



European Medicines  
Verification Organisation



European Federation of Pharmaceutical  
Industries and Associations



PGEU GPUE



# IDENTIFICATION & AUTHENTICATION OF MEDICINES IN EUROPE: “OPPORTUNITIES AND CHALLENGES TO COMPLY WITH EU LEGISLATION”

CHINA/EU PHARMACEUTICAL FORUM 2018  
16<sup>TH</sup> APRIL 2018  
BASEL, SWITZERLAND

Andreas Walter  
(General Manager)

# AGENDA



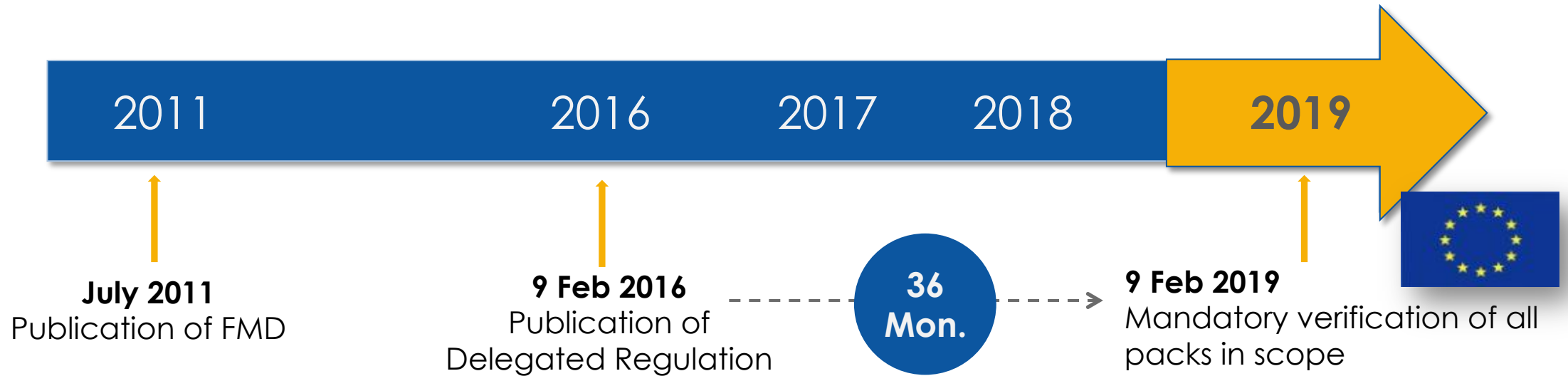
16th April 2018

EFPIA-CPIA WORKSHOP

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

**305:14:59:01**  
DAYS HOURS MINUTES SECONDS

# FMD LEGISLATION AND DELEGATED ACT



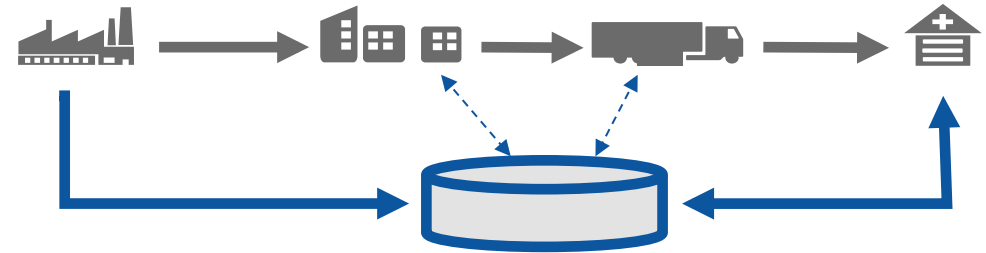
- **Connect approx. 2,291 companies to the EMVS**
- Establish National Systems in 32 countries
- Connect many thousand Pharmacies and Wholesalers
- Serialise all affected pharmaceutical packs (10.5 bn)

# THE DELEGATED *REGULATION* MANDATES RULES FOR R<sub>x</sub> MEDICINES VERIFICATION

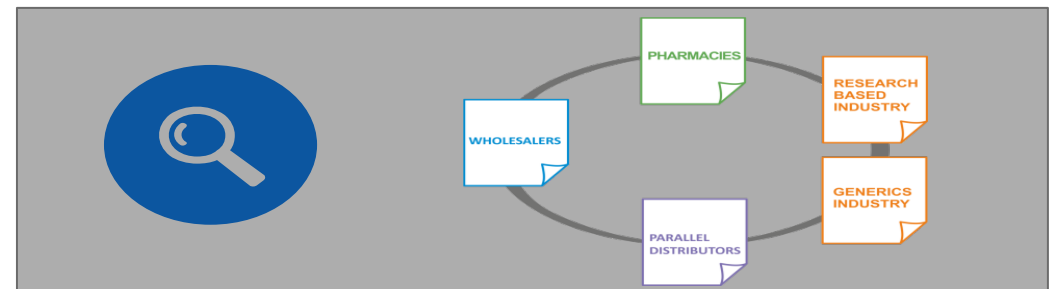
Serialization by manufacturer  
Risk based verification by Wholesalers  
Verification and check-out at point of dispense

Safety features:  
Code ('unique identifier')  
+  
Tamper evidence

System set up and governed by manufacturers and marketing auth. holders in consultation with other stakeholders.  
Oversight by competent authorities



