QUICK GUIDE TO THE EU FALSIFIED MEDICINES DIRECTIVE

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1 The European Falsified Medicines Directive (FMD) Overview

The European Falsified Medicines Directive (FMD) deadline is less than a year away, on 9th February 2019.Those who manufacture, distribute, or dispense prescription medications in the European Union will have to comply with regulations outlined in the FMD to track and trace these medicines.

The FMD includes detailed and diverse rules for API producers, guidelines for GMP of active substances, logos for online pharmacies, and on-package authenticity features (Safety Features). Due to its complexities, it is crucial for pharmaceutical companies, their CMO/CPO partners, and their 3PL partners to start now by meeting the EU FMD with track-and-trace solutions. The various components required include serialization, compliance reporting, verification, system validation, integration with all trading partners and other regulatory requirements.

Two main items for serialization and compliance requirements are:

Safety Features - In summary, manufacturers need to put new "safety features" or codes onto boxes, and report those code to the regulators, via the European Medicines Verification Organisation (EMVO).

The safety features consist of two elements placed on the packaging of prescription medicines:

1. a unique identifier, carried by a two-dimensional barcode allowing the identification and authentication of the individual pack on which it is printed; and

2. a device allowing the verification of whether the packaging of the medicinal product has been tampered with (anti-tampering device).

The associated data management and transaction processing impose challenges for all stakeholders in the supply chain, and companies can't delegate the responsibility to contract manufacturers (CMOs). Most companies will need their validated software system such as rfxcel's proven and robust rTS system. It is essential to start the procurement and installation process now.

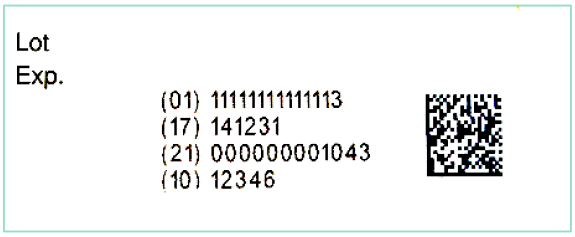
Supply chain and good distribution practice – The Directive introduces new responsibilities for wholesalers and a definition of brokering activities as well as new responsibilities for brokers. Distributors need to check the manufacturer codes, on an at-risk basis. Even though distributors don't check every box, they'll need a validated connection to their local National Medicine Verification System (NMVS). rfxcel provides solutions for that, too.

Dispensers need to check all pack codes before or during the dispensing process. They will also need a validated connection to their local NMVS. rfxcel provides a simple, straightforward solution that doesn't add complexity or disrupt dispensing operations.

2 Traceability Software for EU FMD

2.1 Serialization

The FMD requires serialization at the saleable unit or secondary packaging level (if the primary packaging is enclosed in a carton). For each unit of a drug product, a unique serial number, coupled with the manufacturer product code in the form of a global trade item number or GTIN, batch number, and expiration date, is to be encoded in both a GS1 2D DataMatrix and in human-readable form. A fifth data element, such as a national reimbursement number, may be required based on country requirements.



Serialization at other packaging levels and aggregation of numbers into a hierarchy are not required under FMD. However, many companies are considering or already implementing multi-level serialization and related aggregation activities for their business reasons. If this is something, you think you might need now, or in the future, you should make sure that the solution provider can demonstrate competence in this activity. rfxcel is a very experienced provider with a robust platform that can scale in numbers and also aggregate data as needed.

2.2 Compliance Reporting

The reporting and notification requirements the Marketing Authorization Holders need to submit under the FMD are product master data and serialized product pack data.

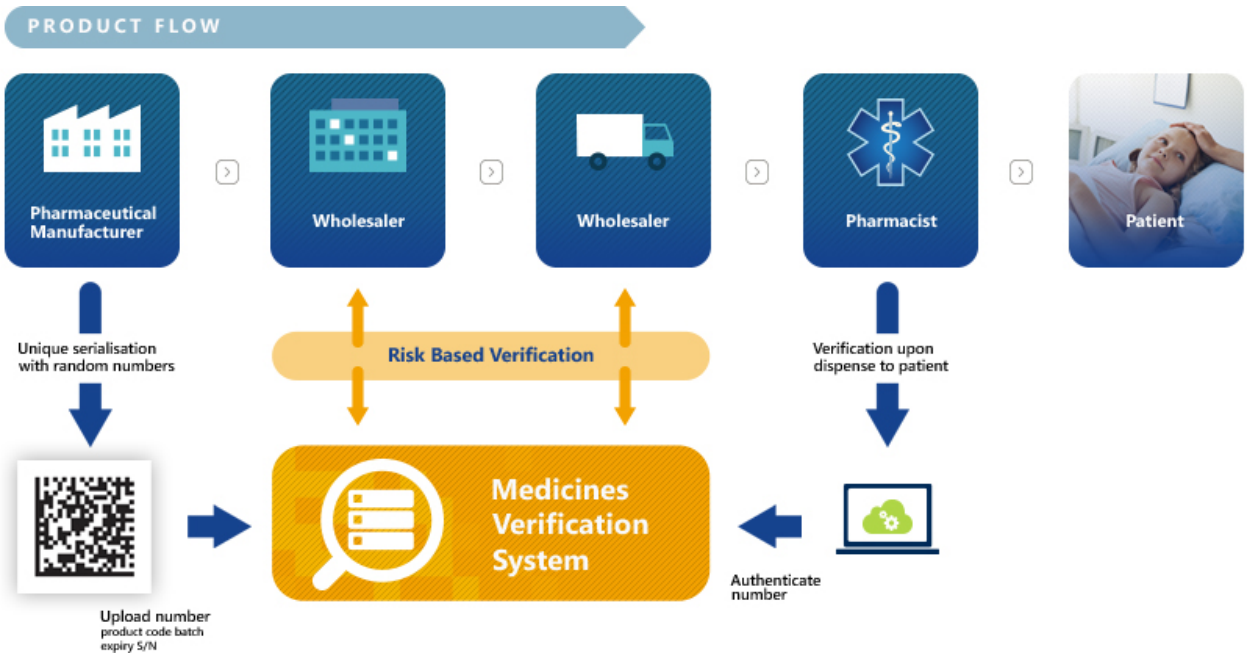
Master data – includes product codes, form, strength, doses per pack, pack type, and target market(s) for distribution must be reported to the European Hub for each unique product form produced. Future and any updates to product master data must also be reported.

