

Evaluating a Verification Router Service: Four Key Questions to Consider

In November 2019, the Drug Supply Chain Security Act (DSCSA) Saleable Returns Verification requirement phases in, requiring wholesale distributors to verify saleable returned products before they can be placed back into inventory and resold.

This requirement introduces enormous challenges for not just wholesale distributors, but pharmaceutical manufacturers as well, as wholesale distributors will need fast, secure access to manufacturers' product data in order to minimise operational impact and ensure that saleable products are returned into the supply chain as quickly as possible. Time is running out before everyone in the drug distribution supply chain will have to routinely verify the serialised product identifiers for any saleable products that have been returned before they can be restocked and resold.

In this article, Dan Walles, general manager of track & trace and compliance at Tracelink discusses the considerations to take into account when evaluating a verification router service (VRS) and offers guidance on how to select a comprehensive solution.

Saleable Returns and the 2019 DSCSA Deadline

Saleable returns are estimated to represent approximately 2% gross sales* for wholesale distributors. A survey by the Healthcare Distribution Alliance (HDA) revealed that nearly 60 million units are returned annually. The present volume of annual saleable returns, the study found, is largely due to the industry's propensity to over-, rather than under-stock drug inventories to ensure supply covers demand.

With an estimated worth of \$10 billion, resold product is critical to helping manage overall supply more effectively and efficiently. Spanning

gaps in production and other shortages, stocks of returned medicines help distributors meet spikes in demand, manage sudden shortages and help replenish depleted stocks. This has become a valuable market segment as resold product is critical to meeting variations in product demand.

November Deadline is Looming

By November 2019, manufacturers will be tasked with responding to hundreds or thousands of verification requests each day from both direct and indirect trading partners. As wholesalers enter 2020, they will be required to verify the GTIN, serial number, lot and expiration date on returned products before re-selling. Failure to respond quickly risks action by the FDA.

The combination of the return volume as well as the number of products the typical wholesaler manages – which could be as high as 20,000 stock keeping units (SKUs) – creates a difficult data management challenge for wholesalers. Although the requirement is the responsibility of the wholesaler, participation from the manufacturer is necessary for compliance. Wholesalers and manufacturers will need to work together to ensure wholesalers have access to information from the manufacturer in a timely manner. It is critical that this new requirement does not slow down the receiving and return receipt process for wholesalers.

A Viable Approach to Meeting the Deadline: VRS

To help distributors and manufacturers minimise the impact of saleable returns on their operations, the HDA Returns Task Force has defined the verification router service (VRS) model to automate verification requests and achieve near real-time request/response performance.

For manufacturers, a VRS automates responses to verification requests from primary wholesalers

that do not choose to “self-verify” against an internal serial number repository, as well as from secondary wholesalers and dispensers that may not have a direct relationship with the manufacturer.

For wholesalers, a VRS ensures that returned products can be verified if a manufacturer is not providing EPCIS data with its shipments or if the status of the product has changed since the original shipment was received, either by a recall, withdrawal, or suspect product investigation. With a VRS, product verification remains with the manufacturer, eliminating the potential liability of self-verifying against an internal serial number repository.

While the HDA VRS task force has established a set of technical guidelines to ensure industry-wide adoption, not all VRS solutions offer equivalent functionality and utility. It's critical that wholesalers and manufacturers discuss their returns verification requirements with each other, and ask these key questions as they consider a VRS solution:

1. Is the VRS based on open, interoperable standards?

A wholesaler may publish a verification request using one VRS, but the responding manufacturer may use another. The process relies on the lookup directory, which operates as a phone book that is synchronised across VRSs. Any VRS based on closed, proprietary technologies puts companies at risk of ending up on an island: no other VRS will be able to publish information to or from their lookup directory.

2. Does the VRS integrate product master data access?

With serialisation, the National Drug Code (NDC) number that was previously used to identify a product will be replaced by an encoded Global Trade Item Number (GTIN). With many

wholesalers managing in excess of 20,000 prescription drug SKUs, they need up-to-date product master data from manufacturers to ensure GTINs are correct to avoid verification failures. The VRS should provide the ability to integrate master data sharing so manufacturers can distribute up-to-date master data to their trade partners. Wholesalers should look for the capability to access product master data directly from their suppliers and use an automated solution to ensure their product master data remains up-to-date.

3. Can the VRS meet sub-second performance requirements?

The HDA task force has specified that wholesalers need near real-time responses to verification requests to minimise any disruptions to warehouse operations. A VRS that offers a scalable architecture and partner connectivity is critical to deliver the performance requirements of the HDA VRS model.

4. Can the VRS work with ERP and WMS systems?

Separating saleable returns verification – including partner connectivity, serialised data exchange, and request routing – from everyday business operations is an important benefit of a VRS. But it's also important that a VRS can integrate with your existing business systems and warehouse scanning solutions to track the status and location of returned products.

In asking these questions, both manufacturers and wholesalers should be able to determine which VRS solution will give them a fast track to

DSCSA compliance, while providing robust performance with master data sharing for uninterrupted business efficiency.

Preparedness Forecast: Partly Compliant with a Chance of Sanctions

A recent poll of attendees from TraceLink's Saleable Returns webinar series found that companies should start their planning immediately to be ready by November, as an alarming percentage of webinar attendees did not have a final plan in place for managing saleable returns.

Less than 10% of the manufacturers and wholesalers attending the webinar indicated that they were ready for the deadline. Only 15% were in the process of evaluating a saleable return solution, while the remaining 75% of respondents said they have only had initial conversations or are just starting to address how they will meet the saleable returns requirement.

How does the complexity of the November 2019 saleable returns verification requirement feel in comparison to the previous DSCSA lot level and serialisation regulations? According to a more recent TraceLink poll during its April 10 webinar, about 17% felt it was more complex. Others responding (23%) found it to be similarly complex, and 17% indicated they felt confident things were less complex because they had an established foundation on a network platform. Some 17% found things less complex, because they had a trusted partnership with a solution provider. Lastly, 26% were confident of their readiness because they could respond affirmatively that things were less complex because they had both an established system and a trusted supplier.

Webinar polling results also explored if attendees have a way for direct and indirect trading partners to digitally access their product master data. Only 3% said yes, for both direct and indirect partners. Another 30% responded yes, but only for direct partners, while 67% indicated, no, it's a manual process.

Lastly, TraceLink asked webinar attendees to share their biggest concern about saleable returns verification. For about 10%, impact on operational efficiency was a major concern. Only 4% felt unauthorised access to product data was a worry. Being overwhelmed by verification requests was concerning for 10% and being cited by the FDA for non-compliance made the top of the list of concerns, with 62% noting anxiety about regulatory scrutiny. Finally, some 14% indicated network performance and reliability was another top-of-mind concern.

Time for Industry to Work Toward Alignment and Collaboration

As manufacturers, wholesale distributors and other parties examine their operational requirements to meet saleable returns verification mandates, they should work toward aligning systems to meet both business and compliance priorities. Solutions that support real-time data exchange through digital information platforms based on open, interoperable standards will inherently be more effective and ensure uninterrupted flow across the supply chain under the DSCSA's requirements.



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