




Falsified Medicines Directive (FMD) Meeting – 23rd EAHP Congress

21st March 2018

Meeting Agenda

- EAHP presentation on FMD status
- EAHP members exchange of views on country-specific FMD implementation
- Q&A



Falsified
Medicines
Directive (FMD)



joined in May 2017
as affiliate member



Active participation in

- EMVO Board meetings
- EMVO Stakeholder meeting
- Meetings of NMVO project managers
- FMD workshop meetings of EFPIA and Medicines for Europe

EAHP functions as conduit of information
between its member associations and EMVO



EMVO-EAHP-HOPE hospital platform

- Founded in summer 2017
- Equal engagement of FMD experts from both EAHP and HOPE
- Involvement of EMVO and all its stakeholders

Aim: Facilitation of the readiness of the hospital sector by 9th February 2019



EMVO-EAHP-HOPE hospital platform – deliverables

- Hospital monitoring
- “Responsibilities Document” outlining steps that have to be taken to be ready by 9th February 2019
- Consensus Paper – detailing concerns, solutions and good scanning practices

Aim: sharing of best practices



EAHP's awareness raising efforts

- FMD meeting with members (March 2017)
- Members mailing (May, July, December 2017, January and March 2018)
- Update during General Assembly (June 2017)

On national level

- Awareness raising campaigns by member associations
- Impact analysis and pilot projects

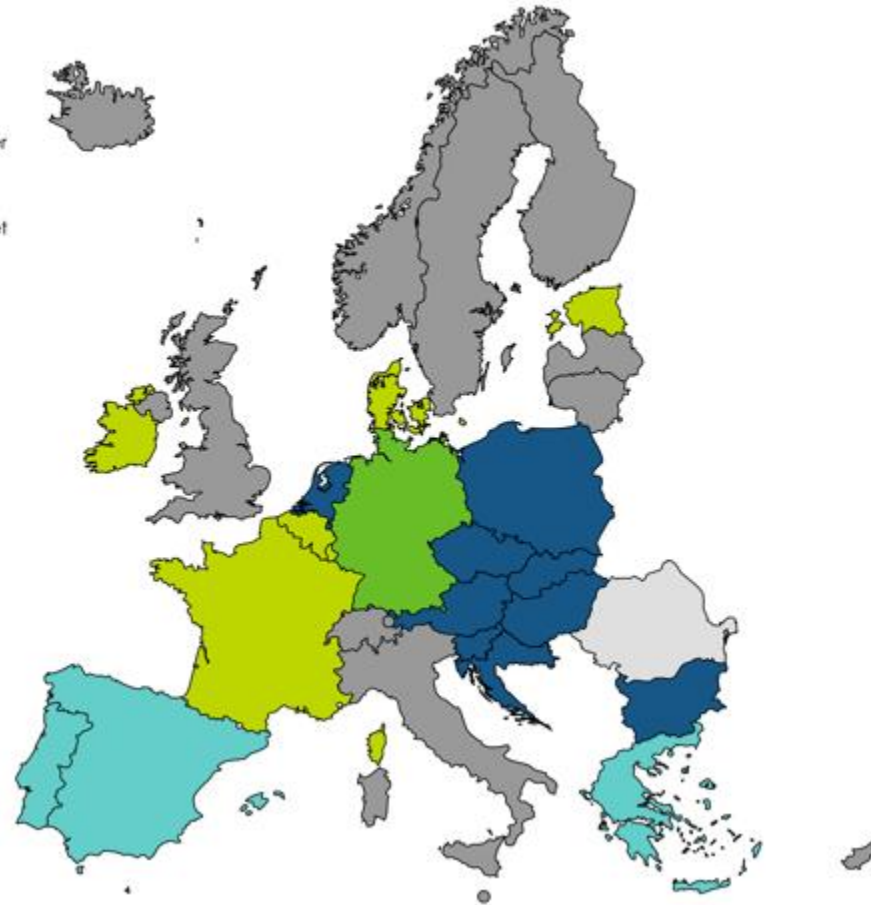
Concerns of hospital pharmacists

Despite the efforts of EAHP and its member associations

- **Lack of involvement** of HPs in activities of **NMVO** leading to
 - Uncertainties; and
 - Lack of awareness about national particularities.
- Lack of general knowledge and scepticism due to **lack of engagement of national competent authorities** leading to
 - Reluctance of hospital managers and owners to get involved; and
 - Budget allocation problems.
- Reluctance of EMVO and industry to use **aggregated coding**.

Hospital sector involvement in NMVO activities

- Direct involvement of EAHP/HOPE member
- Involvement via Chamber of Pharmacists
- Ministry (HOPE member) part of NMVO; no direct involvement of hospital pharmacy/hospital stakeholder
- Engaged in discussions, but no membership
- No involvement/ NMVO not yet founded / no information
- Negotiations to join NMVO



Data based on information from December 2017. Information may not be complete.

Concerns of hospital pharmacists on national level

Prior to FMD implementation

- Capacity issues
- Technical requirements (IT infrastructure problems)
- Scanning high volume of cold supply chain medicines

Post FMD implementation

- Compatibility of NMVS with large volume scans
- False positives

Business impact analysis by NL

Pharmacies must modify the software of their ICT systems, equipment and processes resulting in

- one-time costs (ICT and equipment); and
- annually recurring costs(logistics operations).

EUR 2.2 m - expected one-off costs for hospital pharmacies

EUR 3.2 m - recurring costs, at current volumes and wages

1 of the 110 hospital pharmacies will have

- **EUR 28,800** in annually reoccurring costs; and,
- up to **EUR 19,800** in one-off costs (depending on type of solutions)