RESOURCES

How Do I Prepare Product Master Data for EU FMD?



In the course of working with hundreds of companies across the pharmaceutical supply chain, we receive many questions on the upcoming EU FMD requirements. In this article series, we'll answer one of your questions each week. This week, we look at product master data requirements.

Product master data is a single source of the truth, a reliable record of basic information such as product name, identification code, and dosage. In addition to this foundational information, different markets around the world have additional requirements as part of their serialization or track and trace regulations. For this reason, even if you operate in the U.S. and have already prepared product master data for DSCSA, you still have work to do for the EU Falsified Medicines Directive (FMD), which requires the Marketing Authorization Holder to prepare specific product master data for each target market, including:

- Effective date
- Product type (RX/OTC)
- Marketing Authorization Holder name
- Distribution partner(s)
- EMVS dosage form
- PAC code
- Target market(s)

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Target market is critical, as some markets require a product code in a format specific to that market. The European Hub will route these through to the relevant National System so that the product can be sold there.

If you fail to collate and submit an accurate master data set, your product will not be able to be sold in the EU.

Preparing Your Product Master Data

The first thing to do is identify all of your products that are subject to EU FMD and their respective target markets, in order to create a list of all of the required information, as the requirements vary by market. Once you have that list, you can involve the necessary personnel in your organization and define responsibilities for:

- Gathering the data.
- Collating it in the correct format for upload to the European Hub.
- Establishing a process for keeping it up to date.
- Uploading it to the Hub.
- Developing a policy for capturing master data for new products.

If you sell multiple products to multiple markets in the EU, this will be a substantial task and involve a large volume of data.

Simplifying Master Data Upload to the European Hub

Companies who use TraceLink benefit from a master data management solution that automatically routes your product master data to the European Hub, thus reducing implementation time and risk.

The TraceLink solution helps companies consolidate master data in one central area - something many pharma companies have traditionally struggled with, since there is typically no single place within their organisations where master data is stored. Then, to ensure successful compliance reporting, the TraceLink solution has

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built-in intelligence to manage the mandatory master data for each target market. It automatically populates the necessary master data elements required for each compliance report to the European Hub, which means fewer details need to be manually entered. This reduces time and also the risk of incorrect or incorrectly formatted data being uploaded.

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Learn more about TraceLink's solutions for EU FMD compliance.
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