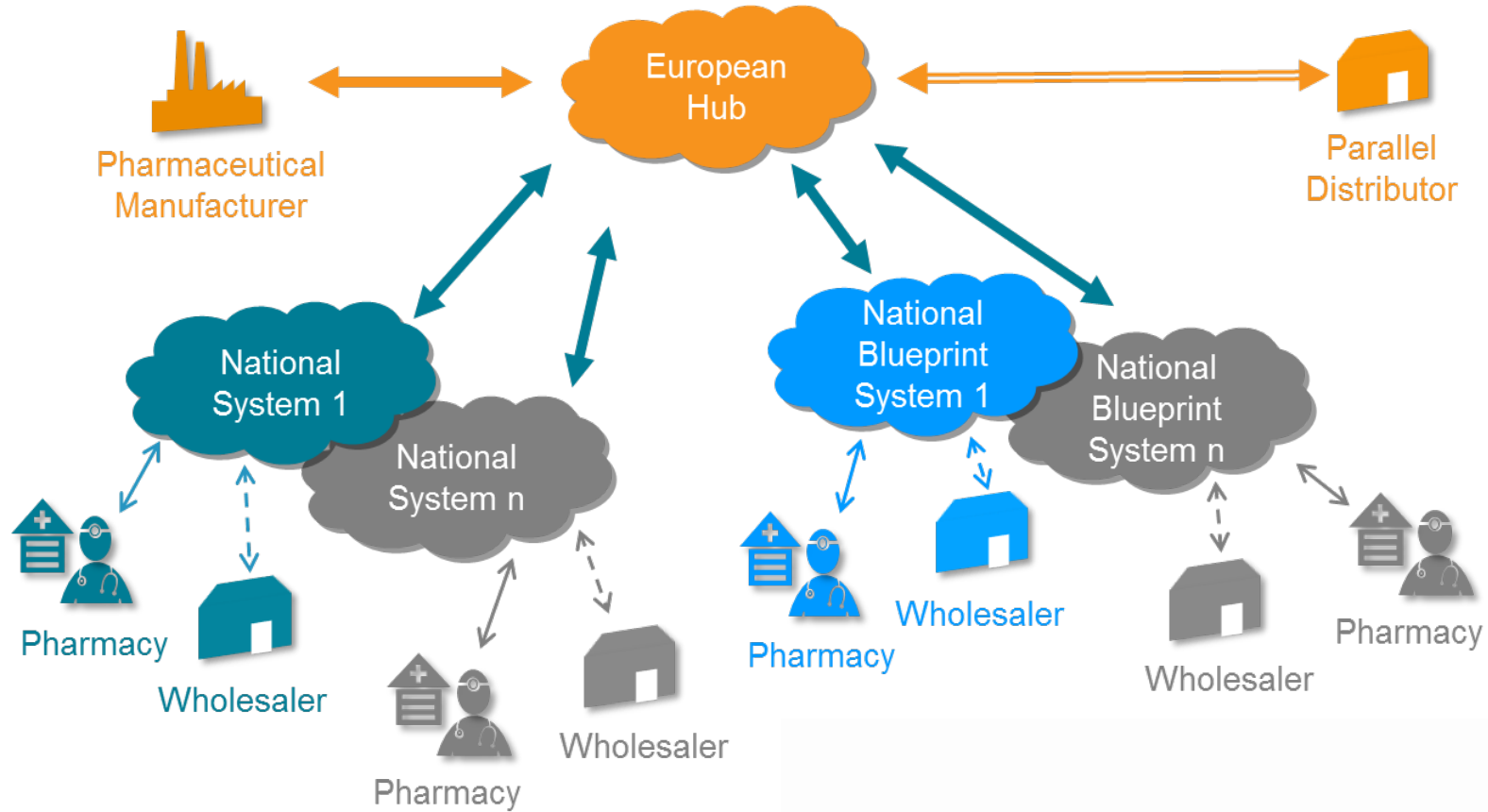
<b>Product #:</b> 09876543210982	
<b>S/N:</b> 12345AZRQF1234567890	
<b>Batch:</b> A1C2E3G4I5	
<b>Expiry:</b> 140531	



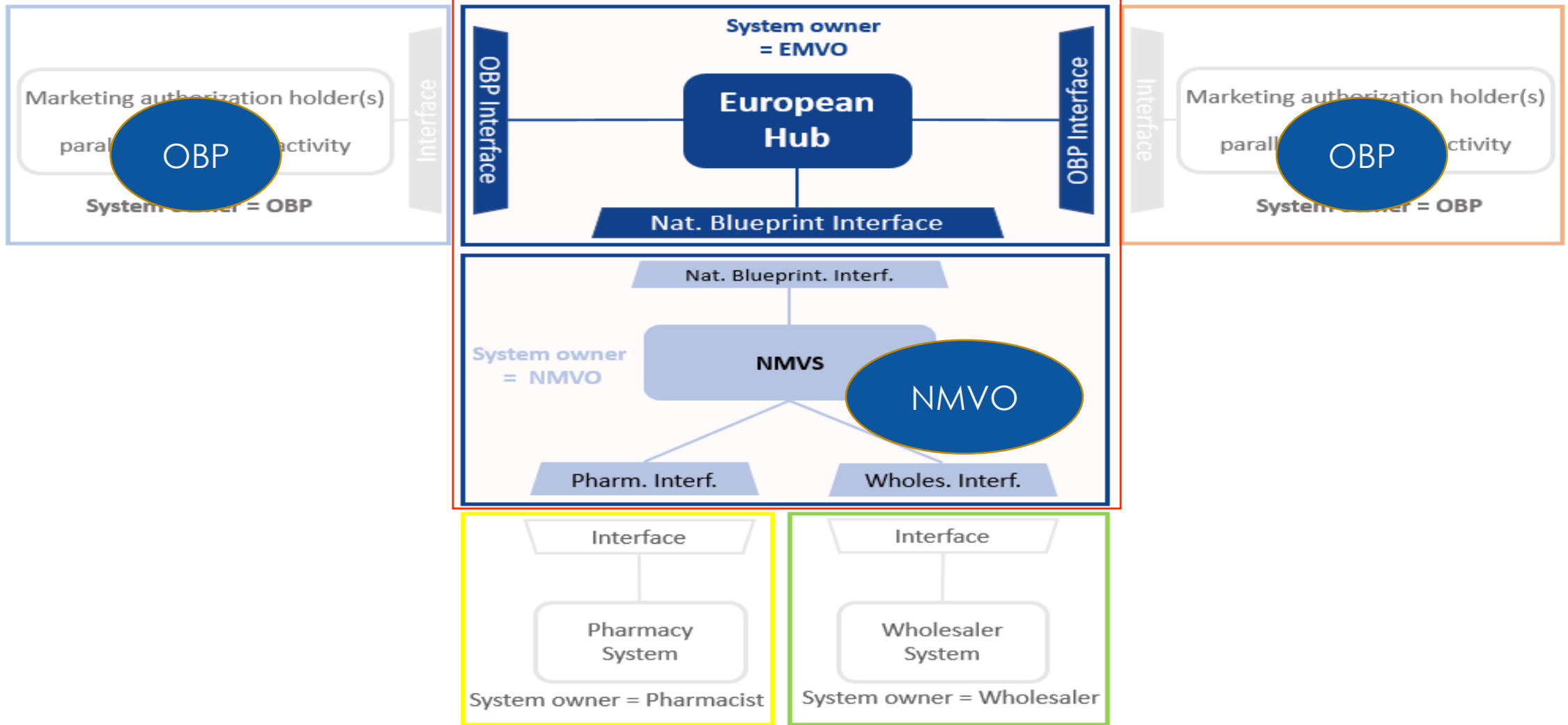
# AGENDA



# SYSTEM LANDSCAPE



# SYSTEM LANDSCAPE



**OBP:** On-boarding Partner  
**NMVS:** National Medicines Verification System  
**NMVO:** National Medicines Verification Organisation



