The Importance of Product Master Data

With incoming requirements coming into effect later this year, the need for manufacturer participation in saleable returns verification and the implications on master data exchange requirements is becoming increasingly necessary

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By November 2019, wholesale distributors will be required to verify the serialised product identifiers for any saleable products that have been returned to them before they can be restocked and resold. With this new saleable returns verification requirement, the challenges of master data exchange for manufacturers will come to the fore.

To manage the scope, scale, and challenges of the saleable returns requirement, wholesalers and manufacturers must re-evaluate their current methods of exchanging product master data information.

The Scale of the Challenge

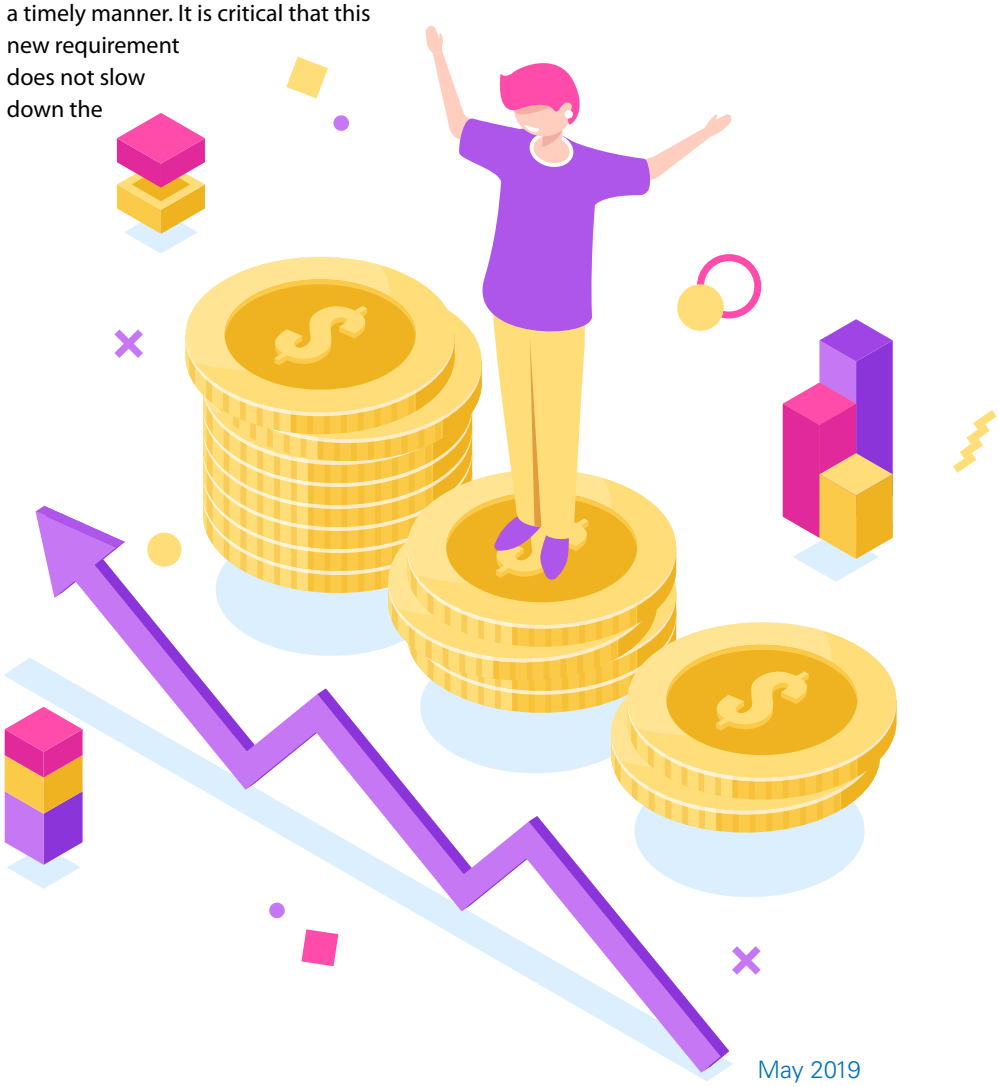
The national organisation representing primary wholesale distributors in the US, the Healthcare Distribution Alliance (HDA), executed analysis of saleable returns. This showed that approximately 60 million units of drug product are returned annually, with the majority of saleable returns caused by overstocking (1).

