



Estonian Presidency  
of the Council of the  
European Union

## Session I: European and National Medicines Verification Organisations – State of Play

8<sup>th</sup> November 2017  
13.30 – 15.00h

Chair: Andreas Walter (EMVO)

Panel: Leonie Clark (IMVO)

Maija Gohlke-Kokkonen (FiMVO)

Illiana Paunova (BgMVO)

Raul Mill (REKS)





European Medicines  
Verification Organisation



European Federation of Pharmaceutical  
Industries and Associations



PGEU GPUE



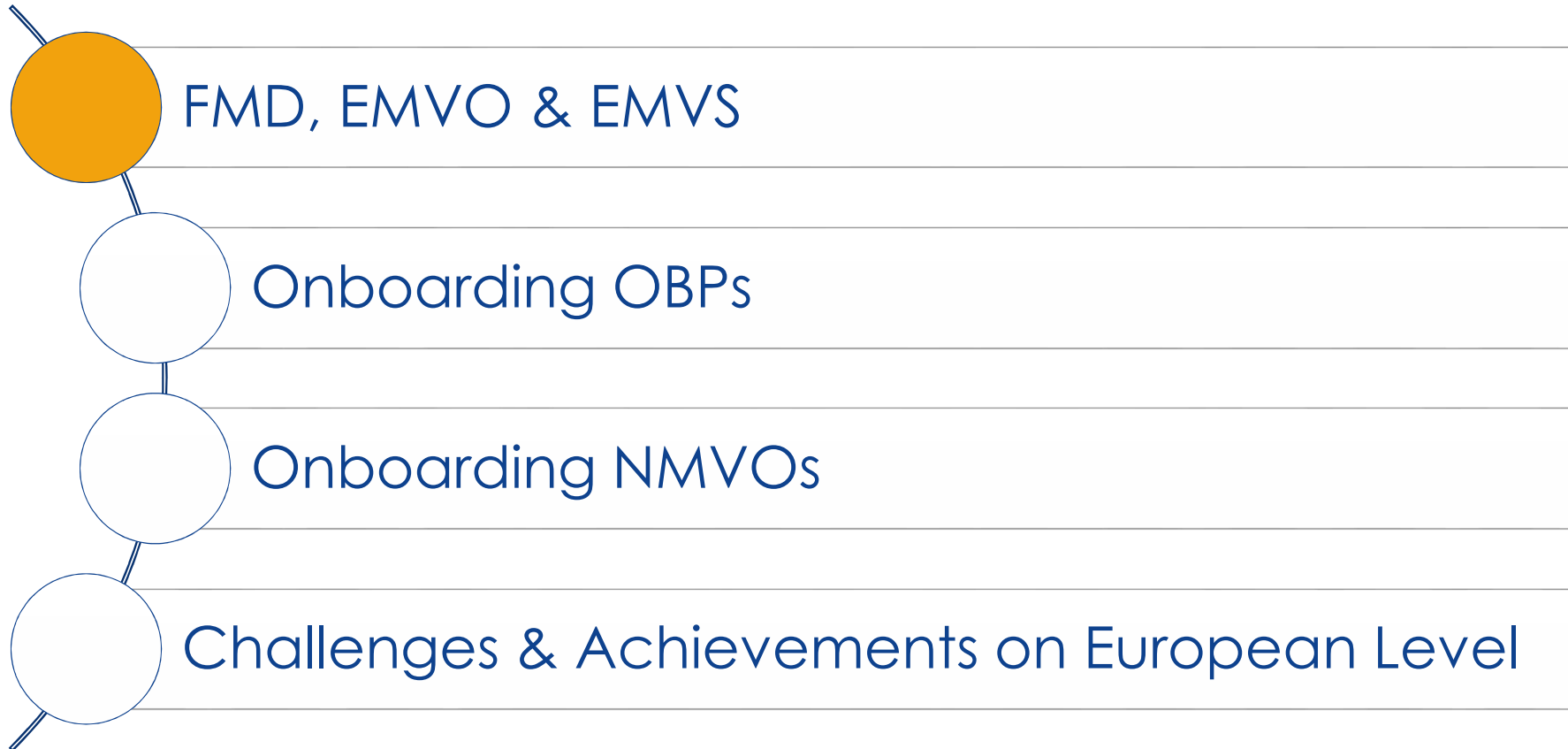
# SAFER EUROPE WITHOUT FALSIFIED MEDICINES

## 08-09/11/2017 TALLINN

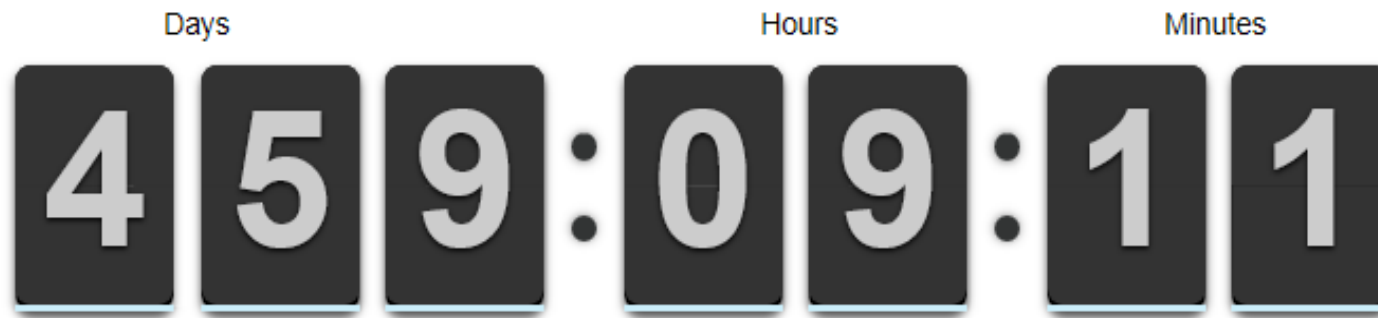
Session I:  
European and National Medicines  
Verification Organisations -  
State of Play

Andreas Walter (EMVO)

