Falsified Medicines Directive in Europe
The Falsified Medicines Directive in Europe

Overview of the legislative process

- **2011 FMD Publication**
  - Published by EU Commission (defines the WHAT)
  - Ratification by Member States

- **Oct 2015 Delegated Regulation Adopted**
  - Technical details for implementation of the safety features (defines the HOW)

- **Feb 2016 Delegated Regulation Published**
  - Scrutiny Process (Parliament and Council can either approve or reject, no changes in content)
  - Immediately applicable, no ratification required at national level

- **Feb 2019 Compliance Deadline**
  - For Greece and Italy, compliance deadline will be Feb 2025
National Medicines Verification Organization and National Medicines Verification System

*Successful & timely local stakeholder engagement is mission critical*
Scope and High-Level Requirements

1. Safety Features
   - **Unique Identifier (UI):** GS1 DataMatrix with GTIN, Serial Number, Expiry Date and Batch number
   - **Anti-Tampering Device (ATD):** tamper evidence label or glued carton

2. Upload of Data to Repositories
   - All data included in the Unique Identifier and additional product master data attributes

3. Verification and Decommissioning
   - Verification by manufacturers, wholesalers, pharmacies, hospitals
   - Decommissioning by Hospitals and Pharmacies

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Standard Product Identification, GTIN
Standard data carrier: 2D Matrix Code

Manufacturers

28 national Databases;
Choice for National organizations with only 2 IT providers

Improves reliability in the supply chain
The FMD also defines the governance model

**European Medicines Verification Organisation (EMVO) will**

- Establish, manage and operate **European Hub**
- Ensure **interoperability** of connected systems
- Conclude **agreements** with NMVOs
- Set **standards** for the EMVS
- Manage ‘national Blueprint’ systems at request of national stakeholders

**National stakeholders govern national systems through**
National Medicines Verification Organisation (NMVO)

- Establish and manage **national** system
- Ensure **interoperability** with European Hub
- Conclude **agreements** with EMVO
- Analyse exceptional events at national level
Milestones for National Medicines Verification Organisation

2015
- Stakeholder coalition in place
- MoU signed

2016
- Fund, found and staff the NMVO
- Contract signed with one of the blueprint vendors

2017
- Design, Define, Build and Test the NMVS in production mode
- Conduct a pilot

2018
- NMVS in production mode
- End Users connected
FMD went live on time, i.e. on February 9th, 2019

- This the beginning of a journey, a lot of activities need still to be performed:
  - Connections of Industries: 965 connected out of 1600 expected
  - Connections of wholesalers, hospitals and pharmacies
  - Alert Handling
  - Report to Health Authorities
Continuous Information by National Medicines Verification Organisations

Internet Site

Announcement of extension to FMD ‘use and learn’ period in Ireland beyond September
2nd September 2019

Protecting Irish patients from falsified medicines

The Irish Medicines Verification Organisation (IMVO) is a new organisation set up to protect Irish patients from the threat of falsified medicines being supplied through legitimate channels.

According to the FIMVO 2020 budget, the current estimate for the operational fees payable to the Finnish Medicines Verification Organisation in 2020 will be 5,000 euro/MAH. Please note that this remains an estimate until the number of MAHs can be confirmed at the end of 2019.
Type of potential secondary use opportunities of EMVS *

- **Commercial**
  - Develop real-time granular insights into commercial performance (incl. volume and market share data) based on local product dispensing data

- **Supply Chain**
  - Obtain real-time visibility on supply chain, optimizing inventory, reducing stock-outs risk, and monitoring regulatory compliance

- **Regulatory**
  - Improving safety tracking and providing enhanced and personalized patient services by linking medicines to patients

- **Pricing & Reimbursement**
  - Enabling fair and patient-centric pricing options, and reducing potential pharmacy fraud

* Subject to compliance safeguards or adoption of an appropriate regulatory basis as required.
FMD: an initiative to protect the European pharmaceutical supply chain from the entry of falsified medicines

Success Key Criteria:

- Compliance to international standards (GS1)
- Interoperability of systems
- Cooperation and Collaboration of all stakeholders
Doing now what patients need next