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New Verification Router Service Upgrade Protects Patients from Illegitimate Products

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The verification router service (VRS) is a foundational system under the U.S. Drug Supply Chain Security Act (DSCSA), facilitating core processes like saleable returns and suspect product investigations. The system is vital to helping trading partners meet the product verification compliance requirements, and doing so in an operationally efficient manner.

This article dives into the recent VRS R1.3 upgrade and how it reinforces the infrastructure supporting the verification process, providing new capabilities that support new use cases and ensure medicines continue to flow across the supply chain without disruption.

What is a “VRS” and how is it used in the context of DSCSA?

DSCSA mandates certain requirements related to the verification of a product identifier (NDC, serial number, lot/batch number, expiration date) in certain scenarios, such as when the product might be part of a saleable return in the supply chain or subject to a suspect or illegitimate product investigation.

A VRS is an interoperable system that facilitates the request for verification of the product identifier applied to a serialized pharmaceutical product to determine if it was put into the supply chain by a licensed manufacturer and whether or not this product is safe to sell, has been recalled or is expired. Product identifiers that cannot be verified cannot be sold and suspect product investigation should begin.

When submitting a verification request, the requesting party does not need to have any direct relationship with the original manufacturer, nor any direct contact or technical connection to that manufacturer. VRS systems such as the **TraceLink Product Information Manager - Product Verification** solution have been designed to be part of an interoperable network that communicates with each other, sharing and routing requests and responses between VRS solutions to meet DSCSA requirements.

What is the R1.3 upgrade?

GS1 is a standards organization which has supported the pharmaceutical supply chain by creating data and interoperability standards for several DSCSA-related issues like EPCIS data exchange and VRS request/response messaging. The GS1 Lightweight

Messaging Standard provides a simple, standardized lightweight messaging framework for asking verification questions concerning serialized product identifiers and receiving actionable information concerning inquiries about those products. Its primary focus is to support VRS systems for DSCSA.

The **R1.3 upgrade initiative** was designed to promote enhancements to the foundational VRS solution network capabilities in support of new needs identified by pharmaceutical and healthcare supply chain members since the original VRS network deployment. Phase one was the development of the R1.3 version of the GS1 U.S. Lightweight Messaging Standard for the DSCSA Verification Implementation Guideline.

The R1.3 guideline update expanded the original capabilities of the VRS systems and the verification network they created. Key features of the enhanced standard include:

- Expanded data model and transaction capabilities to enable verifications for new use cases of suspect or illegitimate product investigation, exception processing, and product status checking.
- New contact data fields (email address, phone number), to be provided by requesters and responders, to facilitate questions and resolution of issues arising from verification requests.
- Support for verification of a product identifier, which has an extended expiration date beyond that which was originally set for the product when it was initially introduced into the supply chain.

- Support for possession or control attestations provided by the requester.
- Support for business rule setting message priority for product identifiers, which may have multiple application status conditions when a verification is requested.

Phase two of the R1.3 upgrade was the enhancement of the VRS solutions to support the enhanced standard and the interoperability testing of those solutions. This phase was executed in the summer of 2023. Solution providers such as TraceLink collaborated to develop 54 test cases and execute over 2,500 individual tests between systems and across the network. As a result of this testing, the VRS network was upgraded to the R1.3 standard in late July of 2023.

Why is the R1.3 upgrade important at this time?

Companies across the supply chain are ramping up their full production readiness to comply with the final phase of DSCSA, including the expiration of the previous saleable returns verification enforcement discretion. The Enhanced Drug Distribution Security (EDDS) requirements of the DSCSA regulations, which include requirements for enhanced verification, go into effect on November 27, 2023. Even though the FDA released updated guidance regarding the EDDS provisions that call for a 12-month stabilization period, it is expected that companies have the systems and processes in place to meet the EDDS requirements, including verification.

In addition, as companies not only look to comply with DSCSA regulations, but to do so in an operationally efficient and effective manner, there has been a growing focus on how to deal with exceptions that may arise from compliance processes. With the industry looking at VRS systems as an important tool for meeting DSCSA requirements, R1.3 and the related systems upgrades will “production harden” the DSCSA infrastructure that supports product verification. This is critical to not only helping companies and their supply/trading partners achieve compliance, but also to ensure that medicines continue to smoothly flow across the supply chain.

What should companies in the supply chain do right now?

Whether you are a manufacturer, repackager, wholesale distributor, or pharmacy/healthcare provider, now is the time to examine your company’s approach to product verification. This includes:

- Determining the verification needs your company may have for saleable returns, suspect or illegitimate investigations, or other use cases.
- Checking on the technical approach that you would use to verify a product identifier or respond to a verification inquiry for a product.
- Validating the operational processes that you would use for verification requests. Who is involved? What are the business rules in place? What data is required?

There is still time to prepare if you cannot clearly answer all of the above questions.

TraceLink can help!

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