# Improving Patient Safety with the Falsified Medicines Directive in the Hospital Pharmacy and the Status of Implementation

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# Introduction

- Falsified medicines:
  - **Harm patients**
  - **Loss of confidence in medicines**
  - **Affect every region in the world**
- Between 2013 and 2017, **400 falsification incidents** were reported in the EU
- In 2017, nearly **7 million Euros** of counterfeit medicines were seized at the EU border

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# EU Legislation against Falsified Medicines

## Directive 2011/62/EU (the FMD)

**4 pillars**

### 1. Safety features

**Mandatory identification and authentication of individual medicine packs.**

**Feb 2019**

### 2. Reinforcing the distribution chain

**Strengthened GDP and requirements for wholesale distributors**

### 3. Active substances

**Tougher rules on importation of APIs; reinforced controls and inspections of API manufacturers.**

### 4. Internet sales

**A common, EU-wide logo to identify legal online pharmacies.**

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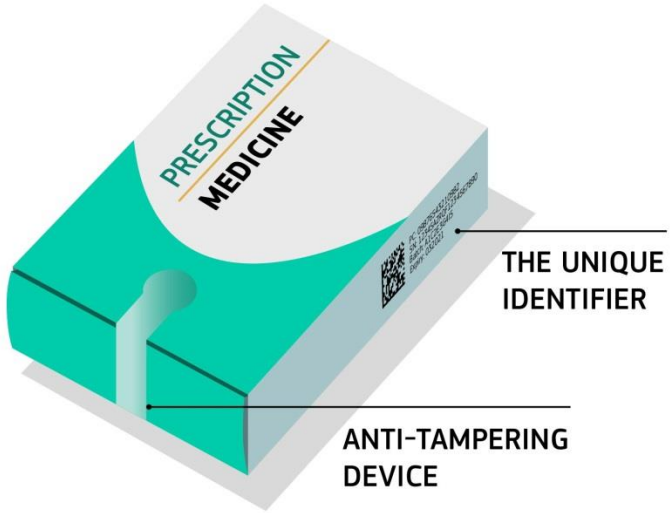
Safety Features

# Safety Features for Medicine Verification

**Delegated Regulation (EU) No 2016/161**



# FALSIFIED MEDICINES

## From 9 February 2019

# EU MEDICINES AUTHENTIFICATION SYSTEM

Introduces end-to-end verification of prescription medicines in the EU

1. Manufacturers will upload the information for each individual medicine

2. Into the EU repository run by the European Medicines Verification Organisation

3. Pharmacies and hospitals will verify medicines at the end of the supply chain

Safer medicines for patients

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https://ec.europa.eu/health/human-use/falsified_medicines_en

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# The Repositories System - architecture


*Distributed System*

emvo

European Hub

Pharmaceutical Manufacturer

Parallel Distributor

National System

National System

Pharmacy

Wholesaler

Health

*modified from EMVO*

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# Obligations of Stakeholders

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

October 2018

**LETTER TO STAKEHOLDERS REGARDING THE IMPLEMENTATION OF SAFETY FEATURES UNDER THE FALSIFIED MEDICINES DIRECTIVE 2011/62/EU [1]**

A key measure to address falsification in the EU and protect the legal supply chain of medicines is an end-to-end verification system introduced by the Falsified Medicines

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# Obligations of Stakeholders

**From the 9th of February 2019**

- **MAHs**
  - Responsible for ensuring safety feautures (UI and ATD) on medicines and information in MA application
  - Sign contract with the NMVO and connect with EMVO
- **Manufacturing and importation autorisation holders**
  - Update production lines to ensure UI and ATD are placed on products
- **Wholesale distributors**
  - Update computer systems to allow connection to repositories to verify and decommission UI

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# Obligations of Stakeholders

**From the 9th of February 2019**

- **Pharmacies, hospitals and healthcare institutions**
  - Ensure the authenticity of medicines delivered to patients by verification of safety features and decommissioning the UI
- **Software providers**
  - Update the computer systems used by pharmacies, hospitals etc.

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# Q&A Document- Version 13

*Safety Features for Medicinal Products for Human Use*

- **Q&A 1.28:** The Delegated Regulation does not require hospital suppliers to provide aggregation services. Suppliers may however offer the service on a voluntary basis, providing the safeguards.

- **Q&A 3.6:** A medicine with either a UI or ATD that has been released for sale before 9 February 2019 and has not been repackaged or re-labelled may remain on the market until its expiry date.

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Health systems and products
**Medical products – quality, safety and innovation**

**SAFETY FEATURES FOR MEDICINAL PRODUCTS FOR HUMAN USE**

**QUESTIONS AND ANSWERS - VERSION 13**

**(Submitted for discussion to the Member State expert group on the safety features[1])**

| **Document history:** | |
|---|---|
| Date of submission of draft to the Member State expert group on the safety features: | January 2019 |
| Date of publication: | January 2019 |
| Supersedes: | Version 12 |
| Changes compared to superseded version: | New Q&As: 1.24, 1.25, 1.26, 1.27, 1.28, 2.22, 3.6, 4.5, 8.9<br>Revised Q&As: 5.7 |

**Important disclaimer:** The views expressed in this questions and answers document are not a formal interpretation of Union law, nor are legally binding. Ultimately, only the European Court of Justice can give an authoritative interpretation of Union law. This document aims at informing on the technical aspects of Commission Delegated Regulation (EU) 2016/161 with a view to facilitating its implementation.

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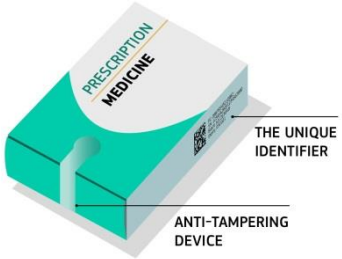
# Status of Implementation

*Delegated Regulation FMD No 2016/161*

- **10 days** since the implementation
- The **European Hub** functions as expected
- All **databases connected**
- **Connection to end-users**: in progress
- **No major issues** identified so far

# Conclusion


- **The Falsified Medicines Directive**
  - Safer and better quality EU medicines
- **Delegated Regulation: safety features (UI and ATD)**
  - No more false/expired/recalled medicines reach patients
  - Easier traceability and recalls
- **Obligations of stakeholders**
- **Q&A document - version 13**
- **Status of implementation**
  - 10 days ago, no major issues identified so far but progess is being carefully monitored

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# Thank you very much for your attention.

*Questions?*