EUROGROUP CONSULTING

2025 Drug serialisation in Italy

What do you know about it?

www.eurogroupconsulting.it

nextcontinent

EU-FMD regulation

The EU **Falsified Medicines Directive (FMD)**, formally known as **Directive 2011/62/EU**, is a regulation introduced by the European Union to combat **counterfeit medicines** and improve **safety** along the supply chain through **serialisation** of medicines.

It is based on **three pillars**:

The introduction of a **unique identifier** for individual packages to enable drugs' authentication and traceability

The unique identifier and other relevant information (e.g. lot code, expiry date, NHRN) should be easily **accessible**, contained in a **Data Carrier** on the package

All in order to make the **intrusion** of **counterfeiters** into the healthcare supply chain much more **complicated**

EU-FMD Timeline

July 2011

Publication of the EU Falsified Medicines Directive (FMD) in the "Gazzetta Ufficiale"

Publication in "Gazzetta Ufficiale" of the related European Regulation (Safety Feature Delegated Regulation)

February 2016

February 2019

Adoption of the legislation in 32 countries in Europe: 27 EU Member States + Norway, Iceland, Lichtenstein, Switzerland and the UK

For Italy and Greece, the deadline is postponed to 2025 as they already have anti-counterfeiting measures in place

February 9th, 2025

From Bollino to EU-FMD

> *"The mandatory implementation of serialization dictated by the EU FMD is a challenge for all players in the pharmaceutical environment. All prescription drugs will be tracked through a central European Hub and an Italian National Medicines Verification System, a completely new traceability system."*

Marcello Matarrelli, General Director NMVO Italia

From the **9th of February 2025, Italy** and **Greece** will be among the last EU countries to adopt the **regulations** described by the **EU-FMD**.

This because Italy already adopts a system to **combat counterfeiting** of drugs through the so-called '**Bollino**', a multiple-layers sticker that contains the drug's data.

Example of a "Bollino"

As part of the European directive, each nation will have to have its own **NMVS** (National Medicines Verification System), which is why **NMVO Italia** (National Medicines Verification Organization) was founded. It will be responsible for **initiating**, **governing** and **managing** the **NMVS** and will collaborate with all the organisations in contact with it.

NMVO network *along the supply chain*

nmvo ITALIA
National Medicines Verification Organization

Italy: further features

The final version of the **legislative decree**, approved by the Council of Ministers, was **published** in the Official Gazette on 7th of February 2025.

This measure **aligns the national legal framework with EU regulations** by establishing detailed rules on the security features displayed on the packaging of medicinal products for human use.

Italy has introduced a **traceability model** that obliges pharmaceutical companies to something more than EU-FDM requirements in terms of:

Additional security element for Rx – prescription medicines will need to carry a special security label ('*security-supported device*') in addition to the Data Matrix and the ATD specified in the EU Regulation 2016/161

Broader scope – the anti-tampering device (ATD) will also be required for non-prescription medicines, not just prescription ones

Moreover, an extended implementation timeline has been planned with a two-year of '***stabilization period***' (until 9th of February 2027), to avoid operational disruptions in the transition to the new system.

Pharmaceutical companies will have the flexibility to choose how and when to transition to the new traceability model — for example, by switching all products at once, transitioning one brand at a time, or implementing changes on a product-by-product basis.

DISCLAIMER

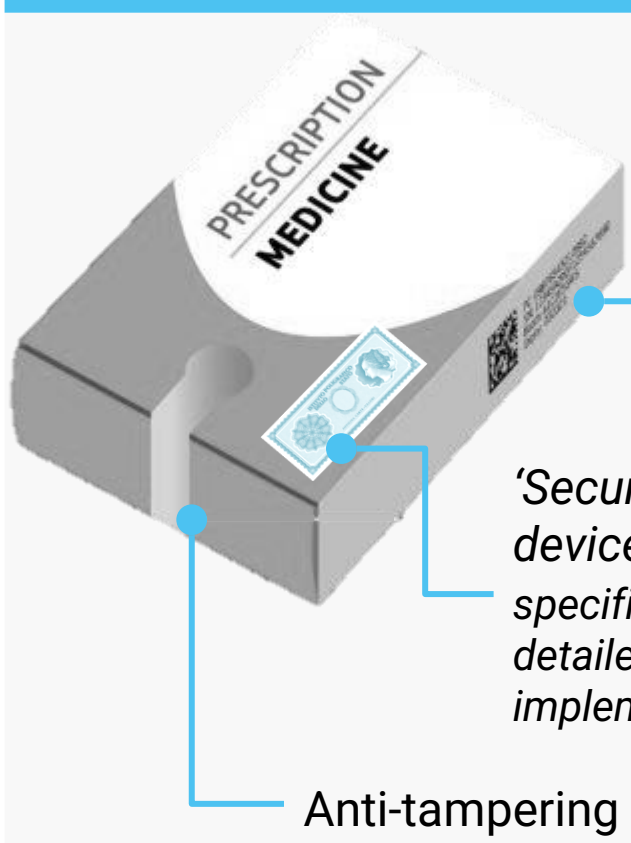
Pharmaceutical companies still require several **implementing decrees**, which will be issued in stages by the Ministry of Health in consultation with AIFA and/or the Ministry of Economy and Finance after the legislative decree enters into force. These include:

- **Within 30 days**, an implementing decree identifying the **list of medicines subject to the unique identifier**, as well as a decree defining the **technical specifications** for the application and verification of the **Data Matrix**
- **Within 90 days**, an implementing decree regulating '***security-supported device***' establishing its technical, graphical, and functional **specifications**

