



European Medicines
Verification Organisation



European Federation of Pharmaceutical
Industries and Associations



PGEU GPUE



FMD IMPLEMENTATION IN EUROPE CURRENT STATUS

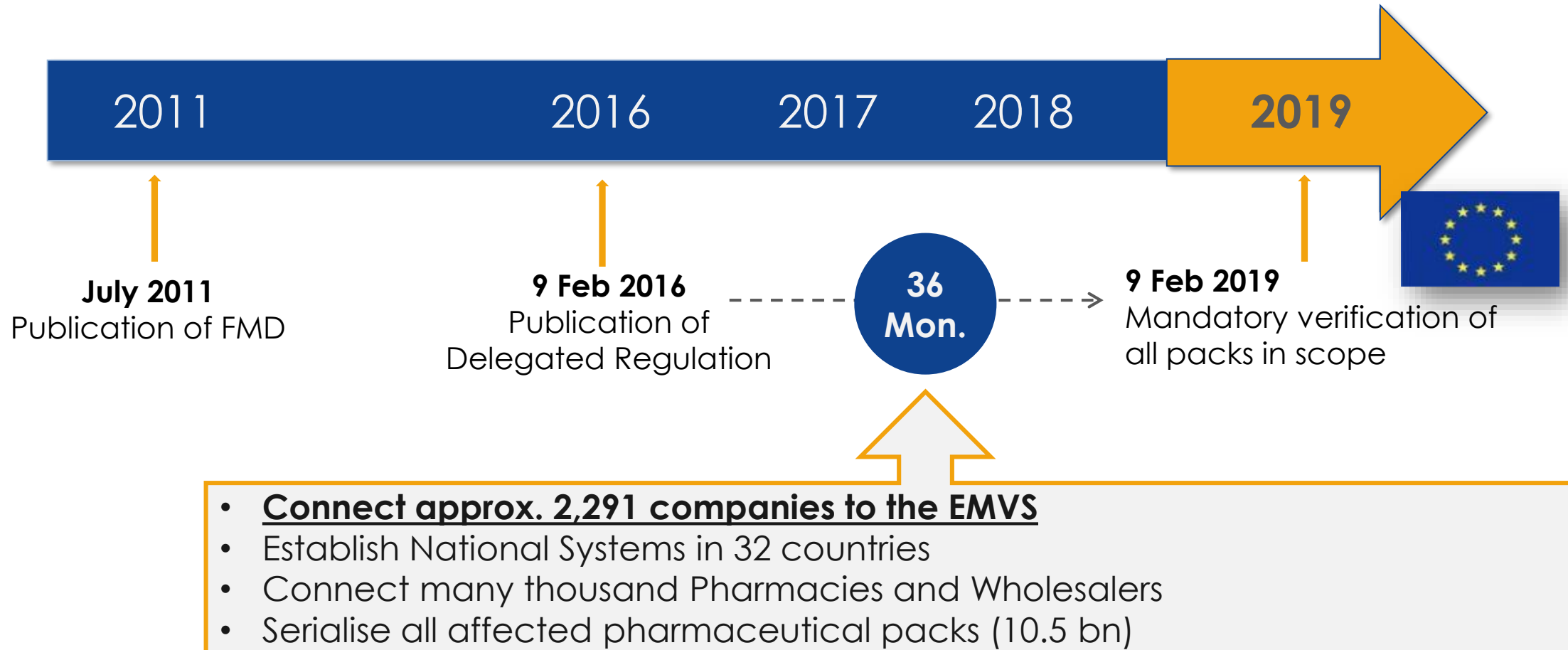
OSMR CONFERENCE
9TH FEBRUARY 2018

Andreas Walter
(General Manager)

"The Countdown is running. Implementation has to be finished till February, 9th 2019."