# EMVO MEMBERS



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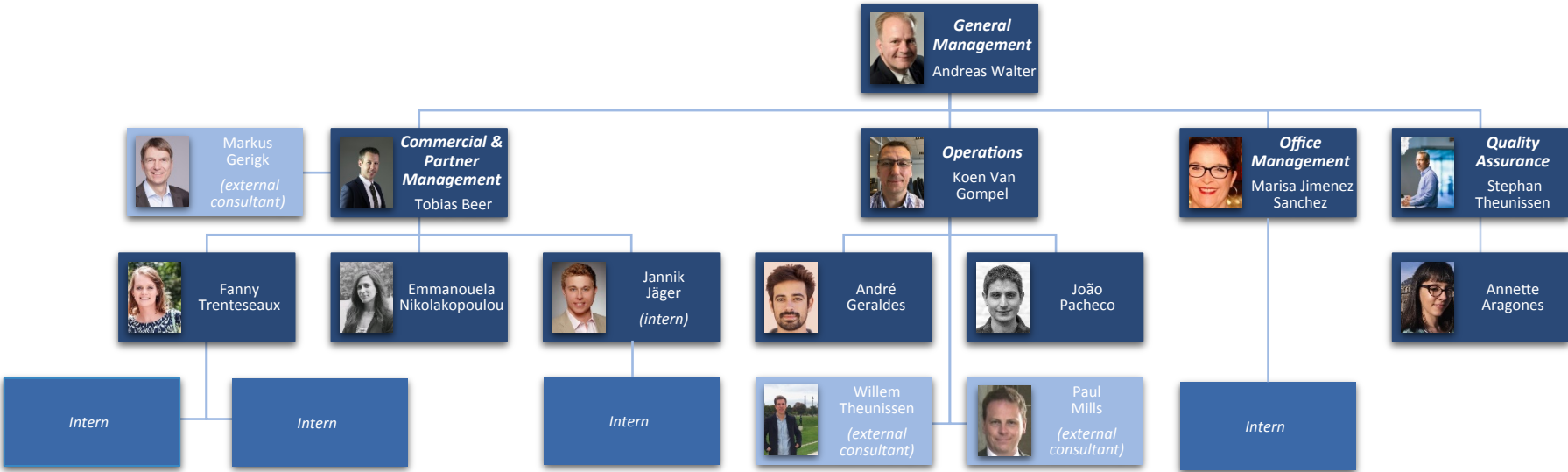
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Tel. Helpdesk  
+372 611 90 44

# ORGANISATIONAL CHART

**EMVO Board of Directors**  
 President: Hugh Pullen (EFPIA)  
 Vice-President: Sonia Ruiz Morán (PGEU)  
 Treasurer: Richard Freudenberg (EAEPD)  
 Monika Derecque-Pois (GIRP)  
 Adrian van den Hoven (Medicines for Europe)



