



**SAFER EUROPE  
WITHOUT FALSIFIED  
MEDICINES**



Estonian Presidency  
of the Council of the  
European Union

## Panel Discussion 'Is Europe Ready?'

9<sup>th</sup> November 2017  
12.00 – 13.00h

Chair: Agnès Mathieu-Mendes (EC)  
Panel: Anci Kvarnström (e-VIS)  
Andreas Walter (EMVO)





European Medicines  
Verification Organisation



European Federation of Pharmaceutical  
Industries and Associations



PGEU GPUE

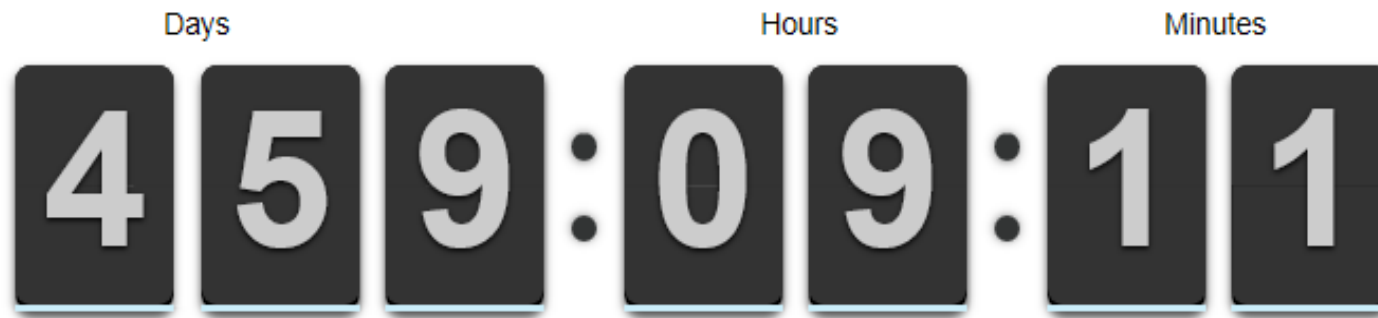


# SAFER EUROPE WITHOUT FALSIFIED MEDICINES

08-09/11/2017 TALLINN

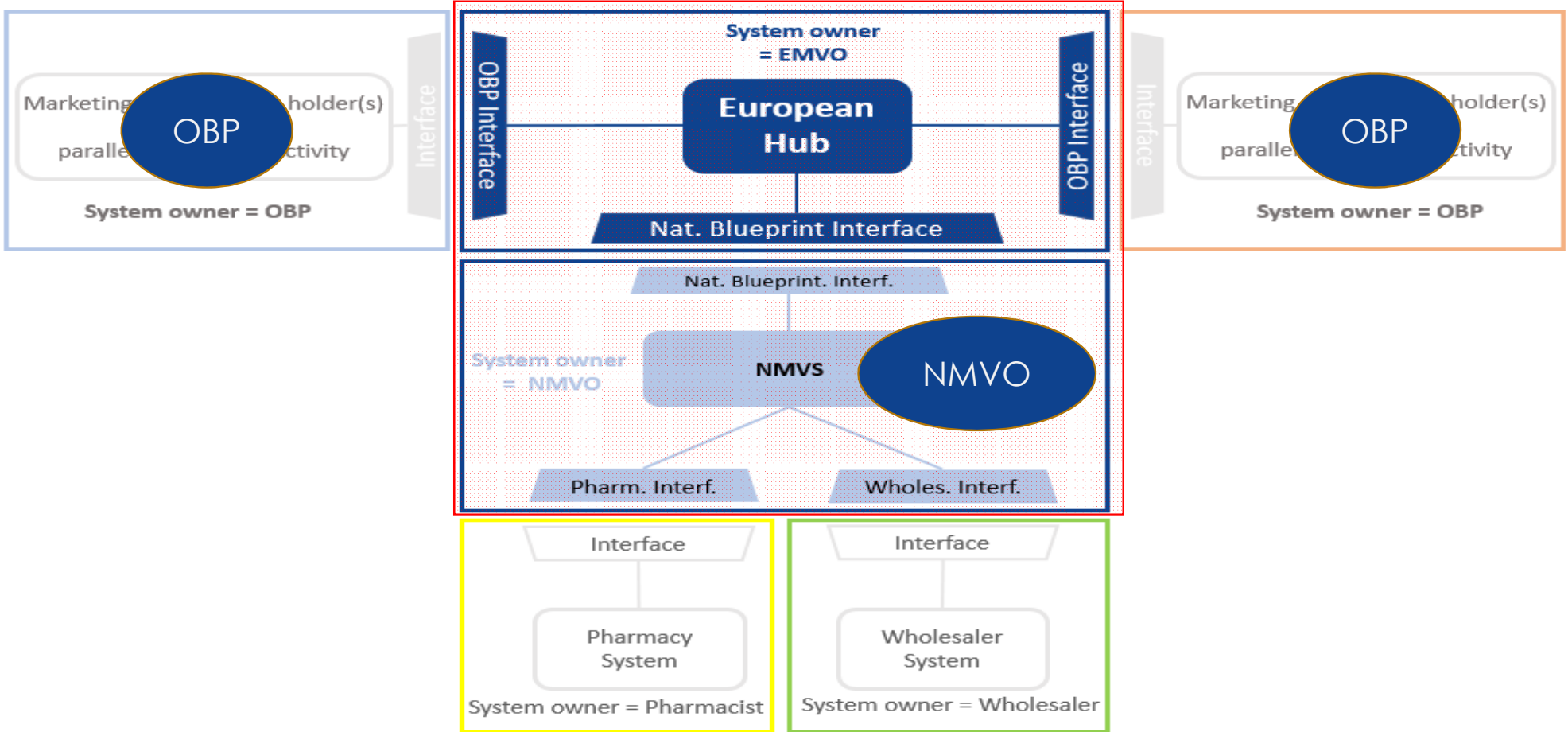
Pannel Session:  
Is Europe ready?

