTPS GET)

Resolver

Product Description Web Page

E-Leaflet

Verification Service

linkType=elLeaflet

linkType=verificationService

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GS1 Verification Messaging Standard

Verification Requests

- In the DSCSA context, a product instance can be uniquely identified by the following four data elements:
  - GTIN - AI (01)
  - Serial Number - AI (21)
  - Batch/Lot Number – AI (10)
  - Expiry – AI (17)

...encoded in a GS1 DataMatrix as (01){gtin}(17){exp}(10){lot}(21){ser}, where {gtin}, {exp}, {lot}, {ser} are placeholders for actual values, e.g.: (01) 00361414567894 (17) 170728 (10) 1908642E (21) 400806
GS1 Verification Messaging - Requests
use of linkType to request specific type of information service

https://id.gs1.org/gtin/00361414567894/lot/1908642E/ser/400806?exp=170728
&linkType=verificationService
&context=dcsaSaleableReturn
&corrUUID=21EC2020-3AEA-4069-A2DD-08002B30309D
&reqGLN=0321012345676

GS1 Digital Link
( GTIN, Lot, Serial Number, Expiry Date )

Verification request
(configured for DSCSA Saleable Returns)

Positive Verification Response

OR

Negative Verification Response

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GS1 Verification Messaging

Next Steps

**Q1/2019**

GS1 US Rx workgroup development of Implementation Guideline for Verification Messaging Standard as part of the forthcoming revision (R1.3) of the GS1 US DSCSA guideline / application standard

**Q2/2019**

Target transition from HDA VRS Request / Response specification to GS1 Verification Messaging Standard
HDA and Industry Next Steps

- Solution Providers adopt new messaging standard in to their systems
- HDA exit planning for Verification Router Service
- Long term governance yet to be determined
Thank you!

• Many companies and team members participated in this effort
• Especially though…
  • Craig Alan Repec and Mark Harrison of GS1, Peter Sturtevant of GS1 US,
  • Jeff Denton of Amerisource Bergen, Elizabeth Waldorf of TraceLink and Allison Sheldon of Pfizer
2023 Requirements: Exchanging Serialized DSCSA Data
Serialized DSCSA Data Exchange

- Historical information sunsets in DSCSA transaction data
- Serial number, Lot Number and Expiry become mandatory in DSCSA transaction data
  - Applies to inbound receiving and outbound sales
  - Significant increases in bar code data capture needs
Questions?