# FIRSYT LINE SUPPORT: EMVO SERVICE CENTRE (Tallinn)



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# Agenda




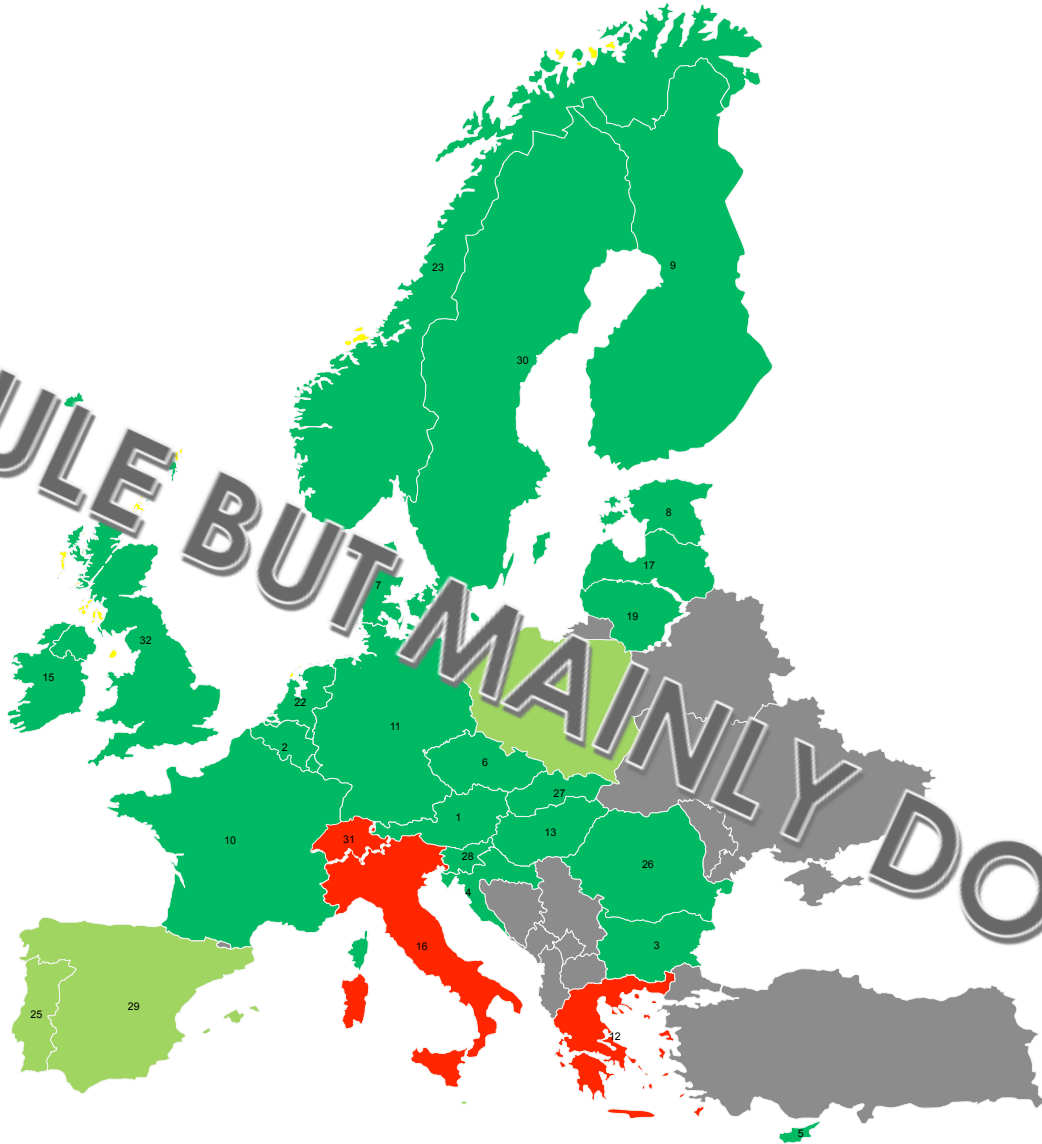
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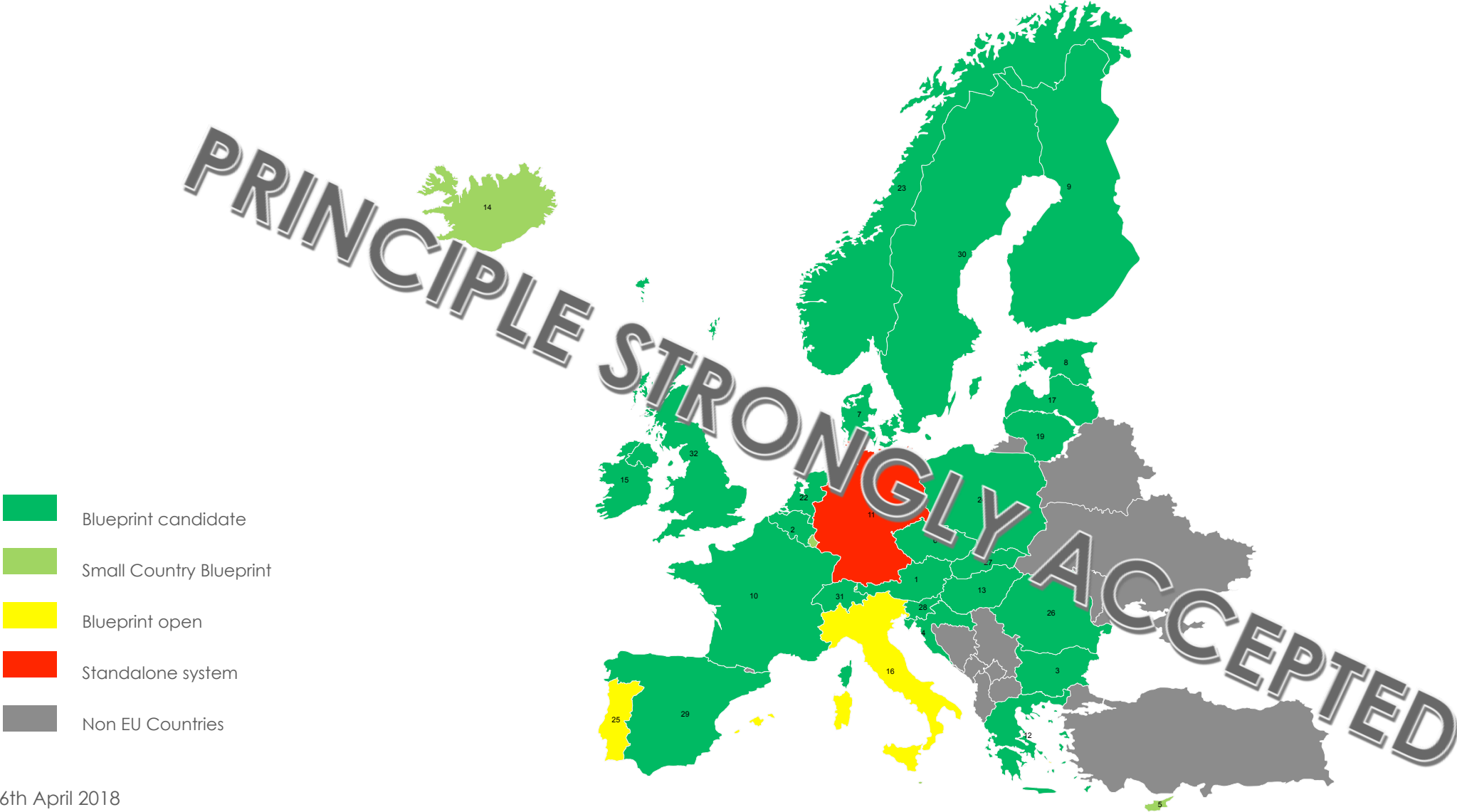
# STAKEHOLDER GOVERNANCE: NMVO

BEHIND SCHEDULE BUT MAINLY DONE

-  NMVO Incorporated (all stakeholders)
-  NMVO Incorporated (stakeholder missing)
-  No NMVO
-  Non EU Countries