With an estimated worth of US $5-10 billion, this is a valuable market segment, as resold product is critical to meeting product demand and minimising shortages and stockouts. As of the November 2019 deadline, wholesalers will be required to verify the Global Trade Item Number (GTIN), serial number, lot, and expiration date on returned products before reselling.

The combination of the return volume, as well as the number of products the typical wholesaler manages (which could be as high 20,000 stock keeping units), creates a difficult data management challenge for wholesalers. Although the requirement is the responsibility of the wholesaler, participation from the manufacturer is essential for them to meet this requirement. Wholesalers and manufacturers 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.

Verification Router Service Versus Self-Verification

Fundamentally, there are two approaches to compliance with the saleable return verification requirement: self-verification and verification router service (VRS).



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With self-verification, primary wholesalers verify returned products against an internal serial number repository that is populated by the Electronic Product Code Information Services (EPCIS) data provided by the manufacturer with each shipment.

The VRS approach is the process of verifying the GTIN, serial number, lot, and expiry data directly against a manufacturer's verification service. When the wholesaler verifies against a manufacturer system, they first submit the GTIN to a lookup directory. The lookup directory provides the URL (or internet address) of the manufacturer's VRS. Once received, the wholesaler's system sends the request to that location and waits for the response. This series of request and response choreography takes less than a second, eliminating any delay to receiving processes.

For wholesalers, a VRS ensures that returned products can be verified if a manufacturer has not provided EPCIS data with its shipments. Even if a manufacturer sends EPCIS, it is likely they will also need a VRS, as there will be some wholesalers that do not have the capability to receive EPCIS shipment, nor the internal systems to self-verify. For these wholesalers, they will want to verify directly against a manufacturer's VRS. Similarly, wholesalers that would prefer to self-verify should also be prepared to use a VRS, as it is unlikely that all manufacturers will be willing and able to send EPCIS shipment data.

Master Data Significance

Whether VRS or self-verification, the availability of accurate, up-to-date product master data and product GTIN information is critical for both. When the wholesaler scans the 2D DataMatrix barcode, the GTIN will be used to complete further processing. If the GTIN is missing or relates to incorrect product information, those processes will fail or result in inaccurate data. Therefore, it is critical that wholesalers and manufacturers agree on automated, electronic methods to receive new and updated GTIN and product master data. The current methods of providing this information through emails, spreadsheets, and faxes have the potential to result in inaccurate and outdated information.

Navigating these complexities and selecting a solution that minimises the impact saleable returns have on workflow disruptions will be crucial to compliance and operational success.

Interoperability

The Drug Supply Chain Security Act (DSCSA) is creating requirements for the industry to exchange information at a scale far beyond what they do today. Whether exchanging product master data, EPCIS information, or verification request and response transactions, standards and interoperability across systems is critical.

Through GS1 and the HDA, industry and solution providers have been working to ensure that standards are adopted for each of these information exchanges. Solution providers that seek to provide proprietary and custom information exchanges are hindering the industry's ability to meet compliance timelines and creating risk for customers and trade partners.

When evaluating solutions and their providers, manufacturers and wholesalers should require that the solution complies with these standards and that providers have performed interoperability testing with other solution providers and are active in the standards groups. Failure to do so may result in the manufacturer or wholesaler not being ready on time as they try to understand the standard and implementation best practices.

Next Steps

As manufacturers, wholesale distributors, and other parties examine their business needs and operational requirements to meet saleable returns verification requirements, they should prioritise system interoperability, risk management, and network connectivity. As such, solutions that facilitate real-time data exchange through a digital information platform based on open, interoperable standards will be inherently preferred to ensure uninterrupted flow across the supply chain under the DSCSA's requirements.

Reference

1. Visit: www.hda.org

About the author

Dan Walles is the General Manager of Track & Trace and Compliance at TraceLink, where he brings more than 20 years of experience in product management, solution consulting, and service delivery to his role. He has focused exclusively on the needs of the life sciences industry for the past 15 years. Since joining TraceLink in 2010, Dan has been instrumental in educating customers on TraceLink's Life Sciences Cloud and partner ecosystem to enable compliance and added business value through supply chain visibility and improved patient outcomes.

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