# THE COUNTDOWN IS RUNNING



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

# SYSTEM LANDSCAPE



**OBP:** On-boarding Partner  
**NMVS:** National Medicines Verification System  
**NMVO:** National Medicines Verification Organisation  
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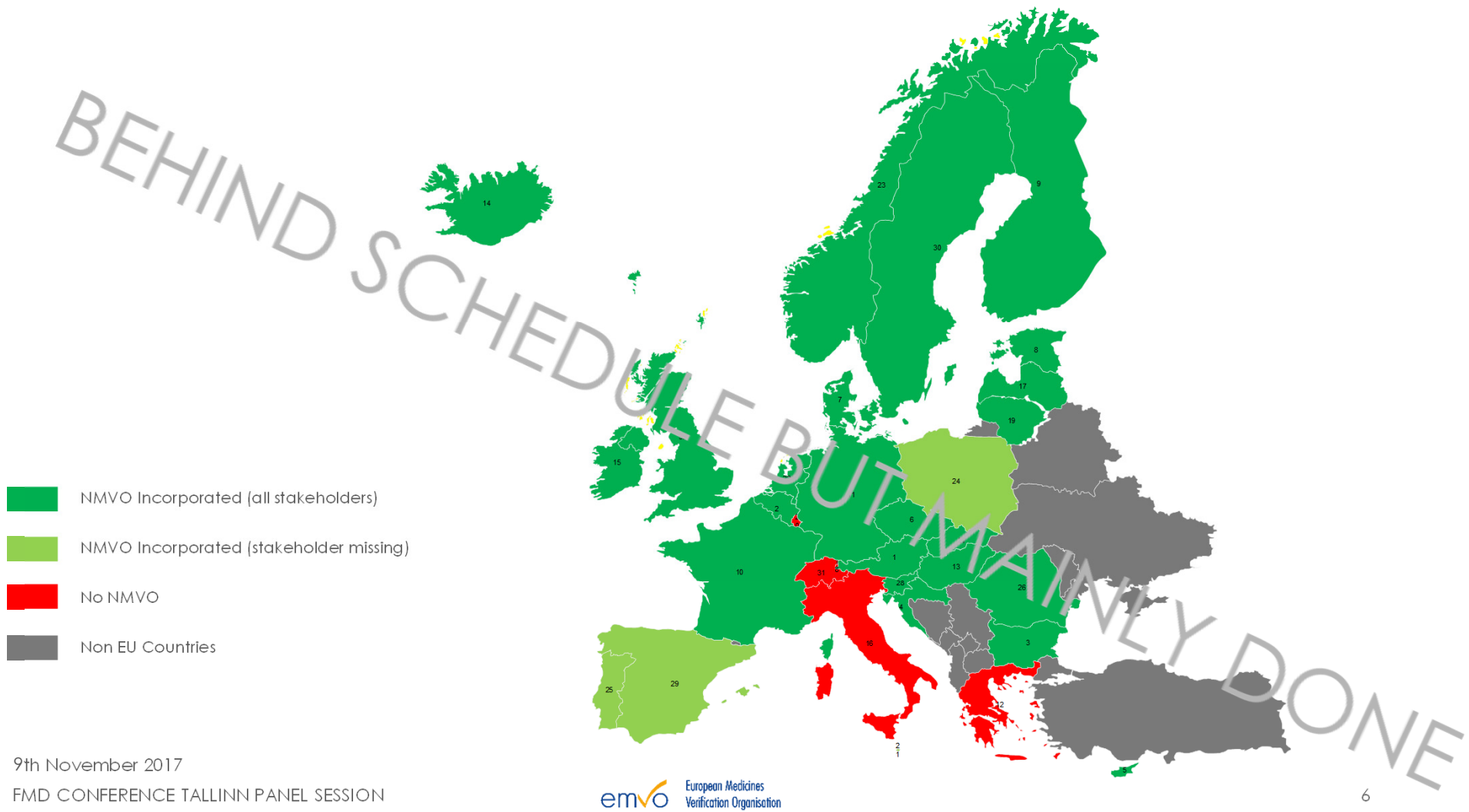
# STAKEHOLDER GOVERNANCE: EMVO (2015)



