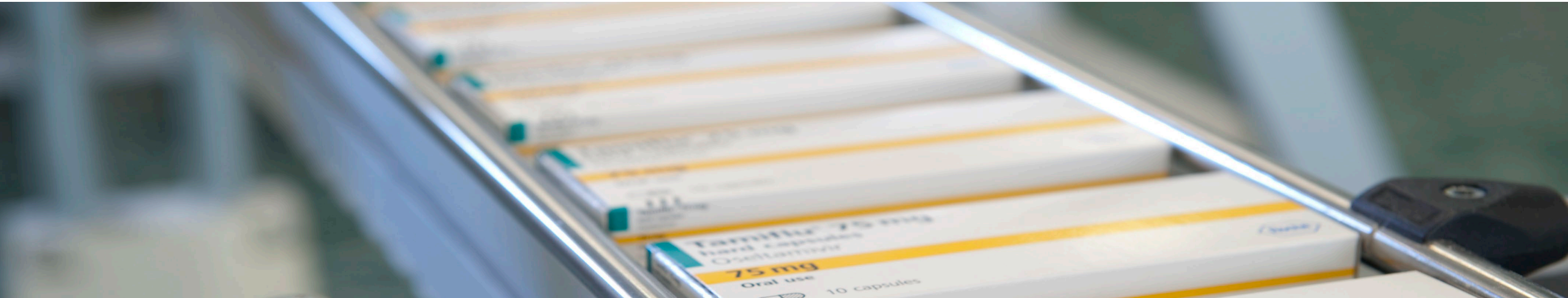
Falsified Medicines Directive in Europe



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**)

Scrutiny Process (Parliament and Council can either approve or reject, no changes in content

Feb 2016
Delegated Regulation Published

Immediately applicable, no ratification required at national level

Feb 2019
Compliance Deadline

For Greece and Italy, compliance deadline will be **Feb 2025**

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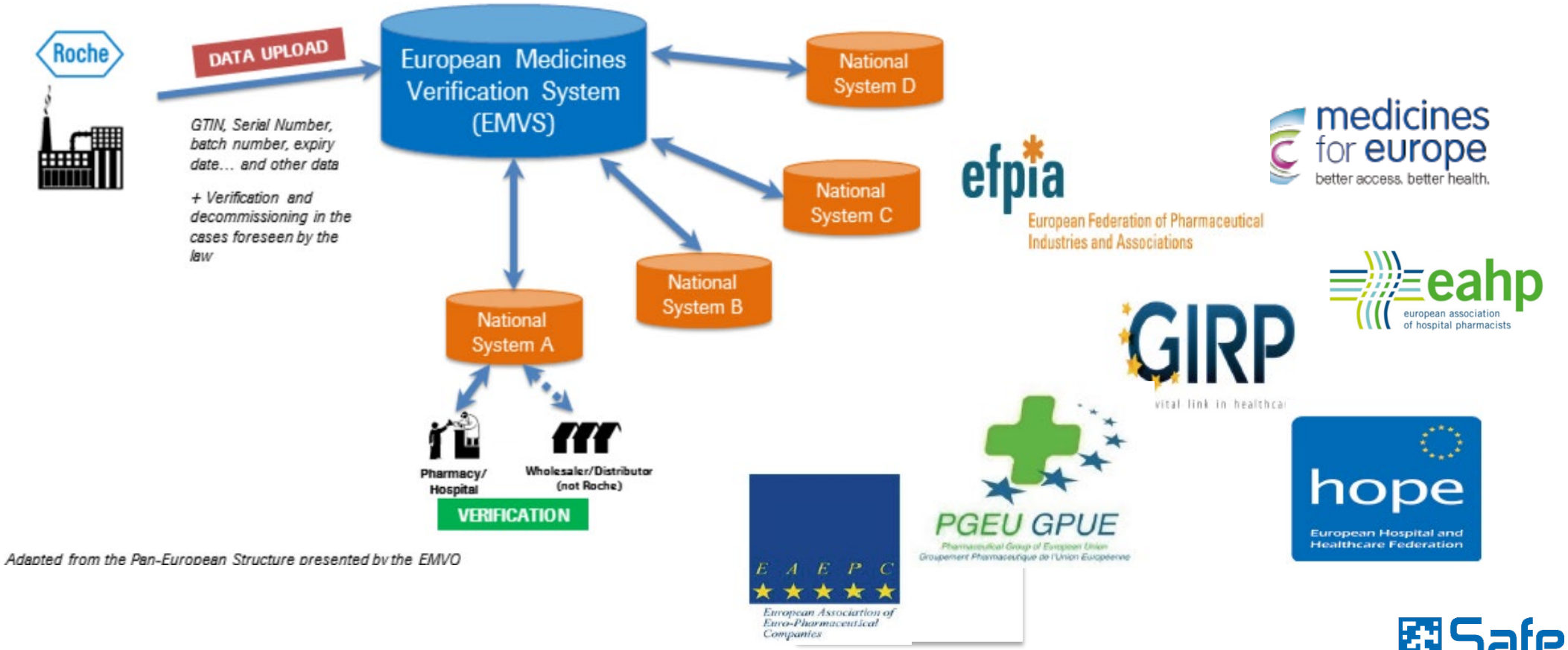
National Medicines Verification Organization and National Medicines Verification System