# AGENDA



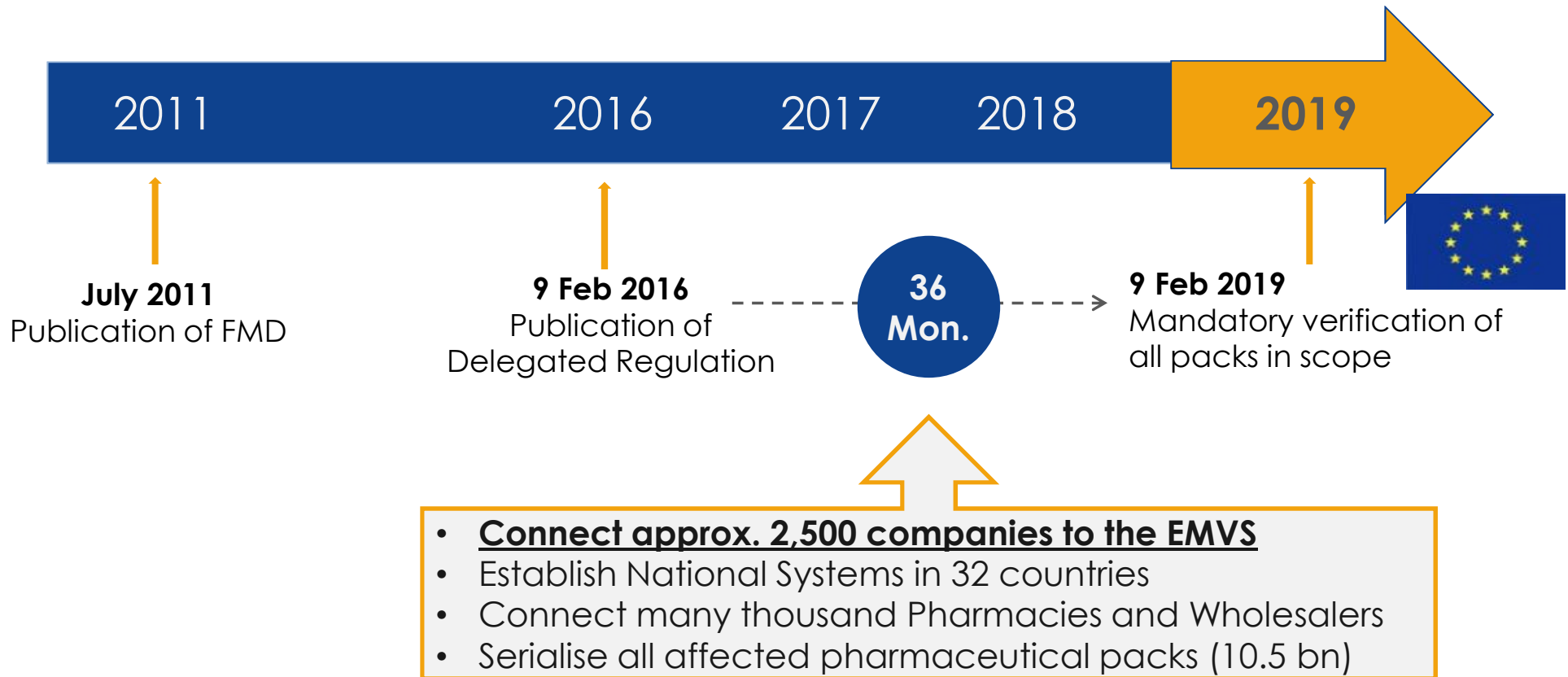
# THE COUNTDOWN IS RUNNING



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



# FMD LEGISLATION AND DELEGATED ACT

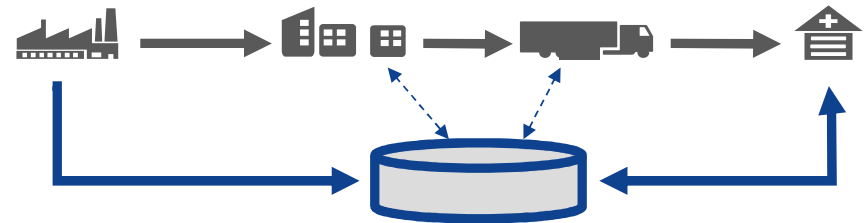


# THE DELEGATED REGULATION MANDATES RULES FOR Rx MEDICINES VERIFICATION

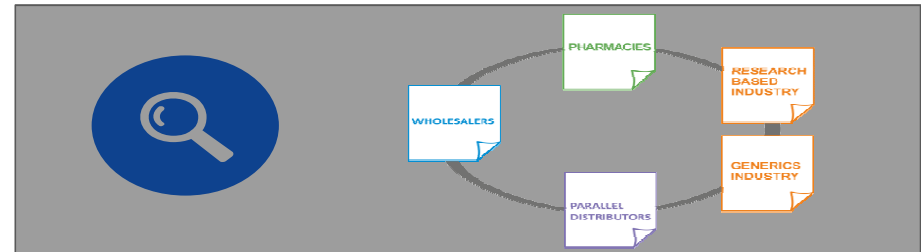

Serialization by manufacturer  
Risk based verification by Wholesalers  
Verification and check-out at point of dispense