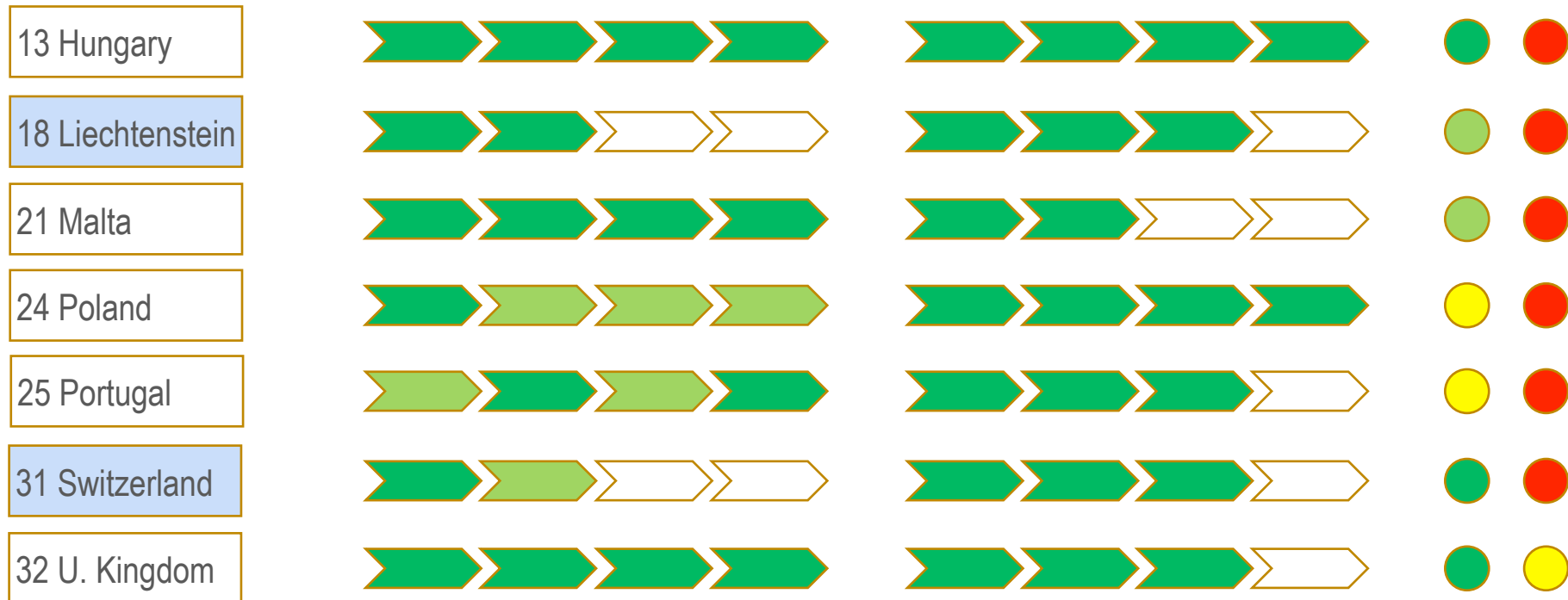
# BLUEPRINT TENDENCY



# DR-COMPLIANCE 02/2019: VERY LATE COUNTRIES

## Governance

## Technical



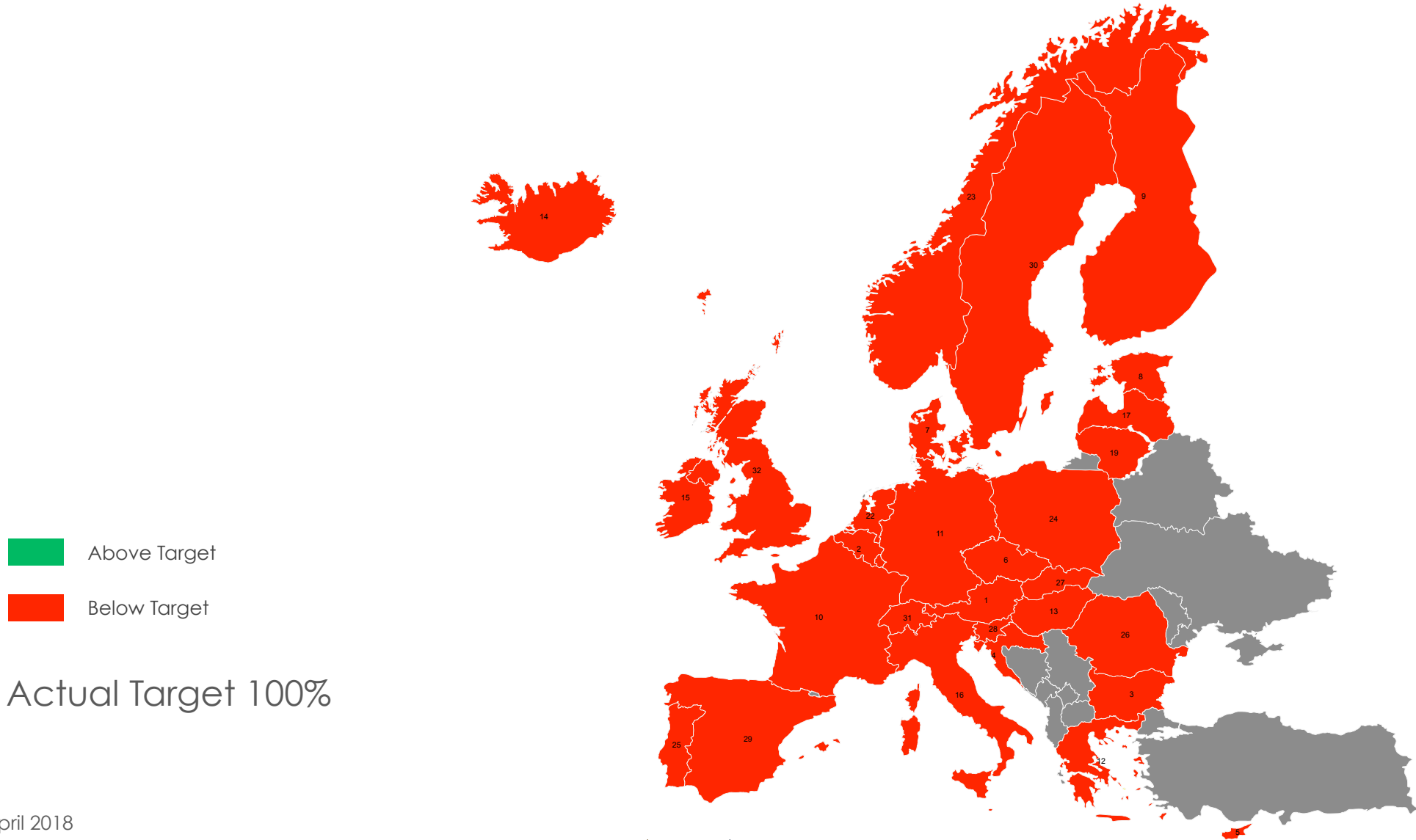
Align = Stakeholder Alignment  
 MoU = MoU signed  
 Stat = NMVO Statutes signed  
 NMVO = NMVO implemented