Successful & timely local stakeholder engagement is mission critical



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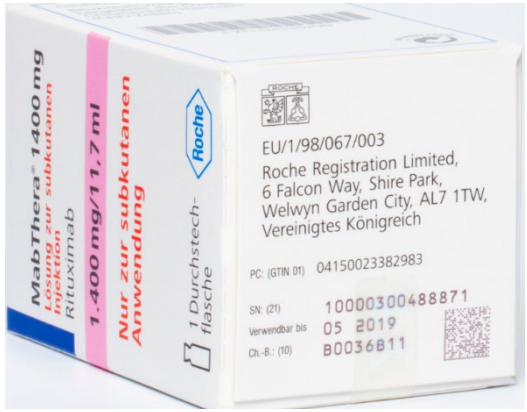
Scope and High-Level Requirements

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



Standard Product Identification, GTIN

Standard data carrier : 2D Matrix Code

2

Upload of Data to Repositories

- All data included in the Unique Identifier and additional product master data attributes

Manufacturers

28 national Databases;

Choice for National organizations with only 2 IT providers

3

Verification and Decommissioning

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

Improves reliability in the supply chain

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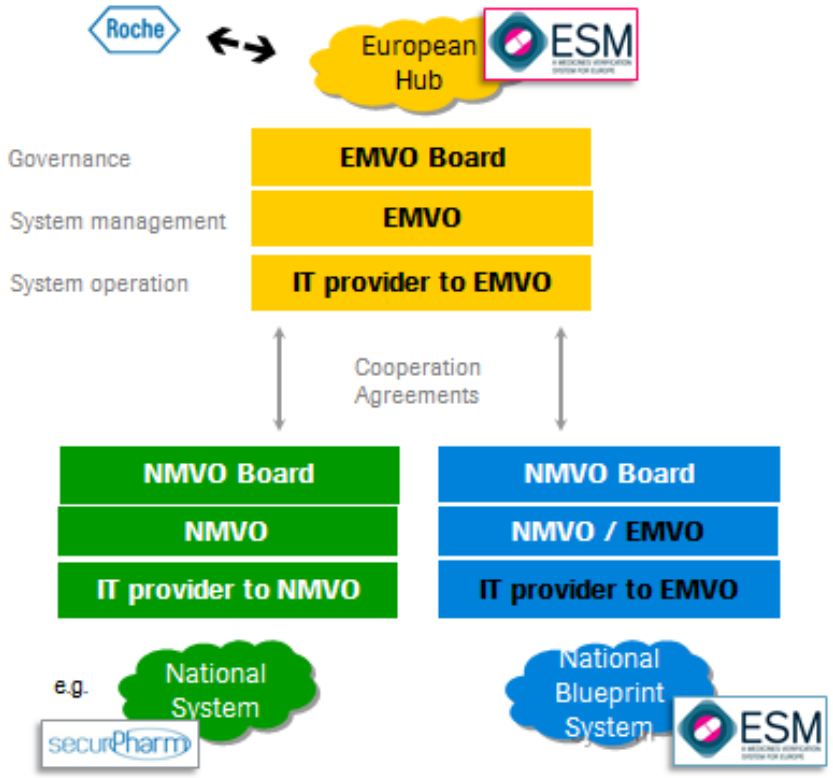
The FMD also defines the governance model



