McKesson Q&A: The Challenge of Saleable Returns Verification



The November 2019 Drug Supply Chain Security Act (DSCSA) Saleable Returns Verification requirement isn't just a challenge for wholesale distributors. Manufacturers will also be impacted by verification requests and need to create a plan now for how they're going to manage them.

TraceLink spoke to Scott Mooney, Vice President of Distribution Operations at McKesson about the challenges wholesalers face with the DSCSA saleable returns verification requirement—and the critical role manufacturers play in keeping legitimate products in supply. Mooney has over 30 years of experience and is an active participant in the HDA group working to address issues around saleable returns and their impact on warehouse operations.

What are the details of the 2019 returns verification requirements?

In the DSCSA requirements, there are two rules coming in November 2019 that will affect how wholesalers handle returns. The first rule is that a customer has to prove that they purchased an item from a wholesale distributor. We have to be able to answer the question, "Did we originally sell that item to that customer?" That means we have to associate the original transaction information (TI), transaction history (TH), and transaction statement (TS) with that product before we can accept it back as a saleable return.

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This process of verifying proof of purchase is something that's typically going to be performed internally by the wholesale distributor and doesn't require any engagement with the manufacturer.

The second rule is that if a product that's being returned for resale has a serial number on it, we have to confirm or verify the information that is in that serialized barcode against the data the manufacturer assigned. That's when the manufacturer needs to be involved.

What is the main reason returns come back from pharmacies to distributors?

Pharmacies either over order or type in the wrong number accidentally—they meant to order 10 bottles but they accidentally punched in 100. Or they keep three on the shelf, but the patient moves on after one bottle, so the other two just sit there. Eventually, those bottles come back to the distributor.

What role does manufacturer's data play in a saleable return?

The DSCSA language is laid out very specifically to say that a saleable return has to be verified "against the data the manufacturer assigned." That means that either the manufacturer has to provide the data they've assigned to the product when they sell it, or the wholesale distributor has to be able to come to the manufacturer and ask about the assigned data.

Why is the manufacturer's master data critical for accurate verification?

There are variances in the information contained in the new DSCSA-compliant 2D barcode that we need the product master data to resolve. Specifically, we need to use master data to interpret how different manufacturers assign packaging level codes in order to determine exactly the number of units inside a container.

It's not only for the new items that you're introducing into commerce. It's for the 60,000 items we already have set up in our systems that will now be displaying 2D

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barcodes. Systemically, somehow, we're going to have to figure out what that master data is and how to get it from the manufacturer.

Are manufacturers beginning to understand their role in saleable returns verification?

Back in 2016 to 2017, I was talking to a lot of manufacturers about returns and they said that saleable returns weren’t a problem for them, because they don’t take salable returns. So they felt that they didn’t have to worry about it.

However, saleable returns are part and parcel of the routine business between a pharmacy and the distributor. In some cases, there could be as many as 1,500 to 1,600 returns per day across a network that will require a wholesale distributor to reach out and check the serial number with a single manufacturer. "I'm looking at Bottle 12345. Can you tell me if Bottle 12345 legitimately matches what you have in your database?"

Can you determine if you can verify a product internally, or “self-verify”?

When we get a return, we open the tote and, for example, find that there are 15 different products inside the tote.

First, the operator in the warehouse picks out that first bottle and scans it to see if we have an original invoice in the system to be sure we sold it that customer. Then, if the manufacturer has pushed data to us that says that they sold us that particular product, we'll check the scan against our internal repository to see if we have that serial number on file.

If we don’t have the manufacturer’s product data, we then need to punch out from our internal repository, find out where the manufacturer data is located, and verify that product using an external repository.

How will wholesaler warehouse operation concerns put pressure on

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manufacturers?

The law says manufacturers have 24 hours to respond to a verification request. That could disrupt the returns process quite a bit. We can't afford to have the operator store a returned item somewhere and then try to find it once we get that verification. We need this to be an almost instantaneous response.

To solve the response time issue, McKesson, TraceLink, and several industry groups have been working on a solution based on a Verification Router Service, or VRS.

What is a verification router service and how does it work?

In layman's terms, a VRS is like using a Google search directory. The distributor scans the returned item and captures the GTIN and other relevant information that's included in its barcode. If we don’t find it in our internal database, we would go out to a VRS, which knows where the manufacturer data is stored, routes the verification query there, and brings the response back.

It's a lot like doing a search on the Internet, which takes a URL and translates it into an actual IP address, so it knows where to bring you.

How can wholesalers and manufacturers connect through a VRS?

There are 120 wholesale distributors and 600 primary manufacturers in the United States, so how do we find all of that data? This is a large part of the challenge we've been trying to solve through a VRS—how to set up rules around maintaining that data and making it available.

What we're looking for as a distributor is simply a table that says, "Where do you store your data?" so that we can use a VRS to route that query appropriately to that manufacturer. The manufacturer may store their data themselves or they may store their data with a solution provider like TraceLink.

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What about recalled or withdrawn products with valid serial numbers?

If the response says the serial number's bad, it's going to trigger an illegitimate product investigation. But in the case of a recall, the serial number may be good, but the product should not be re-distributed because the manufacturer has recalled it.

We're participating on the work being done through HDA and GS1 on the language around the verification query. Mostly, the query is going to say, "I'm looking at this GTIN with this expiry, this lot number, and this serial number. Is this correct?" We're looking for a "yes," a "no," or a "no" and a comment. The comment could be something like, "The serial number's good but this product's on recall."

Can a VRS protect manufacturers from unauthorized requests?

The manufacturer's obligation under the DSCSA is that you need to respond to a verification request from an authorized trading partner. Even though you may be pushing data to the primary distributor, you will get inquiries from somebody else from time to time.

An authorized trading partner could be any pharmacy with a pharmacy license under DSCSA. You may get verification requests from pharmacies not for returns purposes, but just to verify an item. So even if you're pushing data to your distributors, you'll want a VRS as well to verify and manage verification requests from your indirect trading partners.

The HDA working group has laid out protocols for the VRS to include logic to ensure that a requestor is authenticated. The system manages to make sure that requests from unauthenticated parties don't get passed through.

How can manufacturers help distributors be ready for the 2019 requirement?

The most important thing we're looking for, as a distributor, is that manufacturers start moving to saleable returns verification now, just like wholesalers need to be

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doing. As an industry, we’re not going to be ready in time unless all parties get going.

About TraceLink Product Information Manager

Automating the saleable returns verification process depends on the ability for partners to manage and share information on a secure, scalable platform. TraceLink’s Product Information Manager delivers master data sharing, verification routing and verification response capabilities to help both pharmaceutical companies and wholesale distributors meet the DSCSA 2019 saleable returns verification requirement. It seamlessly integrates with TraceLink's existing master data and serialization solutions or can integrate to 3rd party master data, Level 4 serialization repositories or other business systems such as WMS or ERPs.

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