The Global Language of Business

Global Standards Management Process

Messaging for Verification of Pharmaceutical Saleable Returns

Mission-specific work group

Call to Action

Background

Effective 27 November 2019, the U.S. Drug Supply Chain Security Act (DSCSA) requires wholesalers and distributors to verify the unique identifier of returned products before these can be placed into inventory for resale. The DSCSA defines verification as the process of "determining whether the product identifier affixed to, or imprinted upon on a package, or homogeneous case corresponds to the [unique identifier] assigned to the product by the manufacturer or the repackager." A manufacturer who receives a verification request from a repackager, wholesale distributor, or dispenser will be obliged to respond to that request within 24 hours.

The DSCSA expects supply chain parties to exchange information in "a secure, interoperable, electronic manner," adding "the form and format of exchanges shall comply with widely recognized international standards development organization."

Against this backdrop, pharmaceutical supply chain trading partners have asked GS1 to develop a verification messaging standard to enable system interoperability and prevent the proliferation of multiple message formats.

Objectives

GS1's Mission-Specific Work Group (MSWG) will gather the community and expertise needed **to develop a messaging standard for verification of Pharmaceutical saleable returns**. Initially designed to meet the requirements of the US FDA DSCSA, the completed standard could potentially also be leveraged for other regulatory jurisdictions requiring verification of serialized products.

Supply chain parties participating in the end to end distribution of pharmaceutical products have jointly defined the detailed business process steps for formulating a verification message, routing the verification request to the respective supply chain party responder and channelling the verification response back to the requesting party.

Benefits

The outputs of this group will provide:

- a mechanism to **support compliance with DSCSA requirements** for Verification of saleable returns,
- a streamlined, purpose-built **request/response messaging** set,
- a globally standardised solution to enable **interoperability** of systems,
- future-proofing through **protection against vendor lock-in,**
- an approach which can leverage the work of the **GS1 Structured Web URI** initiative.

The issue at hand

The U.S. Drug Supply Chain Security Act (DSCSA) requires Pharmaceutical supply chain partners to verify that the product in their possession is legitimate, not counterfeit, recalled or expired.

This will necessitate a near-real-time response from upstream trading partners when processing thousands of returns daily to determine if the product is resalable and can be returned to inventory, or cannot be verified and needs to be placed in quarantine for further evaluation.

In the wholesaler's distribution center, the receiving operator will visually inspect the returned product, and scan the GS1 DataMatrix for the GTIN, Serial Number, lot number and expiry date. Having captured these attributes, the wholesaler receiving operator becomes the "requestor", sending a verification request for the scanned product attributes directly to the manufacturer or to determine the proper disposition of the product.

Verification of product authenticity has implications beyond saleable return requirements. An extensible message solution would ideally enable manufacturers to respond to scalable set of verification requests from downstream trading partners, regulatory authorities and patients.

Who should join this work group?

Pharmaceutical traceability and supply chain experts who can:

- provide insights into current supply chain visibility practices;
- work towards consensus around a common approach;
- communicate this consensus within their own organisation.

How will the work group operate?

Pharmaceutical traceability and supply chain experts who can:

- **Propose and validate business needs**— analyse business needs from industry and collect additional feedback to ensure that industry objectives are met.
- **Develop standard** — supply chain and messaging experts will draft a standa standard and present it to industry for confirmation and approval.
- **Ratify and publish**— standards are approved by the development community, ratified by GS1 governance bodies and published.

Next Steps

1. Join the work group: https://www.gs1.org/standards/development-work-groups#MVPSR
2. Register for and participate in the group's kick-off teleconference on Thursday, 21st June, 11:00 - 12:00 EDT

"The GSMP is a community-based forum for businesses facing similar problems to work together and develop standards-based solutions to address them. Active GSMP participants represent industries ranging from retail and consumer goods to fresh foods, healthcare, transport and logistics, government and more—a healthy mix of business and technical people from nearly 60 countries."

Help or questions? Please contact:

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