9th November 2017

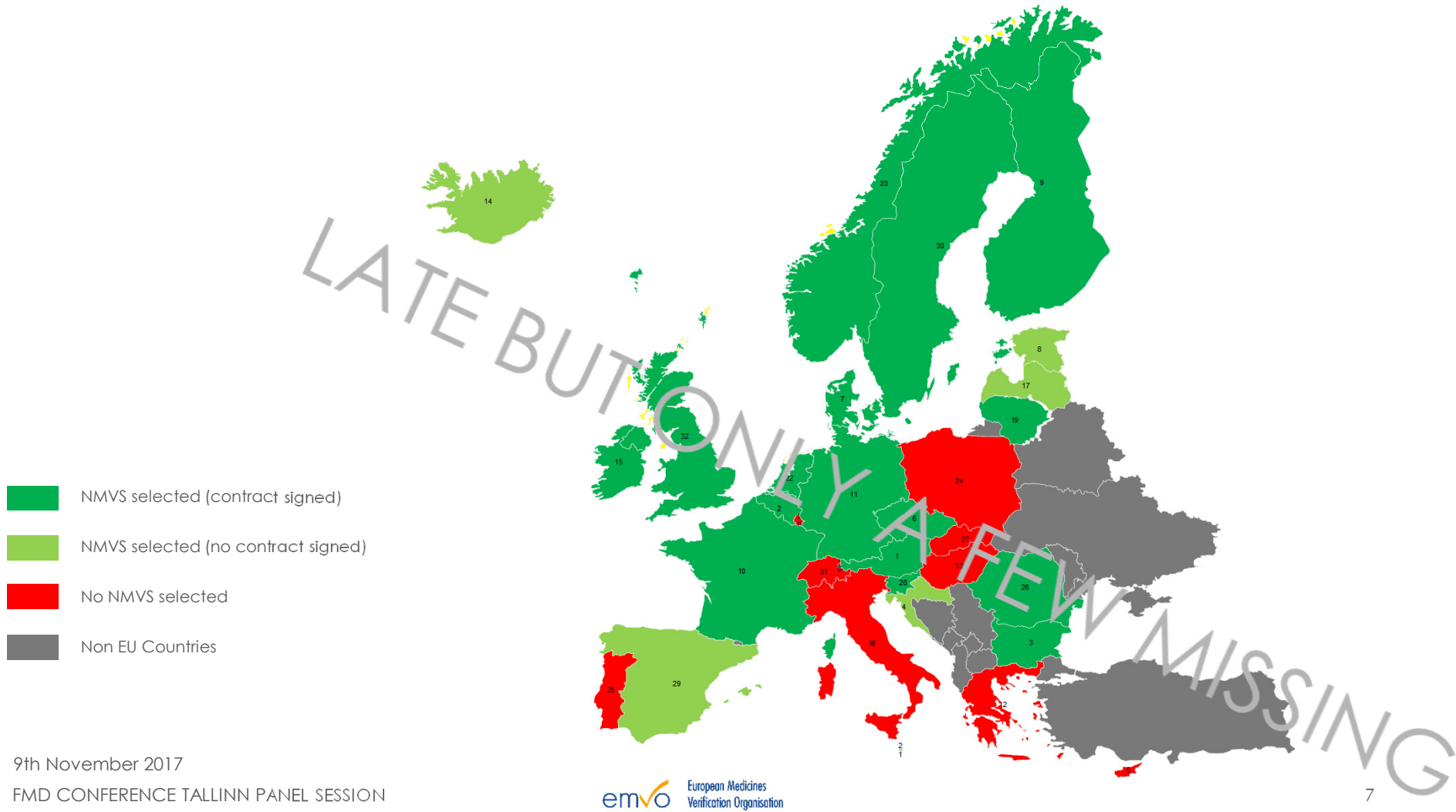
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# STAKEHOLDER GOVERNANCE: NMVO

