RESOURCES

Can You Afford a Manual Approach to EU FMD Compliance?



The European Medicines Verification Organization (EMVO) offers a manual upload portal to allow Marketing Authorization Holders (MAHs) to send their serialized product data to the EU Hub, where it is distributed to the individual National Medicines Verification Systems (NMVS) for point-of-dispense verification at hospitals and pharmacies. For some MAHs—particularly ones with low volumes—the manual option seems like a sensible choice. But is it really as straightforward as it sounds?

Manual data upload through the EMVO portal is simple in concept, but the experience and effort required to prepare, package, and maintain that data presents a significant challenge for companies with limited resources.

EU FMD compliance reporting is more than a “simple” upload

Sending data to EMVO is only one part of a company’s FMD compliance responsibilities. There are a number of other important tasks that require additional time and resources before and after data is uploaded. These responsibilities include:

- **Data preparation:** The collection and formatting of master and serialized pack data as 100% error-free JSON or XML data as required by EMVO.

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- **Data management:** The storage and handling of master data, serialized pack data, product status, and exceptions through the European hub.
- **Notification management:** Understanding how to send and track notifications governing each target market, including product withdrawals, recalls, or suspected falsification alerts.
- **National requirements:** Understanding each country's product coding scheme and additional data requirements such as national reimbursement numbers.
- **Change management:** Monitoring and responding to updates or additions to EMVO or NMVS policies and procedures.
- **Record keeping:** Complying with Article 15, which states that manufacturers must keep records of all operations performed on the unique identifier.
- **Responsiveness:** Ensuring timely information retrieval for auditors, authorities, or trade partners, for example, in case of a suspected falsification investigation.
- **End-user training:** Maintaining competencies in personnel, particularly if uploads happen on an irregular or infrequent basis.
- **Partner management:** On-boarding and integration of CMOs, CPOs, and other production trade partners.
- **User administration:** Keeping track of partner/subgroup accounts and relying on their accurate submission of data.

Before you choose to upload data manually to EMVO, it's important to consider the full set of management and maintenance tasks and if your company has the capacity and expertise to handle them. The goal should be to automate as many routine processes as possible.

Rely on TraceLink—and stay focused on your business

To help small- to mid-size manufacturers that lack the internal resources and expertise to manage the complexities of FMD compliance, TraceLink offers EU FMD Express: a cost-effective, simplified FMD compliance solution based on the same

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proven technology that has made TraceLink the world’s largest, most trusted track-and-trace network.

EU FMD Express is a complete, turnkey solution that lets smaller manufacturers comply with FMD and integrate with partners through a single, secure connection to the TraceLink network. From project start to go-live, EU FMD Express lets you stay focused on your business while TraceLink manages your implementation. And EU FMD Express removes the burden of software maintenance and upgrades—lowering your total cost of ownership and keeping you up to date with regulatory changes.

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Thank you for contacting us; we’ll be in touch shortly.

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