PM = Project Manager assigned  
 ProvC = Provider Contacts established  
 ProvS = Provider selected  
 Contr = Provider Contract signed

 = Incomplete Stakeholder Participation

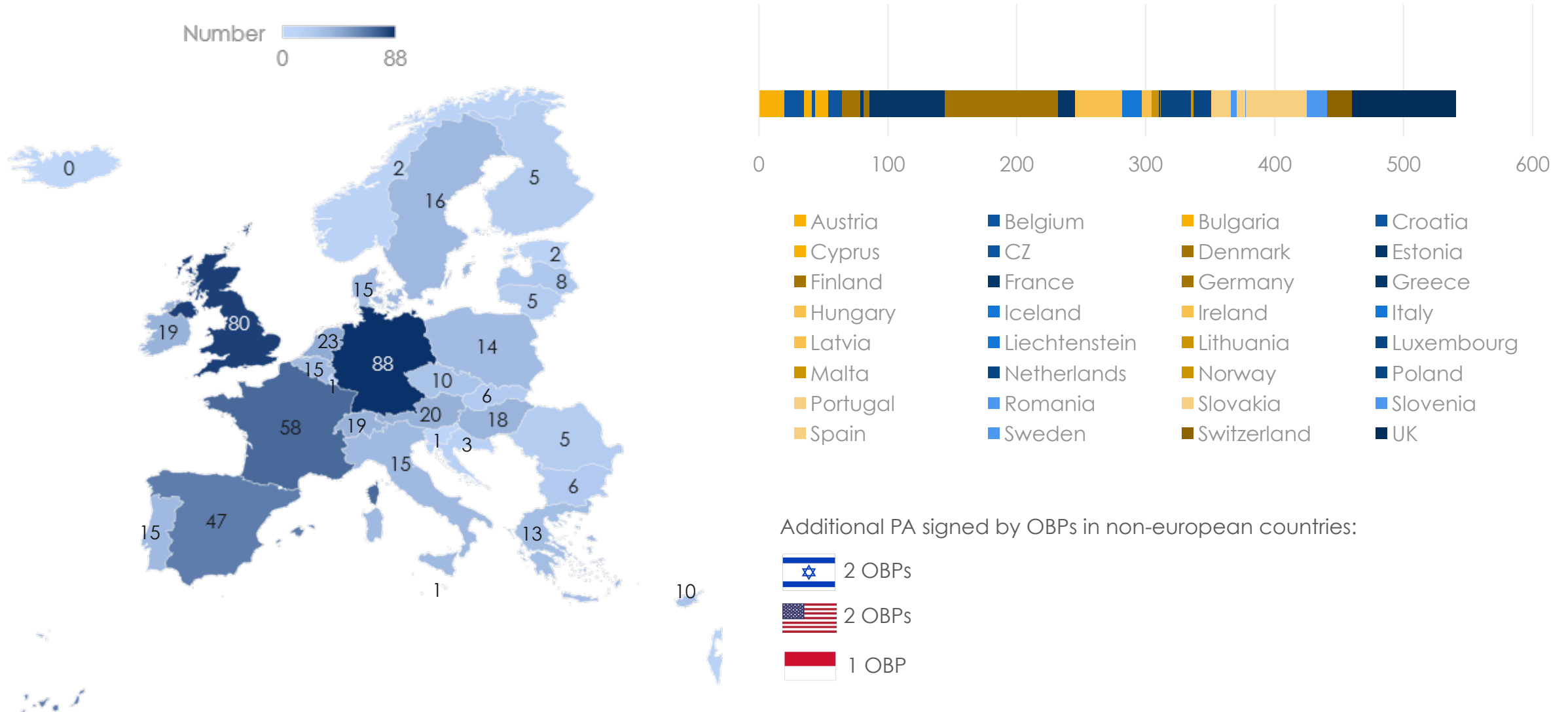
Greece and Italy not heading for 2019

# MAH ON-BOARDING

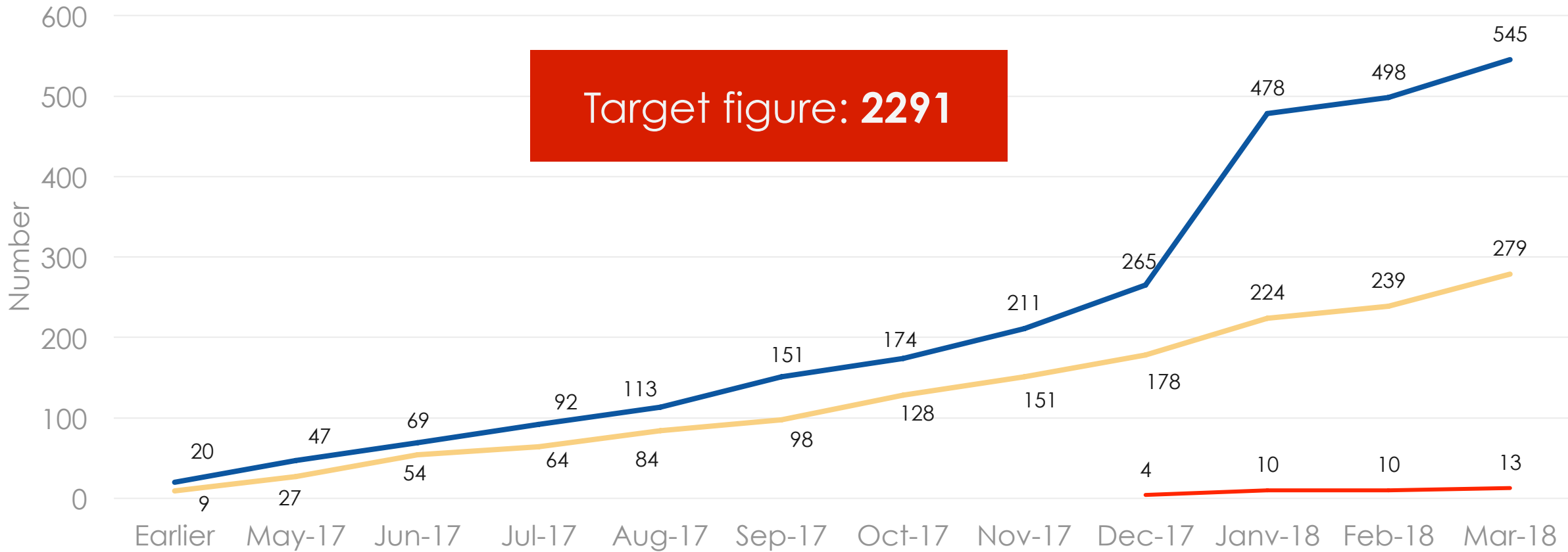




# SIGNED PARTICIPATION AGREEMENT BY OBPs PER COUNTRY



# STATUS ON-BOARDING



— Signed Participation Agreements  
— OBPs connected to Hub V2 (PRD)