Serialized product pack data – includes product codes, lot/batch number, expiry date, and serial numbers for each unit of drug product shipped into the supply chain. Any updates need be reported to the EU Hub. For example, updates may be required at a batch level if a recall is initiated, or at a saleable unit level in situations such as the decommissioning of serial numbers the destruction of the drug product.

2.3 Medicine Verification System and Safety Features

Incorporating a unique identifier (UI) and applying an anti-tampering device on the outer packaging of all medicines for each sales package allows the EU to verify each package that goes through the supply chain. The data will be uploaded by manufacturers (specifically, Marketing Authorization Holders or MAHs) at the point of product release onto the market. This data upload will be via the central European Medicines Verification System (EMVS) and will require specific software linkages. Rfxcel is one of a small number of solution providers technically certified for this EMVS connection. The EMVS then pushes data to relevant National Medicine Verification Systems (NMVSs). At the point of dispense, the medicine will be scanned, checked and verified for authenticity against the national repository. If the UI on the pack matches the information in the repository, the pack is decommissioned and supplied to the patient. Otherwise, if there is a warning related to this pack, then the system will highlight this as an exceptional event, and the package will not be supplied to the patient. An investigation needs to determine whether the pack has been falsified or not. rfxcel also provides software to enable distributors and dispensers to connect to NMVS systems.

Example of Product Flow and Compliance Data Exchange Example for EU FMD *(Image source: [http://emvo-medicines.eu/mission/emvs/)](http://emvo-medicines.eu/mission/emvs/)*



2.4 What are some of the complexities facing the industry?

2.4.1 Cost

EMVO informed charges a one-time On-boarding fee, as shown in the table below. EMVO and the NMVOs are using those fees to undertake all necessary actions to set up the European Medicines Verification System in time and to ensure that the system will be compliant with the FMD provisions.

Please find below the adjusted table of EMVO's On-boarding fee (*Note that EMVO reserves its right to potentially apply an additional rise of the On-boarding fee in 2018.)*

	Early Bird	From the 15th of January 2018	From the 15th of June 2018
OBPs with more than 12 MAHs in Europe	20,000 €	30,000 €	45,000 €
OBPs with 6 to12 MAHs in Europe	10,000 €	15,000 €	22,500 €
OBPs with 3 to 5 MAHs in Europe	8,000 €	12,000 €	18,000 €
OBPs with 2 MAHs in Europe	6,000 €	9,000 €	13,500 €
OBPs with 1 MAH in Europe	3,000 €	4,500 €	6,750 €

Also, each NMVS charges an annual fee for all manufacturer license-holding entities connected to it. For a pan-European company, this can add up to a sizeable recurring charge. To help offset these cost pressures rfxcel is working with companies (MAHs) to implement our solution efficiently and quickly.

2.4.2 Data Alignment

The FMD creates an umbrella regulation covering the member states of the European Union, plus several other countries aligning to FMD requirements. The FMD also acknowledges the uniqueness of each member by providing flexibility in how the regulations apply to drug products targeted for dispensation within a given country.

So, a pharmaceutical company preparing for FMD regulations needs to design their serialization and compliance infrastructure both for the extreme scalability challenges presented by the FMD and the flexibility required to serve the member states.

rfxcel deals with these complexities facing a pharmaceutical company. We provide a very flexible system to prepare companies' internal sites and external CMO network to meet global compliance requirements.

2.5 How rfxcel prepares pharmaceutical companies to meet the 2019 deadline?

The challenge posed by FMD to industry significant. Product information, serialization data, and serialized product events need to be planned for and exchanged with network partners to enable a secure, scalable, and cost-effective EU compliance infrastructure. Some companies don't know where to begin or what to do.

To meet the EU Falsified Medicines Directive requirements by the 9th February 2019 deadline, the thousands of pharmaceutical companies, CMOs, and 3PLs serving the EU market need a solution provider that has a flexible integration system, global network and on-boarding team that will support this project.

Therefore, it is crucial to take an quality-centric view of your serialization project and ecosystem to understand the compliance requirements fully. The collaboration between trading partners is vita to provide a valid product master data and serialized product data exchange. As a flexible solution provider, rfxcel works across internal systems and external partners and generates the operational process changes required in the finished goods distribution network.

We encourage all companies and trading partners to start now. Serialization is a broad business strategy for the company not just one department's project to-do list. It takes time understanding the data companies need to collect and manage, integrate with all other trading partners, and connect with the EU network to exchange information and send to the EU hub.

rfxcel offers the serialization management and compliance reporting software that will ensure reduced time, cost, and risk in meeting FMD requirements.

February 2019 is less than one year away, but serialization and compliance readiness always takes much longer and is much more complicated than expected. The time to prepare for EU compliance is now.

Connect with our EU Team to get you started with your serialization project:

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