RESOURCES

EU FMD: Does Your Compliance Partner Have A Community Behind Them?



The European Union's Falsified Medicine Directive (EU FMD) compliance mandates went into effect on February 9, and no matter where you are in the pharmaceutical supply chain, you're probably still adjusting to your new reality. Complex mandates, unique national requirements, and evolving guidance ensure that the February deadline was more like a starting than a finish line.

In fact, nearly simultaneously with the February deadline, the European Medicines Verification Organization (EMVO) released a number of guideline updates that impact stakeholders across the supply chain, including:

- **Alert Handling and Prevention Process:** An extensive guideline that covers alert handling for level 5 alerts, which are generated when a National Medication Verification System (NMVS) detects a potential falsified pack within the European Medicines Verification System (EMVS). The primary goal is to ensure that procedural or technical issues do not prevent medicines from reaching patients who need them while new systems are being tested for the first time.
- **Stabilization Period:** Similarly, this proposal from EMVO, also referred to as a "soft launch," sets forth a period of time that would allow for the industry to stabilize, including rationales for proper testing, procedural learning curves,

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identifying bugs and inconsistent date formats, and missed call-back messages. Importantly, this proposal does not mean there is any change to the law or the requirements, or any entity's responsibility to meet those requirements. At least 18 country authorities or NMVOs have communicated their own "soft launch" approach.

Learn, Share, and Solve as Part of a Community

As your organization rises to meet the challenges of EU FMD and keep pace with updated guidance, you're bound to encounter roadblocks and questions about the best way to proceed. And, with the scale and complexity of the mandates, it may not be easy to find answers. The stakes are high—failure to comply can prevent you from selling product into the EU marketplace and result in significant financial risks. You need more than just a technical solution—you need a way to keep track of information, get answers to your questions, and understand how to solve your organization's problems.

TraceLink is the market leader in EU FMD compliance with a proven network: nearly 50% of companies connected to the EU Hub are TraceLink customers. And behind the TraceLink solution, there is the TraceLink Cloud Community EU FMD Special Interest Group (SIG): a wholly unique forum available only to TraceLink customers. Specifically dedicated to EU FMD challenges, the EU SIG is a biweekly dynamic network for members to stay up-to-date on regulations, share knowledge with peers, and ideate on solutions.

TraceLink's Cloud Community at-a-glance:

- 1,000+ member organizations
- 4,500+ individual members
- 30+ bi-weekly EU SIG sessions since 2018
- 2,000+ live event attendees in 2018
- 174 peak weekly attendance (9-FEB-2019)

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TraceLink's EU SIG creates opportunities for its participants to learn and contribute to live discussions on a range of critical topics:

What is new or changing? Receive unparalleled access to compliance information, including the latest industry news, regulatory updates, and guidance, all in one place.

How does it impact me? Be among the first to get insight and interpretation of key takeaways from EMVO and NMVO updates, how they will affect your organization, and how the industry is reacting.

Where can I get answers to my questions? Join a community of shared knowledge that includes industry experts and authorities, including NMVO representatives, and professionals like you to ask questions, share lessons learned, and communicate best practices.

How are TraceLink's products solving these challenges? Participate in product discussions and solutions in direct communication with the TraceLink product team.

EU FMD has created a complex and fluid environment for your business to navigate. With TraceLink's Cloud Community, you get even more value out of your EU FMD solution—information, expertise, and product innovation to help you understand and overcome the challenges you're facing, with a community at your side.

European Union Falsified Medicines DirectiveEuropean Union
Contact TraceLink to discuss your EU FMD compliance solution.
Contact us
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Thank you for contacting us; we'll be in touch shortly.

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