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EU FMD for Pharmacists: At-a-Glance

What is EU FMD?

EU FMD stands for the European Union Falsified Medicines Directive, and it comes into force on the 9th of February 2019.

It was developed to eliminate falsified medicines by implementing uniform product identification and verification requirements across the pharmaceutical supply chain, from manufacturer to pharmacist.

Belgium, Greece, and Italy have an additional 6 years to comply, as they have existing serialization requirements in force. Switzerland, although not part of the EU, has decided to voluntarily comply with FMD.

Which medicines are in-scope?

EU FMD covers prescription medicines, plus a “blacklist” of over-the-counter (OTC) medicines that are deemed to be at high risk of falsification. The Marketing

Authorization Holder (MAH) is responsible for ensuring that their in-scope products bear the safety features.

What does EU FMD mean for pharmacists and dispensing doctors?

Under EU FMD, every pack of in-scope medicines must bear safety features, consisting of an anti-tamper device and a 2D Data Matrix code containing a unique product identifier.

Before in-scope medicines are dispensed to a patient, the pharmacist or dispensing doctor must scan and verify the 2D Data Matrix code against the National Medicines Verification System of the country in which they are being dispensed. If the medicines are genuine, the pharmacist decommissions them, to signal that they have left the supply chain. This will prevent falsified medicines bearing duplicate or false identifiers from being dispensed to patients. In addition, the pharmacist or dispensing doctor must check the anti-tamper device is present.

What is a National Medicines Verification System?

A National Medicines Verification System, or National System for short, is a database set up by the country's National Medicines Verification Organization (NMVO) specifically for EU FMD.

The National System receives product data that the Marketing Authorization Holder uploads to the central European Hub once it (or its CMO) has manufactured the product.

The European Hub is a separate system that acts as a central router to direct product information to the relevant National System(s). It is managed by the European Medicines Verification Organization.

Pharmacists are advised to register with their country's National Medicines Verification Organization (NMVO) for local information. **A full list of NMVOs and their contact details can be found here**.

As a pharmacist or dispensing doctor, what do I need to do?

In order to satisfy EU FMD requirements, pharmacists and dispensing doctors will need to be able to scan the 2D Data Matrix code on medicine packs. This may mean purchasing new scanning equipment, because many scanners are only capable of reading linear barcodes.

Pharmacists and dispensing doctors then need to check that scanned information against the National System. This will require an account with the National System, an internet connection, and secure software specifically designed to connect to the National System to submit a verification or decommission request and receive its status back from the national system.

Are EU FMD requirements the same for doctors' surgeries and hospital pharmacies as for retail pharmacies?

All establishments dispensing medicines to patients are subject to EU FMD. While retail pharmacies and doctors' surgeries must verify and decommission medicines immediately before dispensing them to a patient, hospitals may verify and decommission medicines at any time after receiving them.

What are the next steps for pharmacists and dispensing doctors to prepare?

EU FMD will have a profound impact on the pharmaceutical supply chain across Europe, and on the daily operations of retail and secondary care pharmacies, and dispensing doctors. If a dispensing operation is not prepared by the deadline, they will not be able to legally dispense medicines to the patients who rely on them.

It is critical to begin preparing now by contacting your NMVO, evaluating your scanning equipment needs, and selecting the interface software that will enable verification submissions so that you have time to implement these systems, test, resolve any issues, and ensure you are ready in advance of the deadline.

Where can I get additional information?

TraceLink is working with more than 190 customers to achieve EU FMD compliance, and provide best practices for how to prepare. TraceLink is participating in the Irish pilot and is supporting retail and hospital pharmacies to understand more about meeting the challenges of EU FMD.

The TraceLink mobile Pharmacy Application provides pharmacies and dispensing doctors with a secure way to meet their EU FMD requirements and interface with the

National Medicines Verification Systems. Whether verifying and decommissioning at the point of receipt, at the point of dispense or somewhere in between, the application can be easily integrated into operational workflows to minimize business disruption.

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