EU FMD and Risk-Based Verification in the Warehouse: Top Questions Answered



Under EU FMD, if you are a wholesale distributor and bring product into your facilities that you didn't purchase directly from the Marketing Authorization Holder (MAH) or a designated wholesaler, then you need to verify that product. There is a common misperception amongst companies preparing for EU FMD that warehouses will only have to verify 10% of products. In fact, the law will require that you verify every single product that meets those criteria before it can be resold.

Here are six commonly asked questions and answers regarding EU FMD compliance and risk-based verification:

After EU FMD goes into effect on February 9, do I have to go back and verify products in my warehouse that aren't serialized?

Wholesalers are required only to verify products that bear the safety features (the anti-tamper device and the unique product identifier) mandated under EU FMD. The application of those safety features is optional until February 9, 2019 when the law goes into effect. There is no requirement to go back and verify products that come in without safety features before that date.

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How is verification going to impact my warehouse operations?

Under EU FMD, you will have to implement the new process of risk-based verification into your warehouse operations, including figuring out staffing and creating standard operating procedures (SOPs) for how it will work.

Besides those issues, there is going to be a point in time when you start to receive more of the same product already in your warehouse, but the new product will be serialized. That new serialized version of the product will need to be verified and scanned, while the old non-serialized product will not. Having the two versions of the same product stored together could lead to potentially picking a serialized product for distribution without verifying/scanning it, which would result in your warehouse being non-compliant. One way to handle this is to segregate the new serialized product in your warehouse and manage that separately from the older non-serialized product, so the non-serialized product is distributed first.

We participate in the Good Distribution Practices (GDP) wholesale standards and are active in cross-docking activities, where products come into our warehouse from a supplier and are distributed directly to a customer with little if any handling or storage time in our warehouse. Do we need to verify cross-docking shipments according to EU FMD?

Yes, verification is required for cross-docking as the products are leaving the physical possession of the wholesaler. The only time that you wouldn't have to verify when cross-docking is if the product was being distributed to another wholesaler in your same parent company.

When my wholesale business imports products from one EU market to another, and we receive shipments and hold them before delivery to the buyer, do we need to verify those products?

Yes, you would need to verify the products being imported since you are receiving them into your warehouse. There is one caveat to this requirement—products that

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are shipped directly from the manufacturer or a designated wholesaler do not require verification, but any damaged products from the manufacturer would need to be decommissioned.

Can inbound verification be done on the aggregate level for the sake of warehouse operational efficiency?

The National Systems do not support aggregation, so packs must be scanned individually instead of on an aggregate level. Aggregation enables you to associate the "child" items of the saleable units with their "parent" case to build a "parent-child" relationship of those serial numbers and scan just the parent case instead of having to scan each saleable unit.

What's the most efficient way to perform risk-based verification in the warehouse?

TraceLink's Smart Inventory Tracker manages risk-based verification for warehouse operations. It's a mobile application that can be used on handheld scanners or smartphones in the warehouse to verify and decommission products, including in the case of saleable returns. Smart Inventory Tracker enables the scanning and interpreting of a serial number, and stores it in a company's TraceLink serialization repository.

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