**EU Falsified Medicines Directive (FMD)**

**Getting Started**

**WHY WAS EU FMD DEVELOPED?**

The regulation aims to prevent illegitimate medications from:

- Entering the supply chain
- Circulating in the supply chain
- Being sold, prescribed, or administered

**WHY WAS EU FMD DEVELOPED?**

The European Medicines Verification System (EMVS) applies the principle of Unique Identifier, Unique Transaction, and Unique History, which is essential to prevent counterfeit medicines from entering the market.

**WHEN DOES IT BEGIN?**

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- February 2016
- February 2019
- February 2025

**WHERE IS IT MANDATORY?**

- 260,000+ wholesale and retail businesses
- More than 80 countries

**WHICH PRODUCTS ARE INCLUDED?**

Prescription and some OTC drugs are subject to EU FMD requirements:

1. **Product master data**
   - **Features**
     - Unique identifier
     - Unique transaction
     - Unique history
   - Data that is uploaded and maintained must include:
     - Identification of the medicine
     - Identification of the patient
     - Identification of the healthcare provider

2. **Product pack data**
   - **Features**
     - Package size and type
     - Form and strength
     - Code scheme used
     - Data elements from the 2D barcode
   - Data that is uploaded and maintained must include:
     - Auditable record of the product's history
     - Auditable record of the product's location

3. **Recall notifications**

4. **Status updates**

**WHO DOES IT AFFECT?**

- Manufacturers/Marketing Authorization Holder (MAH)
- Importers
- Wholesalers
- Distributors
- Dispensers

**HOW DOES IT WORK?**

- TraceLink was the first external provider to obtain formal acceptance from the European FMD authorities.
- The Delegated Act on safety features was published, and the regulation aims to prevent counterfeit medicines from entering the market.
- The European Medicines Verification System (EMVS) applies the principle of Unique Identifier, Unique Transaction, and Unique History, which is essential to prevent counterfeit medicines from entering the market.

**BENEFITS**

- Reduce the time, cost, and risk of achieving compliance
- The most proven track and trace solution for EU FMD

**SERIALIZE**

- Test integration with all key system partners
- Enter the supply chain to achieve compliance in the U.S., EU, and other geographies

**VERIFY**

- Continuous compliance monitoring and updates
- Reduce the risk of a validation project
- Cost savings from reduced validation cycles

**REPORT**

- The most proven track and trace solution for EU FMD

**PARTNERS**

- Local support
- 20
- 80

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**TEAM MEMBERS IN THE EU**

- Located near you, speaking your language

**RESOURCES**

- CMO to serialize drug product at the final step of production
- Importers
- Parallel importers

**A NOTE ON GRANDFATHERING**

- Grandfathering for EU FMD requirements: Products packed and released prior to relabeling and repackaging are not subject to a new rule or regulation.

**A NOTE ON COUNTRIES WITH DEFERRED DEADLINES**

- Belgium, Italy, and Greece have an additional 6 years to comply.

**A NOTE ON COMPLIANCE REPORTING**

- Reporting of any suspected or confirmed cases of falsified medicines
- Verification of the identity of the medicine
- Verification of the identity of the patient
- Verification of the identity of the healthcare provider

**A NOTE ON WHITELIST AND BLACKLIST PRODUCTS**

- Certain OTC drugs at the national or regional level may be subject to EU FMD requirements.
- Medications with special handling under EU FMD are listed in Annexes I to the Delegated Act.

**A NOTE ON CODE FORMAT**

- Code format
- Data elements from the 2D barcode

**WHERE IS IT MANDATORY?**

- More than 80 countries
- 260,000+ wholesale and retail businesses

**WHICH PRODUCTS ARE INCLUDED?**

- Prescription and some OTC drugs
- Medications with special handling

**WHAT IS IT?**

- A method to prevent the falsification of medicines in the EU
- A system to verify the authenticity of medicines in the supply chain

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