Path forward in Italy

Starting from 9 February 2025, pharmaceutical companies will need to **adapt authorized medicines** in Italy to the **new model**:

Prescription medicines (Rx)



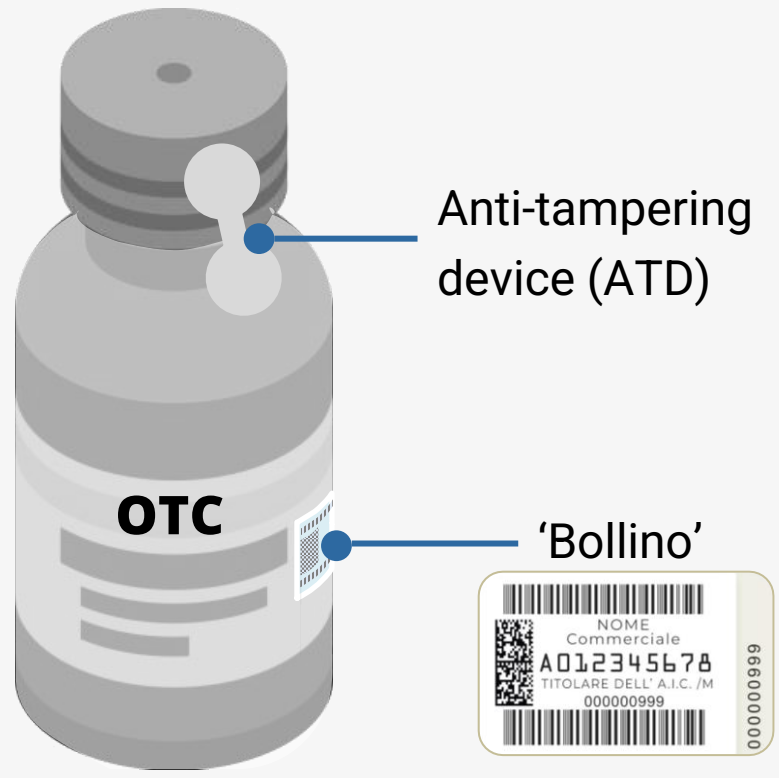
Unique identifier

'Security-supported device'

specifications will be detailed into dedicated implementing decree

Anti-tampering device (ATD)

Non-prescription medicines



Anti-tampering device (ATD)

'Bollino'

During the 'stabilization period' (9 February 2025 - 8 February 2027):

- the pharmaceutical industry will be **allowed to continue using the 'Bollino' on new batches** produced from 9th of February onward (for Rx, this means that 'Bollino' is alternative to the DM, the European ATD and the '*security-supported device*')
- **Penalties** for the supply chain will be frozen or reduced
- **A technical committee will be set up to monitor the progress of the transition** and support the operators involved

Impacts on the industry

The **EU-FMD** will impact differently each **player** along the **pharmaceutical supply chain**, mainly in the following areas:

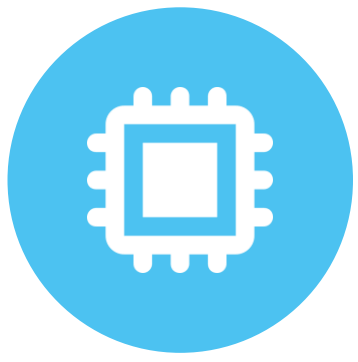
Business Processes

- Maintain master data for artworks and support compliance across functions.
- Update packaging, production, and quality processes to meet FMD requirements.
- Support stock management and traceability for products and packaging.
- Upgrade systems (traceability, ERP, WMS, …) for regulatory adherence and record management.

External Stakeholders

- Integrate Italian products with onboarded CMOs and manage onboarding and readiness checks for new CMOs as needed.
- Coordinate EU FMD implementation, support 3PLs onboarding on level 4 systems.
- Manage the information flows with the European Hub and setup the communications with NMVO Italia.

Technology



- Adapt the manufacturing footprint (packaging lines, line software, production systems) to comply with the EU-FMD requirements.
- Integrate Italian product data on the EMVS platform in coordination with the track and trace central function.
- Upgrade IT systems to incorporate traceability for production, logistics, and quality functions, ensuring consistent data management.

How can EGC help you?

Eurogroup Consulting Italia has been developing a deep **expertise** in the **healthcare** and **pharmaceutical** industry in last **20 years**, serving its clients in every area that could be impacted by the new **EU-FMD** regulations.

Some examples where **EGC** could help you as **PM** or Subject Matter Expert (**SME**):

Process Re-engineering

- Adapt the various systems (e.g. SAP) to new production needs
- Implement new information flow (e.g. decommissioning)
- Align production lines to new requirements (e.g. printing on packaging, ATD)
- Design a new data management protocol

Regulatory Compliance

- Design a new and AIFA-compliant artwork
- Adopt reporting systems to the authorities

Supply Chain Management

- Re-define agreements with 3PLs and CMOs (e.g. reporting duties and responsibilities)
- Update local SOP to include FMD requirements
- Manage stock and cutover plan to minimize obsolescence

Change Management

- Train and onboard internal staff and possible interlocutors on the new procedure and FMD regulations and restrictions

CONTACT DETAILS

Antonio FOIS
Partner
a.fois@eurogroupconsulting.it

Francesca TONI
Senior Manager
f.toni@eurogroupconsulting.it

eurogroupconsulting.it
www.linkedin.com/company/eurogroup-consulting-italia