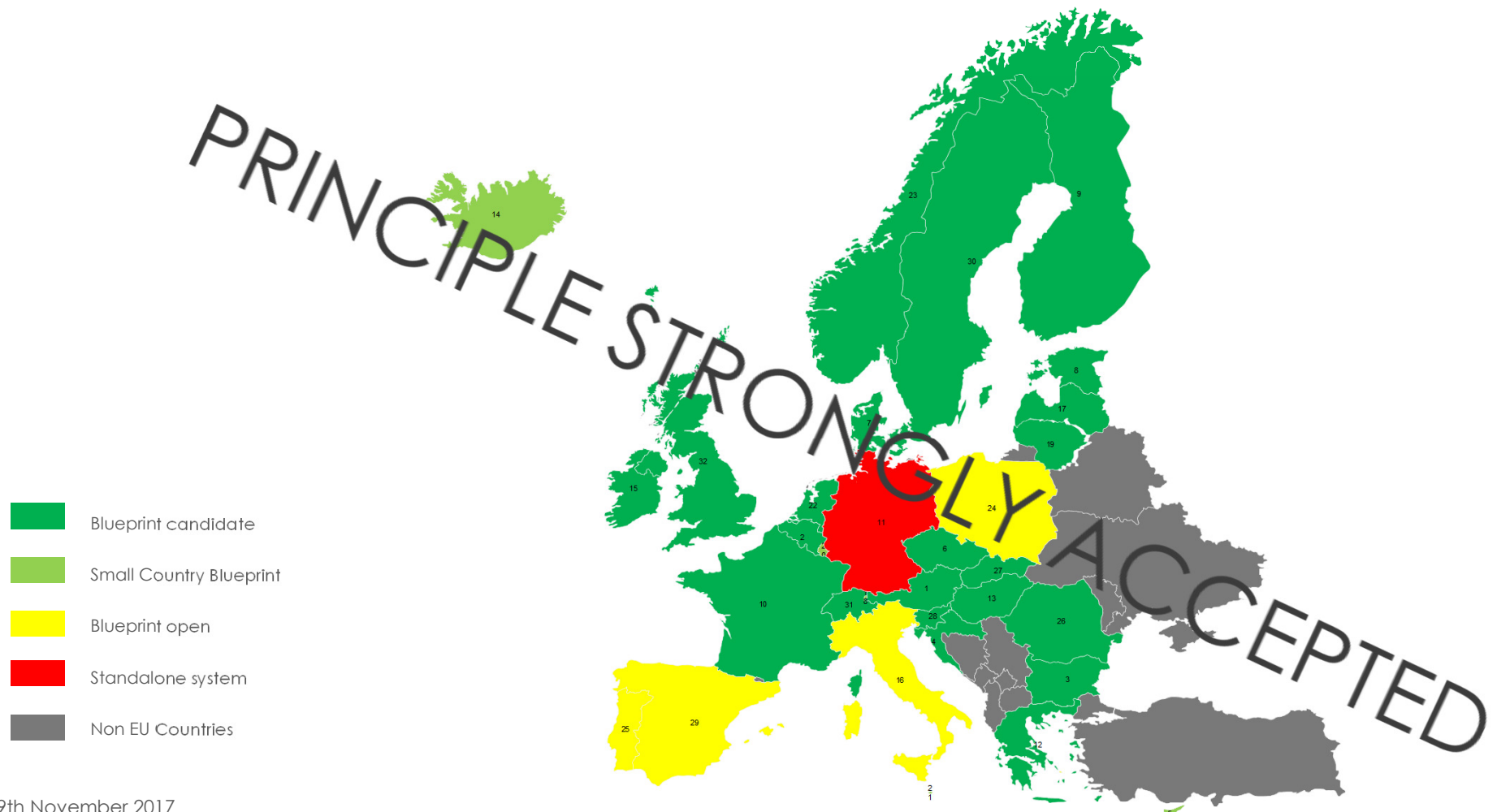


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# NMVS SELECTION



# BLUEPRINT TENDENCY



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# CHALLENGES & ACHIEVEMENTS ON EUROPEAN LEVEL – EMVS OPERATIONS

## CHALLENGES

- Set-up EMVO & EU Hub
- NMVO incorporated & NMVS selected (provider contract signed)
- Connect approx. 2,500 On-boarding Partners (OBPs) to the EU Hub
- Connect 27 (+4) NMVS to the to the

### EU Hub:

- Cooperation Agreement (CA) signed
- NMVS assessments & technical onboarding
- Onboarding/certification of connection providers

## ACHIEVEMENTS

- EMVO incorporated & EU Hub upgraded 2.0 (but limited resources)
- 26 NMVOs (>75%) founded, 15 contracts signed, 7 countries provider chosen (contract not signed)
- 27 countries choose Blueprint
- 263 OBPs in Portal, 174 PA signed, 8 in ITE. Scheduled: 1.900 end of Q4 2017
- 2 CA signed, 12 under negotiations
- No assessments planned, only Germany connected
- 15 countries started the Implementation Phase; Approximately 50% of the countries seem to start too late into the Implementation Phase
- Connection providers: 21 out of 120 in process.

