

EU FMD: 3 Key Compliance Challenges for Your Warehouse—and How to Solve Them

The European Union Falsified Medicines Directive (EU FMD) is now in effect, and companies with warehousing operations will want to make sure that warehouse-specific requirements have not gone overlooked in the frenzy to prepare. Both a clear understanding of the compliance requirements and a strategy to overcome potential threats to your warehouse's operational efficiency are fundamental to your success.

First, it's important to understand how these regulations apply to your business. Companies impacted by these requirements include manufacturer authorization holders (MAHs) that manage their own distribution, MAHs that are also licensed as wholesale distributors, wholesale distributors, and some third-party logistics providers (3PLs). For these entities, there are three key use cases, each with unique compliance challenges that need to be met:

1. Shipping and distribution
2. Risk-based verification
3. Serial number status management

Second, you should understand what's at stake. The compliance risks are clear—if you fail to adhere to EU FMD regulations, you will pay higher fees to the EU and not

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be legally able to ship your medicines, potentially damaging your revenue stream and reputation. But equally important are the operational risks you face as you rise to meet these challenges.

The following use cases illustrate both the challenges and the opportunities you can leverage to achieve compliance and create efficiencies in your processes.

Use Case 1: Shipping and Distribution

Requirement

There are three articles of EU FMD that address distribution and shipping and require decommissioning of serial numbers:

- Article 16: Decommission before repackaging or relabeling for free samples or clinical trial product.
- Article 22: Decommission for product exported from the EU, unsaleable product, and product to be destroyed.
- Article 23: Decommission for product distributed to non-healthcare institutions such as schools or nursing homes that aren’t required by law to decommission medicines.

Adherence to each article requires reporting to either the EU Hub or the National Medicines Verification System (NMVS).

Warehouse Impact

To comply, your warehouse operators will need to decommission serial numbers of products for many reasons, including these three:

- Article 16: When a product's safety features (consisting of a unique identifier in the form of a 2D data matrix code and an anti-tampering device) are removed, for example, by a clinical trial channel partner.
- Article 22: When a product that was originally slated for sale in the EU is exported to a country outside the EU or is now being offered as a free sample.

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- Article 23: When the product is being supplied to an entity other than pharmacies, hospitals, or other healthcare institutions, for example, prisons or schools.

Clinical Trials and Article 16: When products are used in a clinical trial, their safety features are removed and the drugs are placed in different containers so patients do not have visibility into whether they are taking an active drug, placebo, or ineffective drug for the trial.

Each of these articles results in exceptions to your normal warehouse operations, along with complex decision making for your warehouse operator and systems.

Solution

To meet these requirements, your warehouse needs a compliance solution that will decommission serial numbers of products and report that decommissioning to the EMVS or NMVS. For Article, 23, your compliance solution should also offer unique logic that takes information about the country and the entity being shipped to, along with all batches and serial numbers, to understand what's there and how/where to declare it.

Use Case 2: Risk-Based Verification

Requirement

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. Under EU FMD, this risk-based verification will require that 100% of returned products be verified before they can be put back into the market for resale.

Warehouse Impact

To comply with EU FMD, you will have to implement the new process of risk-based verification into your warehouse operations, including figuring out staffing and

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creating standard operating procedures (SOPs) for how it will work.

As returns or verification requests come into your warehouse or your 3PL's warehouse, the status for each corresponding serial number needs to be updated with the new status for the product, which could be:

- Available for resale
- Needs to be destroyed

Solution

For risk-based verification compliance, you need a compliance solution that scans the serial numbers of the products in question and verifies them against the national repository. You will receive a response that the unique identifier is valid or not. If it's the latter case, those serial numbers will be locked for further use until they are investigated.

Use Case 3: Serial Number Status Changes and Updates

Requirement

In the pharmaceutical supply chain, serial numbers are assigned as "commissioned" to product packages to say that those products are ready for sale in the European Union supply chain. The practice of decommissioning serial numbers serves to keep drugs out of the supply chain once they are expired or dispensed, so criminals can't resell or distribute them.

Warehouse Impact

There are many times when a serial number status changes/needs to be updated in your warehouse before it is dispensed. The two primary reasons are:

- **Damaged Product:** The serial number needs to be decommissioned from the supply chain and temporarily locked for investigation, with the status

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update reported to the national repositories (EMVS or NMVS).

- **Suspect or Stolen Product:** The serial number needs to be decommissioned from the supply chain or temporarily locked for investigation. In the case of a suspect or stolen product, the 10 business days/240 hours rule does not apply as it’s known that the investigation could take longer than that timeframe.

Solution

For EU FMD compliance, your warehouse needs a compliance solution that will verify and update the status of the serialized product in your Warehouse Management System along with appropriate reporting of status updates and changes to the EMVS or NMVS based on your credentials.

Compliance and Efficiency Rolled into One

With all of these complex requirements, it's easy to see how meeting your compliance requirements may seem to be in direct opposition to running an efficient warehouse operation. Without the right approach, these requirements can turn into operational challenges in the future, such as time-consuming and error-prone manual processes, and costly software integrations with existing systems that aren't designed for the job.

TraceLink's compliance solution includes Smart Inventory Tracker, which is a mobile application warehouses can use to streamline these processes, reduce errors, and assure compliance with EU FMD mandates. Usable on hand-held scanners and smartphones, Smart Inventory Tracker enables the capture of complex reportable transactions with a single scan, including verification and decommissioning, risk-based verification, and managing serial number status changes. That information is in turn stored in TraceLink's highly scalable cloud-based architecture and can be used to make direct reports to the National System for wholesalers using a wholesaler connection or in some circumstances can be reported directly to the EU Hub for marketing authorization holders.

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With the right approach, solving for the EU FMD's complex mandates not only achieves compliance and reduces risks to your business—it also opens the door to improvements in operational efficiency across your warehousing functions, now and in the future.

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