374:13:57:57
DAYS HOURS MINUTES SECONDS

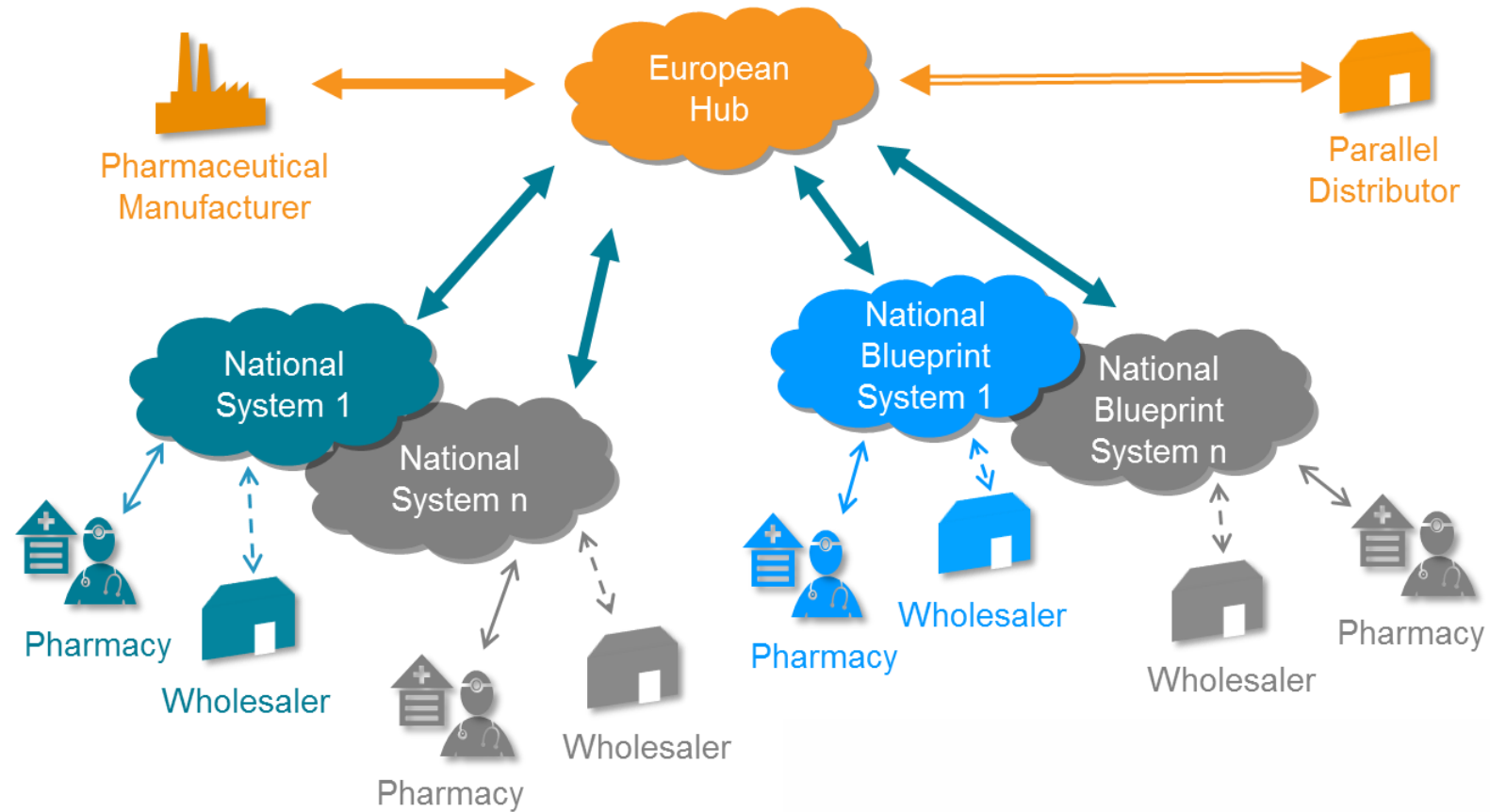
FMD LEGISLATION AND DELEGATED ACT



EMVO MEMBERS



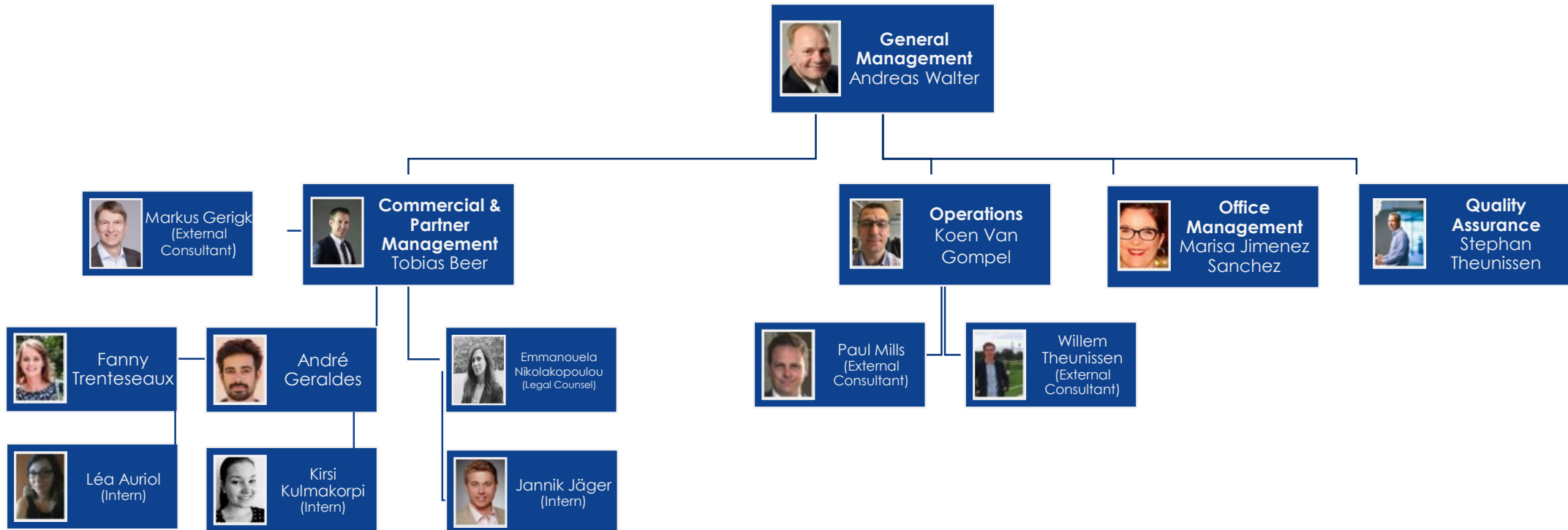