# CHALLENGES & ACHIEVEMENTS ON EUROPEAN LEVEL – CODING/SERIALISATION

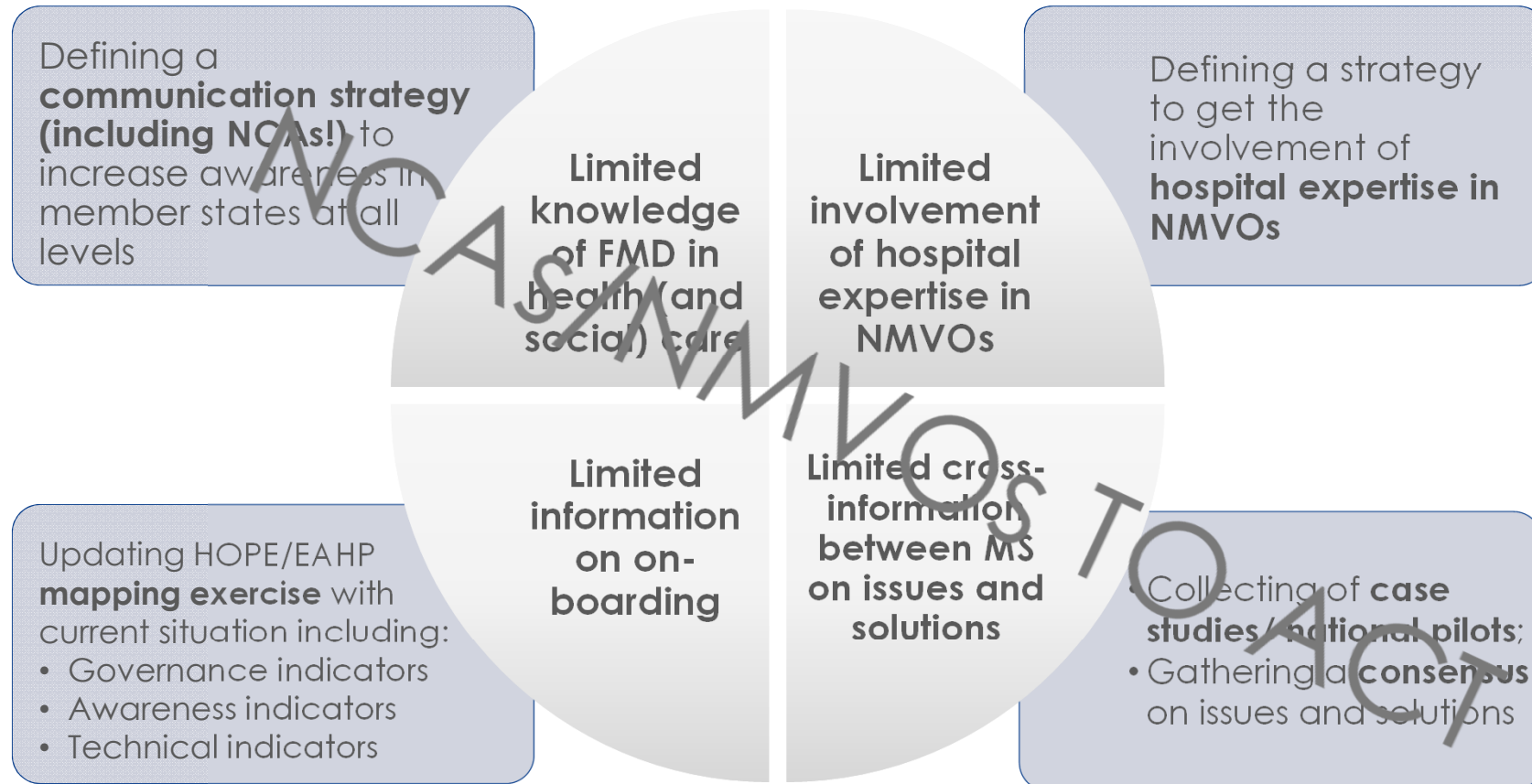
## CHALLENGES

- Choice of coding schemes
- Human readable text order and prefix (heading) location
- Use of labels to apply coding
- Barcode transition requirements
- Encoded data order
- Application identifier use
- Printed format of the 2D Data Matrix

## ACHIEVEMENTS & PROPOSALS

- Harmonisation on a good way
- The layout of the elements should not follow a specific order and header location should follow current common practice
- The use of labels/ stickers to apply the Unique Identifier should be allowed
- Removal of the linear barcode should be at the MAHs discretion
- Mandating specific order violates International Standards—therefore no specific order mandated
- Application Identifiers in the human readable text should be at the discretion of the MAH, in accordance with International Standards
- Square, Rectangular, White & Black 2D barcodes must be accommodated