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

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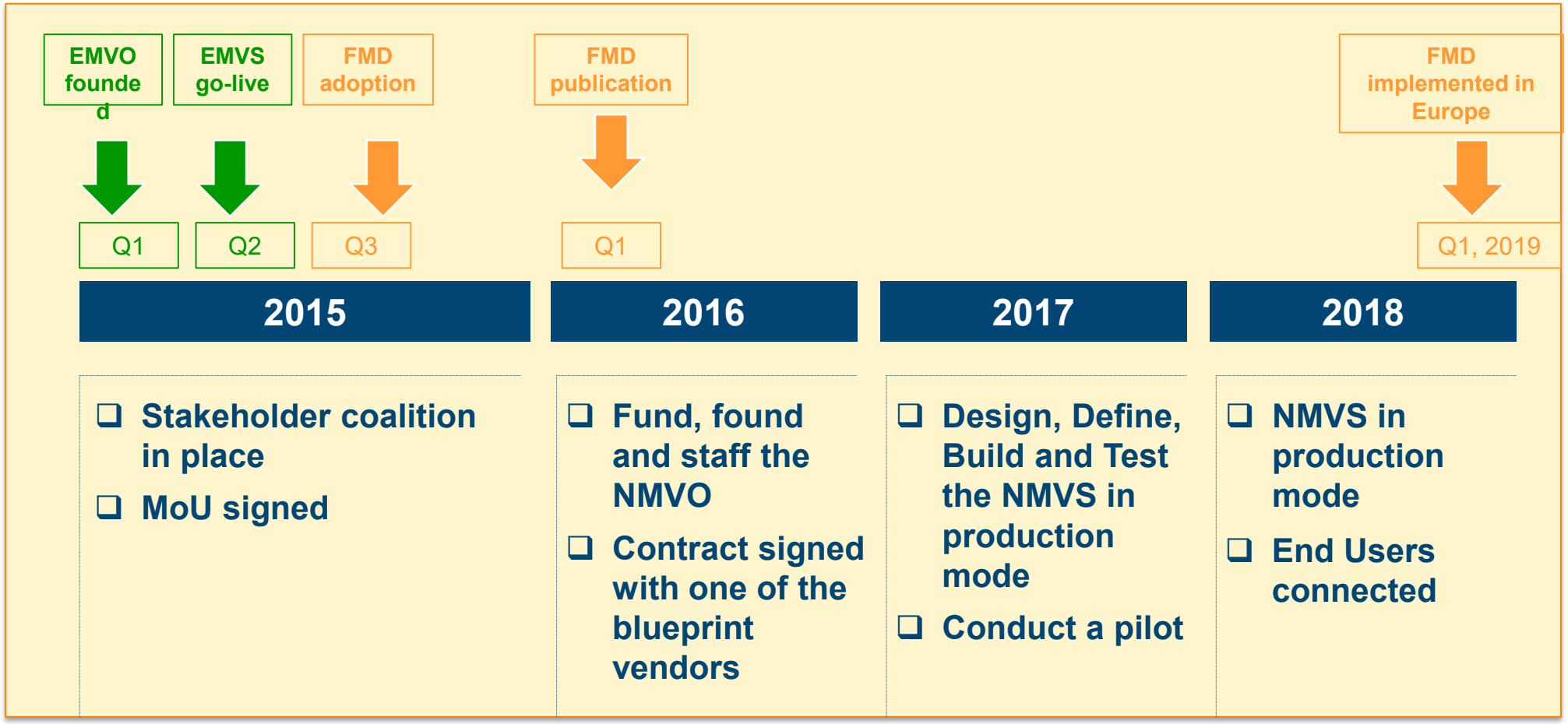
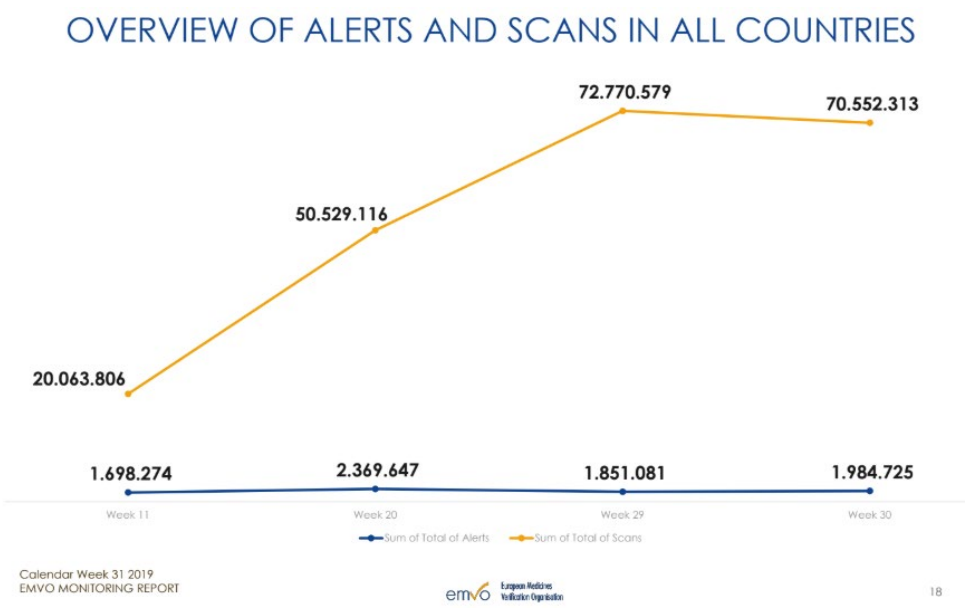
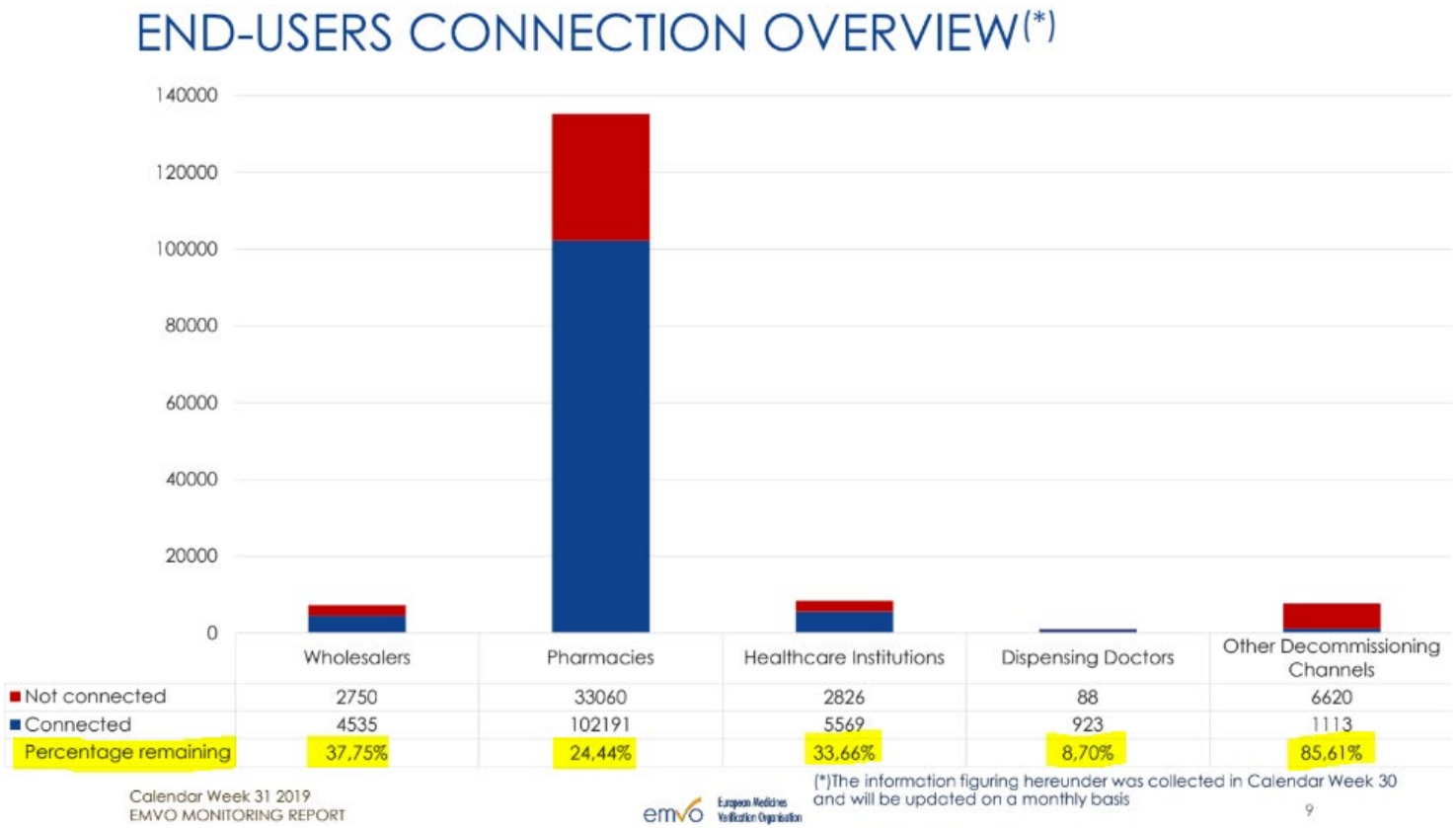
Milestones for National Medicines Verification Organisation



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

IRISH MEDICINES VERIFICATION ORGANISATION



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.

News

Announcement of extension to FMD 'use and learn' period in Ireland beyond September

2nd September 2019

Latest news

NMVO Stichting Nederlandse Medicijnen Verificatie Organisatie

Newsletter 4 September 2019: the national self-assessment tool; what you can do yourself to prevent scanning problems; new date for the webinar.

September 4, 2019

FiMVO Finnish Medicines Verification

According to the FiMVO 2020 budget, the current estimate for the operational fees payable to the Finnish Medicinies 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.

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Type of potential secondary use opportunities of EMVS *

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

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

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

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 Colloboration of all stakeholders

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Doing now what patients need next

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