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Understanding how Serialised Data Can Impact Warehouse Operations

The EU Falsified Medicines Directive (FMD) deadline is now days away and all segments of the pharmaceutical supply chain are focused on finalising their solutions to comply with the regulation.

Many companies responsible for distribution in the European market have prioritised connecting to the European Hub so they can exchange product master data across the supply chain to verify product before it is released or dispensed. It is vital that companies are also prepared for three important exception-based use cases that, if unaccounted for, will mean non-compliance with the FMD.

Larry Hall, General Manager of Smart Supply and Logistics at TraceLink, describes each use case and the solution required for all three.

1. Product leaving the supply chain prior to point of dispense

Articles 16, 22 and 23 of the Delegated Regulation affect companies responsible for pharmaceutical distribution in the EU when it comes to decommissioning and reporting on products that leave the supply chain without being dispensed.

The articles provide for several instances where responsible parties will be required to decommission and report this event to either the European Medicines Verification System (EMVS) or the appropriate National Medicines Verification System (NMVS).

Specific occurrences are:

- Article 16 – when products have had safety features removed or covered and been put into a different container or re-labelled. This can occur often when supplying clinical trials where returns from trial sites are more prevalent and supply requirements can change regularly as a result of attrition rates.
- Article 22 – when a product is:
  a) Being exported outside the EU to another country and was originally created for the EU market
  b) Returned to a wholesaler from an authorised party and cannot be added to saleable stock
  c) Scheduled to be destroyed
  d) Requested as a free sample by a competent authority
  e) Distributed to an institution that is declared to be outside of the pharmaceutical supply chain.
- Article 23 also addresses product that is shipped to certain entities within the EU other than a hospital or pharmacy such as universities, veterinary surgeons and government bodies. Its implementation is open to interpretation by each Member State's healthcare authority.

Warehouse operations are directly impacted by each Article and there are a number of inherent complexities to be managed. Most prominently, warehouse operations must figure out which system, the NMVS or the EMVS must be notified for each product and then spend time on the actual decommission reporting. These additional processes could distract operations teams from their core activities where resources are more efficiently spent managing inventory or receiving, packing and shipping within the warehouse.

2. Risk-based verification for saleable returns

Currently, warehouses do not have to verify saleable returns, defined as a returned product intended to be put back in stock for redistribution, but this will be a requirement under the FMD. Warehouse teams currently rely on manual, paper-based processes and phone calls for verification when asked to confirm and decommission a product that came from their site. Bringing risk-based verification into your processes to ensure compliance is going to create the need for operational warehouse changes.

When a product follows its normal distribution path – moving from the manufacturer to the wholesaler/3PL and on to the point of dispense – and decommissioning only occurs at the point of dispense, risk-based verification is not required by FMD.

However, products can deviate from this 'normal' path and when they deviate it adds complexity to tracking down the origin of a product, verifying it and validating its authenticity. This can cost a warehouse a tremendous amount of time. A typical example of deviation is when a wholesale distributor sells a product to another wholesale distributor or 3PL, or when a 3PL sells a product to another 3PL or distributor.

With risk-based verification, product must be verified against a national system by rescanning product to verify identity and isolate any potential risks as much as possible. Without an automated solution in place to verify product, the process could be quite lengthy and the costs could be significant.

3. Serial number status change or updates

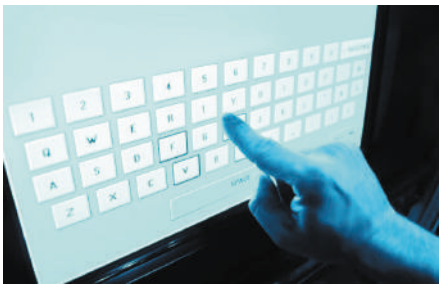
As stated above, a normal path of distribution is defined as product moving from the manufacturer to wholesaler/3PL and then pharmacy or point of dispense where the product is decommissioned from the supply chain. There are a number of events that can occur along this path that will require reporting.

For instance, if a product has been damaged or locked for investigation, its serial number status must be changed in the respective NMVS. This can also occur if a product was incorrectly reported to the NMVS, in which case an organisation will have ten business days to make the correction to the appropriate government system.

Preparing for and Managing these Use Cases

For some organisations, only a small percentage of shipments may be impacted by these use cases, a number small enough to weaken the business case for changing the scanning operations of an entire warehouse, but large enough that it can't be ignored. So what is the answer?

Since compliance is a main priority for companies, particularly with the regulation being enforced on 9 February 2019, you will need a solution to deal with these exceptions, and selecting a solution provider with proven expertise in serialisation will be essential to making sure you are prepared and compliant. Warehouse management systems are highly complex and customised and most can't handle serialisation requirements, including the storage of the massive amount of data generated, connecting with the EU Hub and delivering the necessary reporting capabilities and updates necessary to accommodate future



FMD mandates. Further customisation to include these use cases could be a time-intensive, costly and high-risk undertaking. Therefore, a seamless solution that minimises disruption in workflow is essential.

An application that can layer serialisation requirements alongside a warehouse management system, rather than embed them into one, would allow for real-time information scanning and ensure compliance while increasing business efficiencies. Additionally, with a cloud-based network approach, automated verification can be done in real time, freeing warehouse staff from the complex and error-prone manual verification processes and allowing them to focus on core operational tasks.

Larry Hall

Larry has over 30 years' experience in management, business process design and enterprise software solution sales, design and implementation for global corporations in pharmaceutical, logistics, aviation, defence, high-technology and other industries. As an individual contributor, he has defined implementation methodologies and implemented major solutions for a number of Fortune 100 companies. Larry was the co-founder and Vice President of Sales and Operations of ROC IT Solutions, the leader in intelligent edge data capture for serialised product inventory in the pharmaceutical supply chain, before it was acquired by TraceLink in 2017.