# CHALLENGES & ACHIEVEMENTS ON NATIONAL LEVEL: HOSPITALS

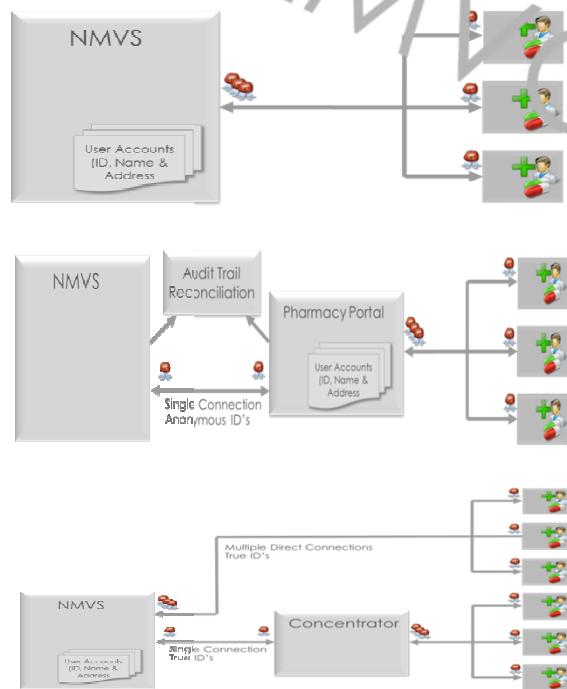


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# CHALLENGES & ACHIEVEMENTS ON NATIONAL LEVEL: NATIONAL RAMP UP & PILOTING

## END USER SYSTEMS & END USERS CONNECTED & LIVE



## CHALLENGES & ACHIEVEMENTS

- Blueprint facilitates timely implementation of NMVS & end user systems
- NMVS implementation delayed (late NMVO incorporation & provider selection/contracting)
- (Harmonised) End user connection at risk (system architecture/design, number of end user not always known, Provisions to accommodate specific characteristics of Member States' supply chains (Art 23, DR), etc.)
- Piloting delayed (delayed NMVS onboarding, delayed system implementation, delayed availability of serialised products)

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# 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.

## 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.)

