EU FMD **COMPLIANCE**

WHAT DOES IT MEAN FOR PHARMA WHOLESALERS AND DISTRIBUTORS?

Counterfeit medicines have always been a major concern for the European Union (EU) as they represent a serious threat to public health and safety. To address this concern, the European Commission (EC) has released the Falsified Medicines Directive (FMD), detailing the safety features designed to protect European patients by ensuring they have access to safe, high-quality medicines. The Delegated Regulation will become effective on February 9, 2019.

Wholesalers and distributors will soon be obligated to guarantee the authenticity of prescription drugs and identify whether or not the outer packaging of medicines has been altered.

WHAT ARE THE EUROPEAN SERIALISATION REQUIREMENTS?

Pharma stakeholders must place unique identifiers (UIDs) on each product and provide that information to their regulatory government institution/ministry of health. Each country's database is connected to a European hub.

HOW DOES IT WORK?

To implement the EU FMD, data will be exchanged between the European Medicines Verification System (EMVS), also known as the European Hub, and the National Medicines Verification Systems (NMVS), developed by each country within the European Union. The EMVS will receive a unique identifier from the manufacturer for each prescription medicine to be sold in Europe, and will act as a "router" to distribute them to the proper NMVS.

Each country's NMVS database will include the UIDs of all medication currently active in that country.

emvo European Medicines Verification Organisation

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WHAT DO PHARMA WHOLESALERS AND DISTRIBUTORS HAVE TO DO?

DECOMMISSIONING

Decommissioning a pharmaceutical product is the process of turning its status to inactive.

When a product is removed from the European market, its serial number must be decommissioned. There are many reasons to remove products, including: when products are exported* outside the European Union; when non-saleable products are returned*; when products or their packaging are damaged*, such as a broken tamper-proof seal; and when legal samples* are requested by the competent authorities or products are supplies to non-healthcare institutions**.

** EU FMD – Article 22*

*** EU FMD – Article 23. For example, veterinarians and retailers of veterinary medicinal products, optometrists, dental practitioners, paramedics or emergency medical practitioners, armed forces, police, etc., universities, prisons, schools, hospices, nursing homes.*

RECOMMISSIONING

Recommissioning reverses the status of a decommissioned product. When a company has decommissioned a product, it can recommission that product within 10 days after the decommissioning occurred, as long as the product has not expired and its status was not changed. A status would change in the following situations: supplied to the public, destroyed or stolen.

EU FMD – Article 13

VERIFICATION

Verification is the process of verifying the authenticity of a serial number on a product.

Verification must take place when the product is bought from outside the market or from another wholesaler. When wholesalers or distributors don't buy from a marketing authorisation holder, they must verify 100 percent of the serial numbers.

The serial number should also be verified in the case of saleable returns before the products are resold, regardless of the product source.

EU FMD – Article 20

DESTROYING SERIAL NUMBERS

Serial numbers must be destroyed when products are damaged or their expiration date has passed.

EU FMD – Article 22

CONNECTION TO NMVS

For both decommissioning and recommissioning, wholesalers and distributors will need to connect to the local National Medicines Verification System (NMVS).

They cannot communicate with the EMVS directly – only a marketing authorisation holder (MAH) can communicate with the European hub. The EMVS will share all relevant information with the NMVS, which wholesalers and distributors can access.

INVENTORY AND REPORTING

Wholesalers and distributors will have to capture and record all events associated with verification and decommissioning after the product has been decommissioned, for a period of 1 year after the expiry date of a medicinal product or 5 years after the pack has been released for sale or distribution.

EU FMD – Article 51

OPTEL has developed serialised solutions specifically designed to help pharmaceutical wholesalers and distributors comply with the EU FMD.

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