SYSTEM LANDSCAPE



ORGANISATIONAL CHART

EMVO Board of Directors

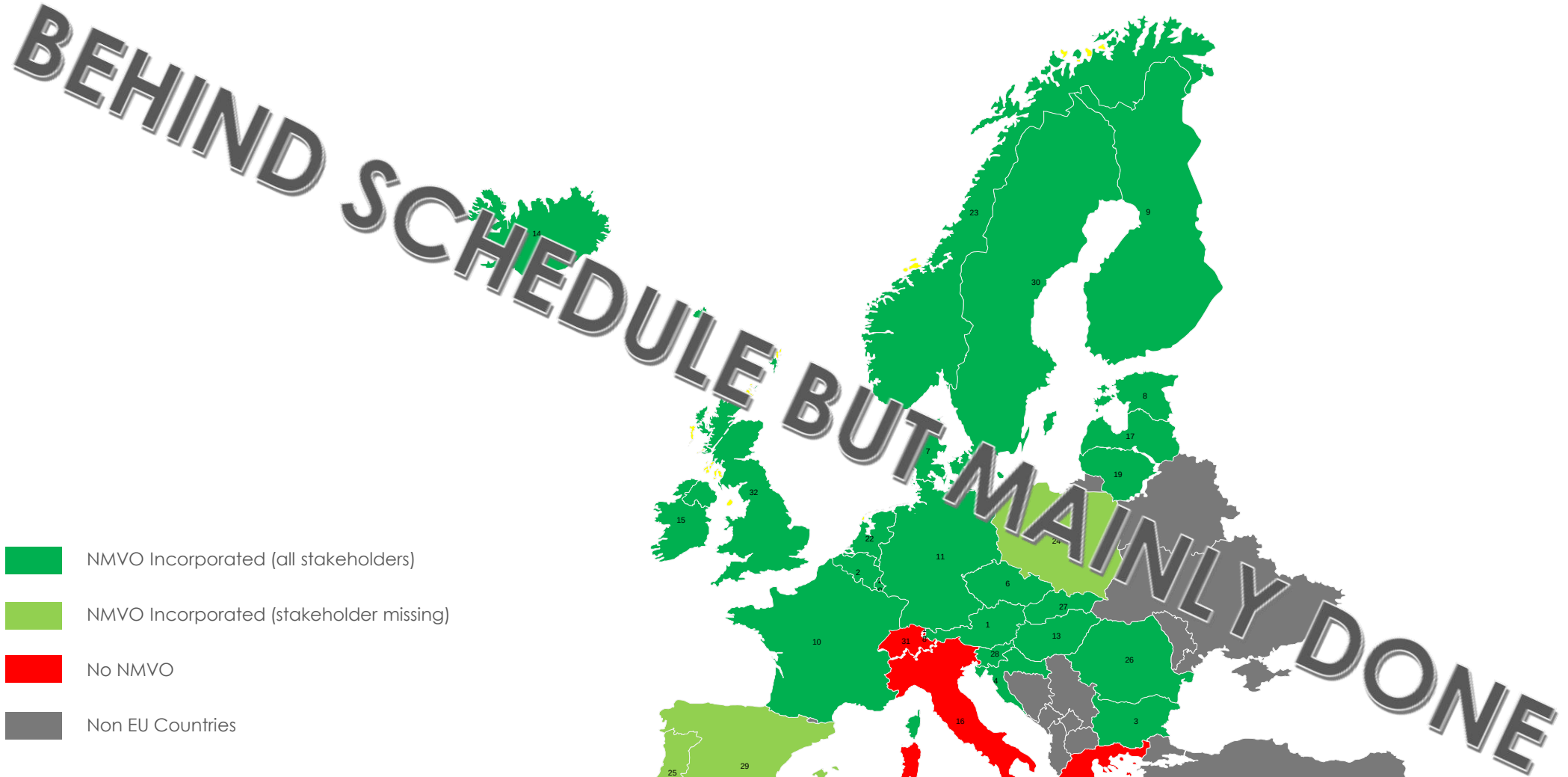
President: Hugh Pullen (EFPIA)
Vice-President: Sonia Ruiz Morán (PGEU)
Treasurer: Richard Freudenberg (EAEPC)
Monika Derecque-Pois (GIRP)
Adrian van den Hoven (Medicines for Europe)