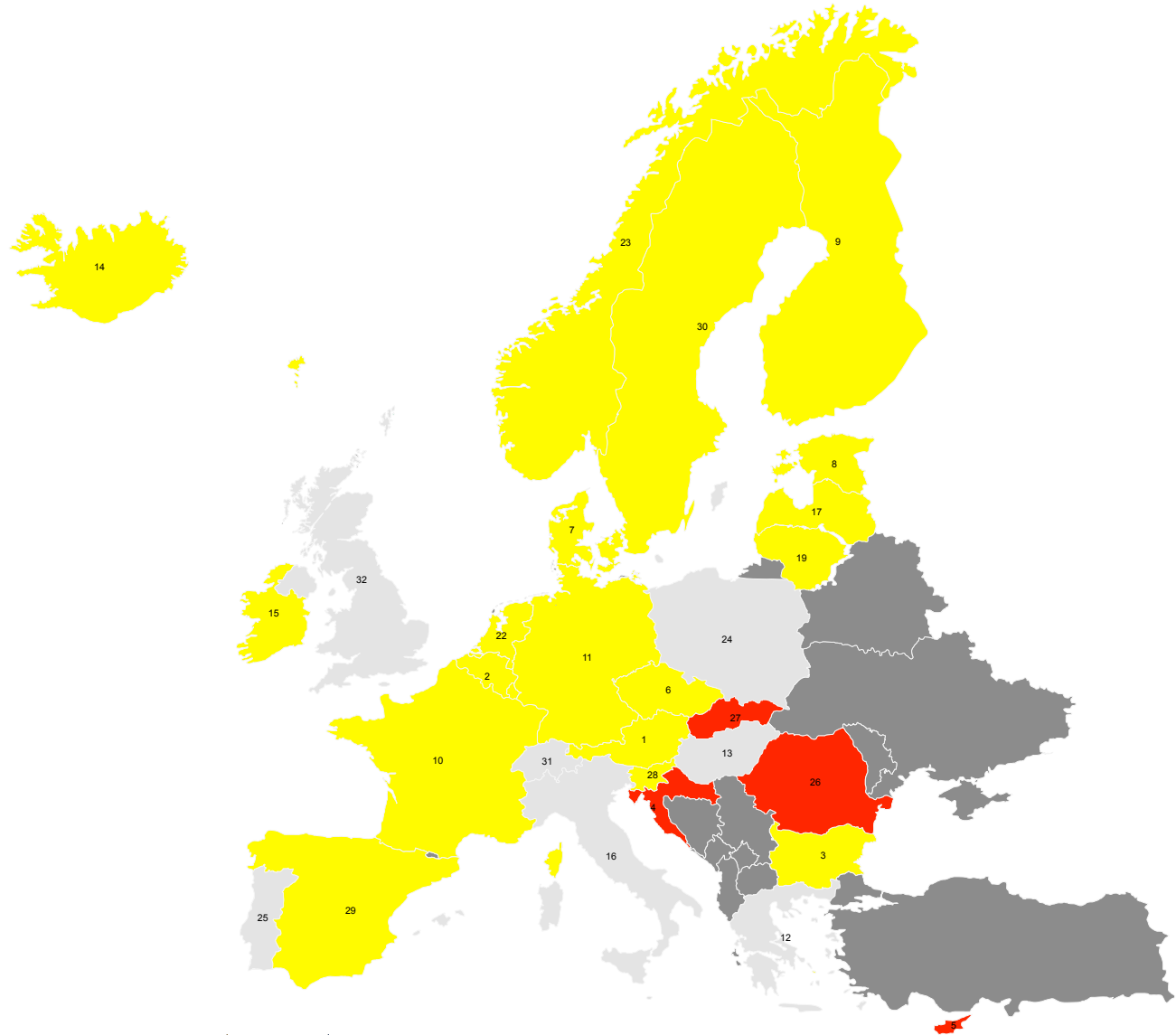
— Legitimacy check passed

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# NMVS READINESS



- Early Adopter
- Main Stream
- Late Follower
- Not started



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# END USER READINESS

Not yet activated

-  Above Target
-  Below Target



# AGENDA



# CHALLENGES & ACHIEVEMENTS ON EUROPEAN LEVEL

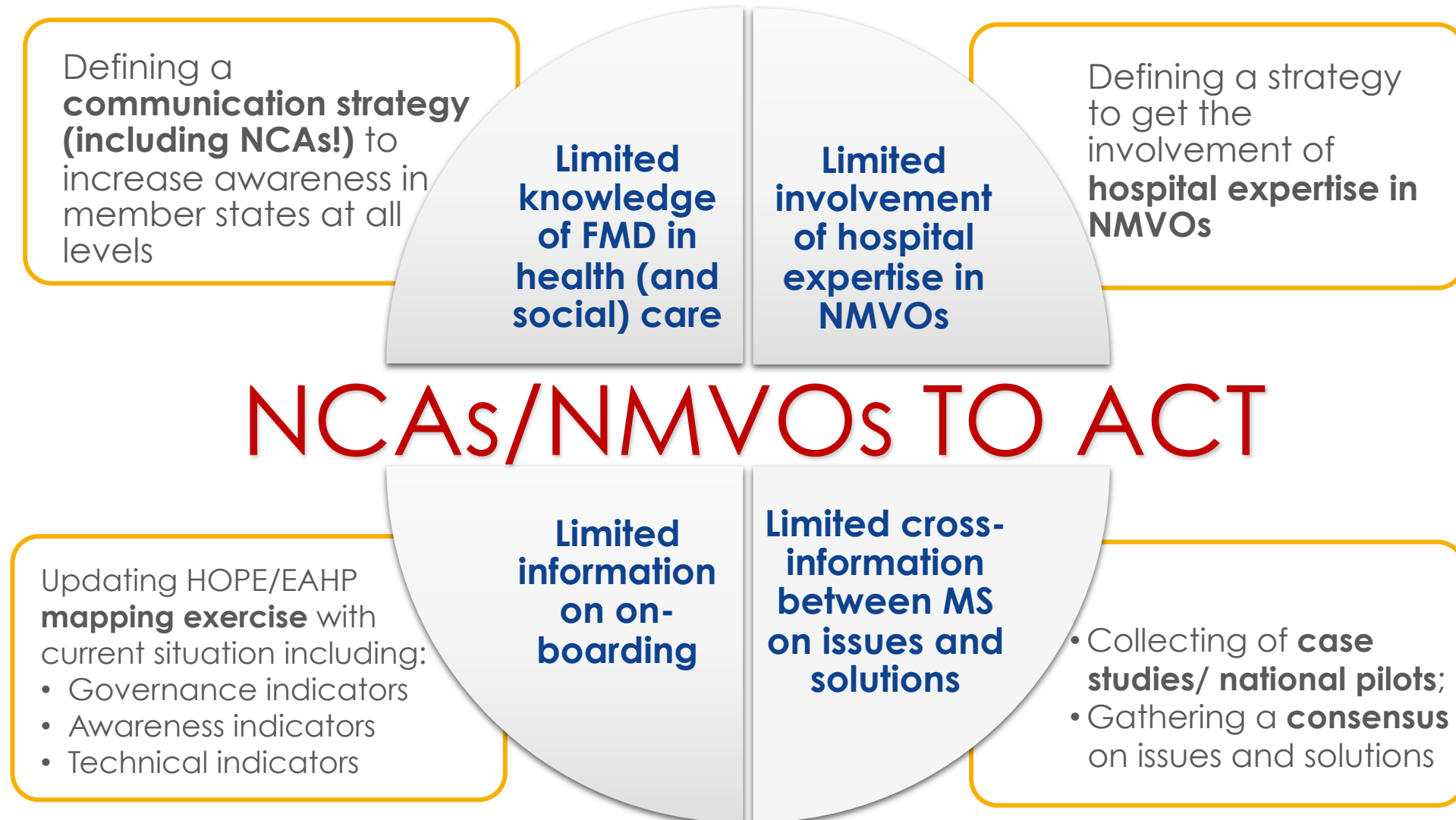
## Challenges

- 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)
- ✓ 29 NMVOs (>75%) founded,
- ✓ 30 countries choose Blueprint
- ✓ 656 OBPs in Portal, 545 PA signed, 13 in PRD. **Scheduled: 1.900 end of Q4 2017**
- ✓ 21 CA signed
- ✓ Only Germany connected to EU Hub (PRD)

# 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.....

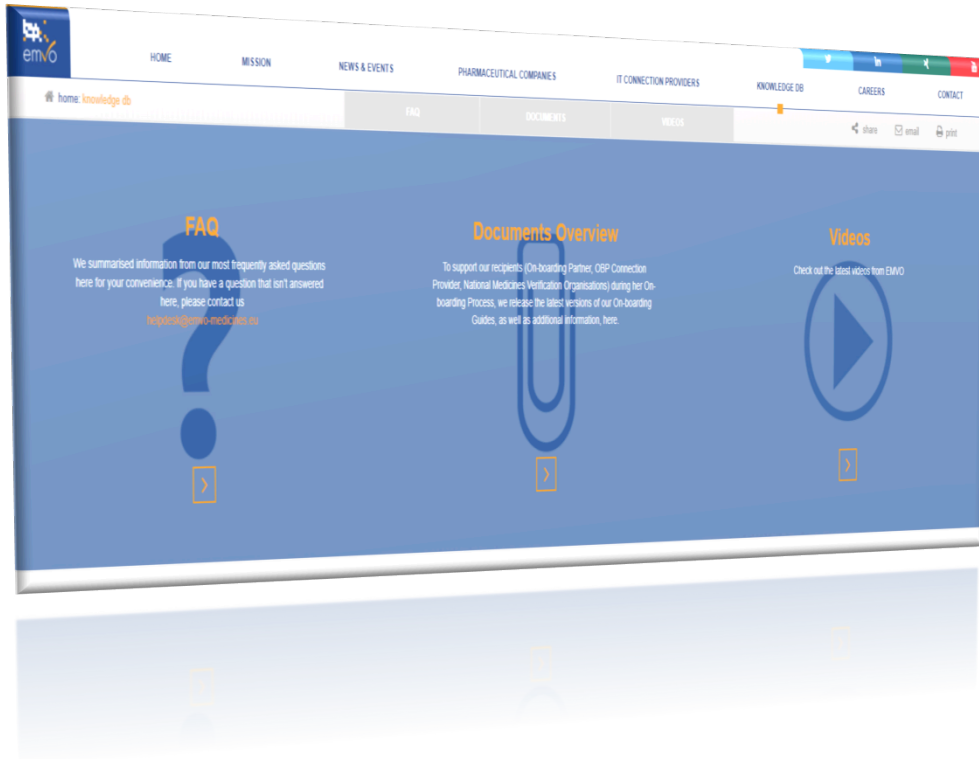
- ➔ There is strong involvement, commitment and cooperation of all supply chain stakeholders on European and national level: It is a European, not only a national project!
- ➔ NCAs play their role: Raising awareness, supporting the implementation process, hospitals, coding requirements, voluntary use 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.)



**Tel. Helpdesk: +372 611 90 44**

**E-Mail: [helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)**

# BACKUP



## ○ EMVO Website

- Process Description for Pharmaceutical Companies & OBP Portal  
<https://emvo-medicines.eu/pharmaceutical-companies/>
- Knowledge Database & Documents Overview  
<https://emvo-medicines.eu/knowledge-database/>

## ○ Documentation

- On-boarding Checklist  
<https://youtu.be/SvmHYSEOBdl>
- Presentation, Guideline, Master Data Guide  
<https://emvo-medicines.eu/knowledge-database/>