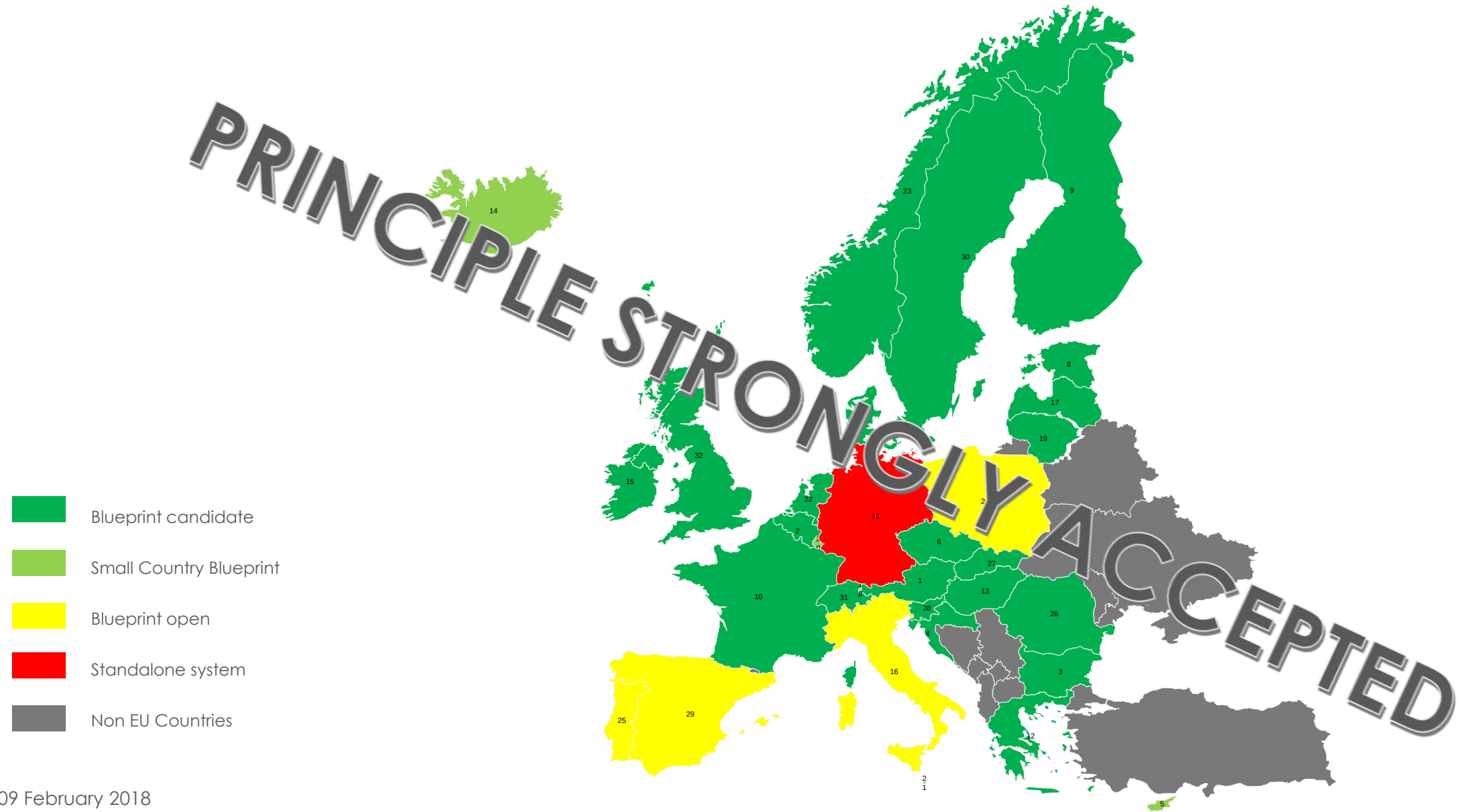
09 February 2018

EMVO 0086 OBP ON-BOARDING PRESENTATION V6.0

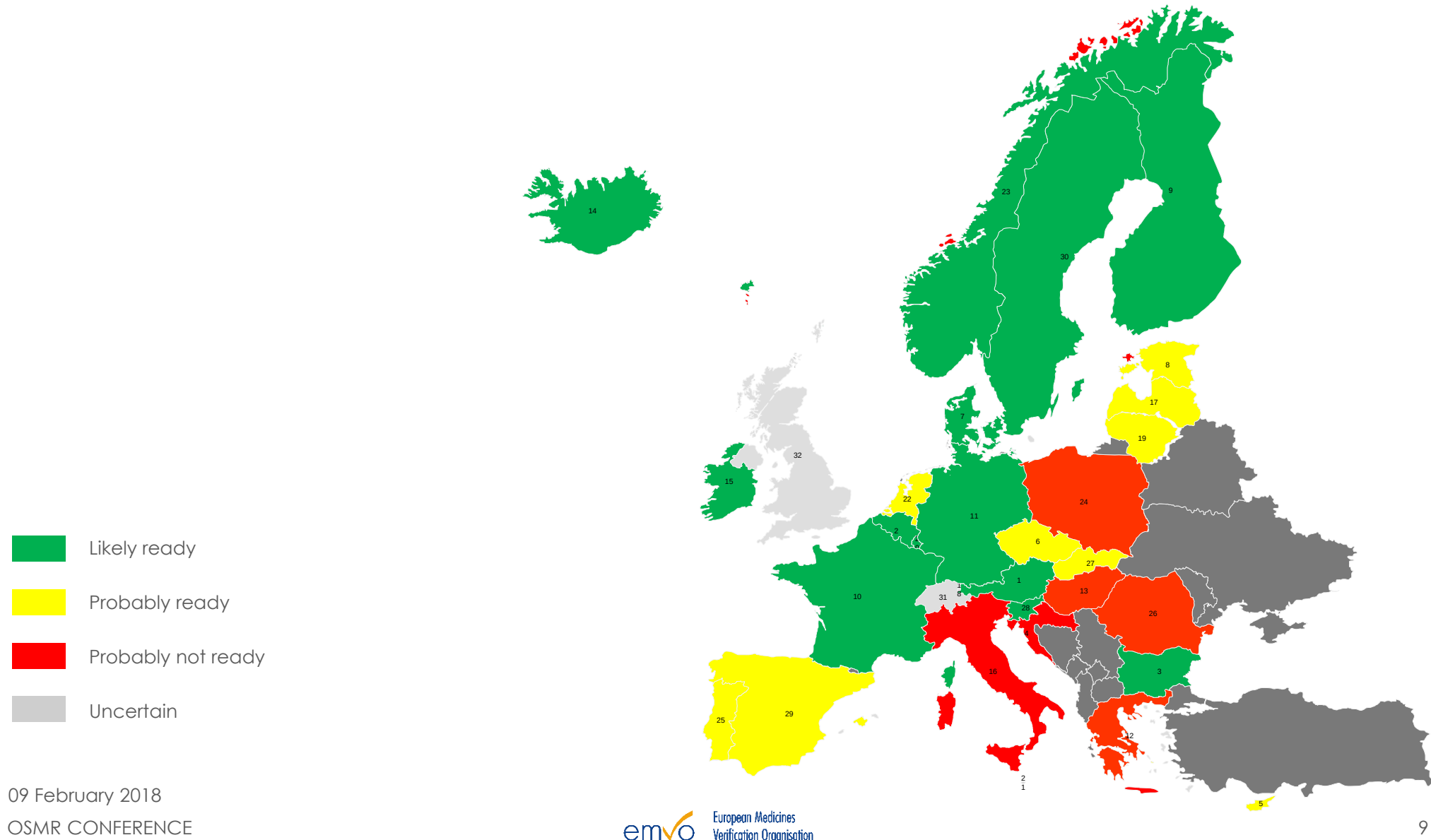
STAKEHOLDER GOVERNANCE: NMVO



BLUEPRINT TENDENCY



DR-COMPLIANCE 02/2019: HIGH-LEVEL ASSESSMENT



09 February 2018
OSMR CONFERENCE

CHALLENGES & ACHIEVEMENTS ON EUROPEAN LEVEL

Challenges

- Set-up EMVO & EU Hub
- NMVO incorporated & NMVS selected (provider contract signed)
- Connect approx. 2,291 On-boarding Partners (OBPs) to the EU Hub
- Connect 27 (+5) NMVS to the to the

EU Hub:

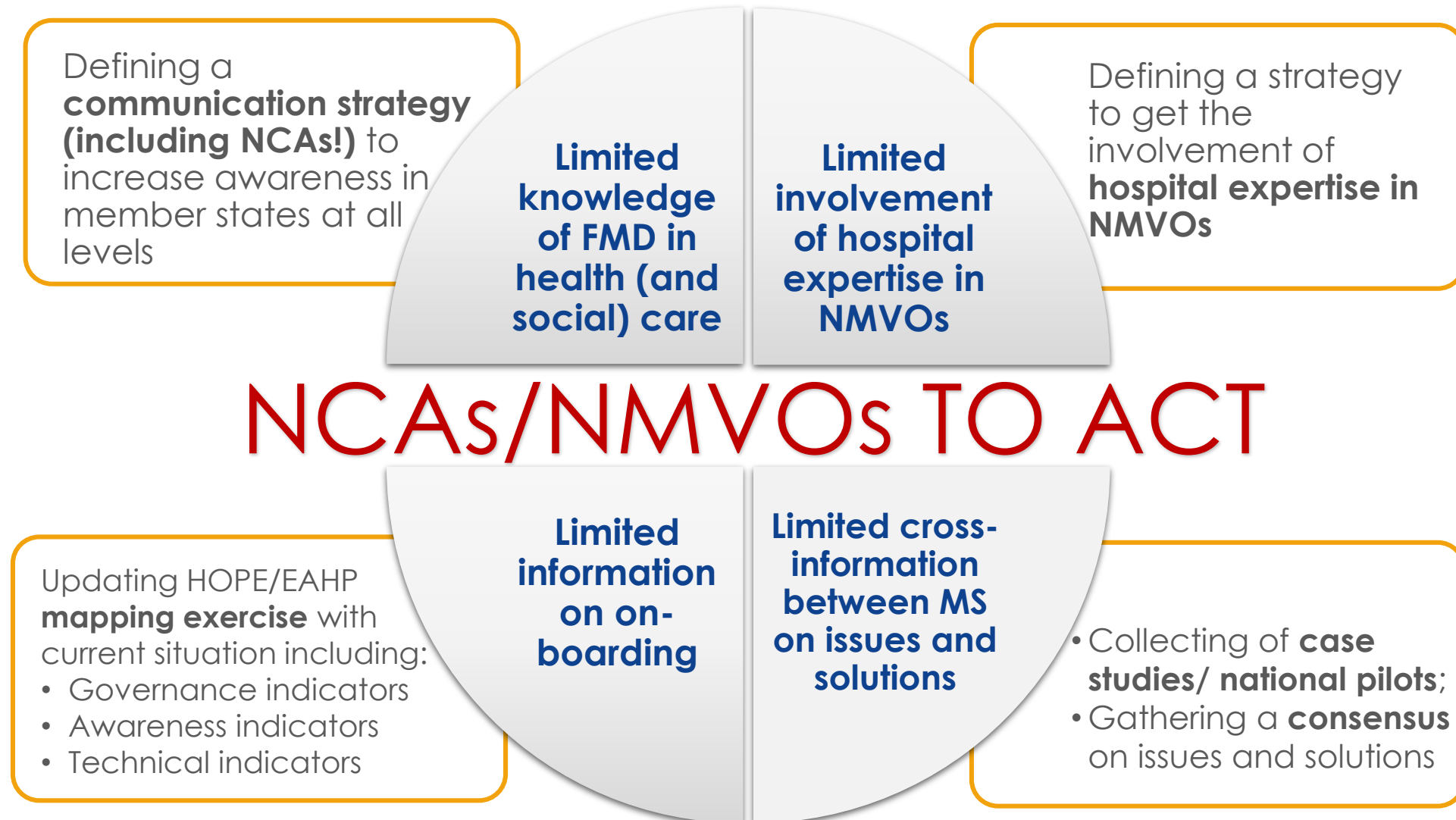
- Cooperation Agreement (CA) signed
- NMVS assessments & technical on-boarding
- On-boarding/certification of connection providers

Achievements

- ✓ EMVO incorporated & EU Hub upgraded 2.0 (but limited resources)
- ✓ 26 NMVOs (>75%) founded,
- ✓ 27 countries choose Blueprint
- ✓ 500 OBPs in Portal, 460 PA signed, 6 in PRD. **Scheduled: 1.900 end of Q4 2017**
- ✓ 18 CA signed
- ✓ Only Germany connected to EU Hub (PRD)

Support by NCAs needed

CHALLENGES & ACHIEVEMENTS ON NATIONAL LEVEL: HOSPITALS



CHALLENGES & ACHIEVEMENTS ON NATIONAL LEVEL: INVOLVEMENT NCAs

Challenges

- NCAs in several countries not involved reg. operations (awareness raising of end users and national manufacturers/MAHs)
- Nearly no support of NCAs reg. hospital integration in almost all countries (ownership, budgeting, awareness, etc.)
- Access to data by NCAs: Extended reporting requested

Achievements

- ✓ Slow progress and low feedback (despite EMVO circular)
- ✓ No progress or feedback (despite EMVO circular)
- ✓ Constructive dialogue NCAs (WG II)/EMVO in order to harmonise access to data/reporting throughout Europe. Common position possible.

NCAs/EMVO/NMVOs TO ACT

CONCLUSION: EUROPE CAN BE READY, IF.....

- ➔ There is strong involvement, commitment and cooperation of all supply chain stakeholders on European and national level: It is a European, not only a national project!
- ➔ NCAs play their role: Raising awareness, supporting the implementation process, hospitals, coding requirements, voluntary use of the safety features, regulatory pathway to implement the Safety Features, art work requirements, etc. Without support, the timely implementation could be at risk!
- ➔ COM supports the implementation process and clarifies the legislation (awareness, Q&A, etc.)