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

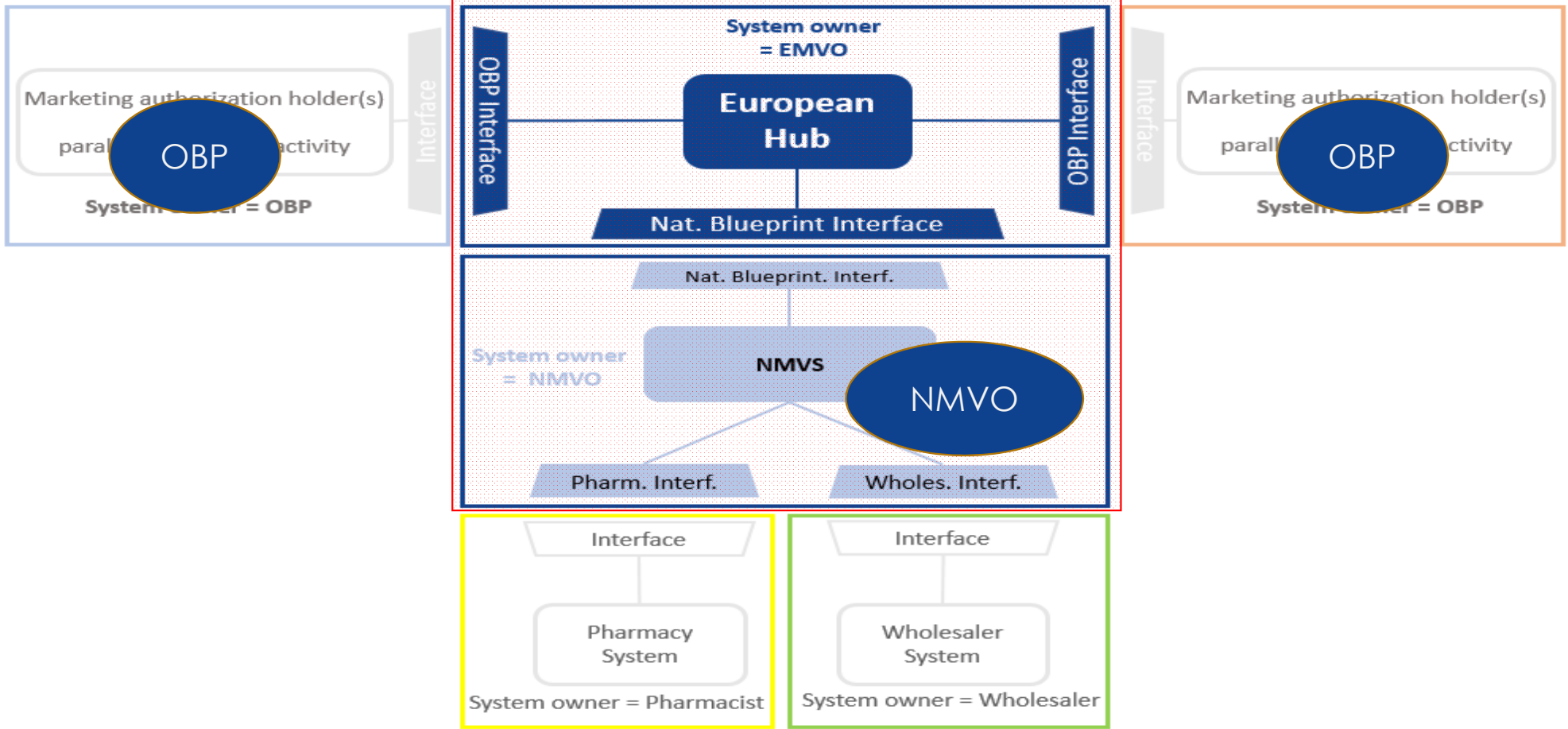
System set up and governed by manufacturers and marketing auth. holders in consultation with other stakeholders.  
Oversight by competent authorities



**Product #:** 09876543210982  
**S/N:** 12345AZRQF1234567890  
**Batch:** A1C2E3G4I5  
**Expiry:** 140531



# SYSTEM LANDSCAPE



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

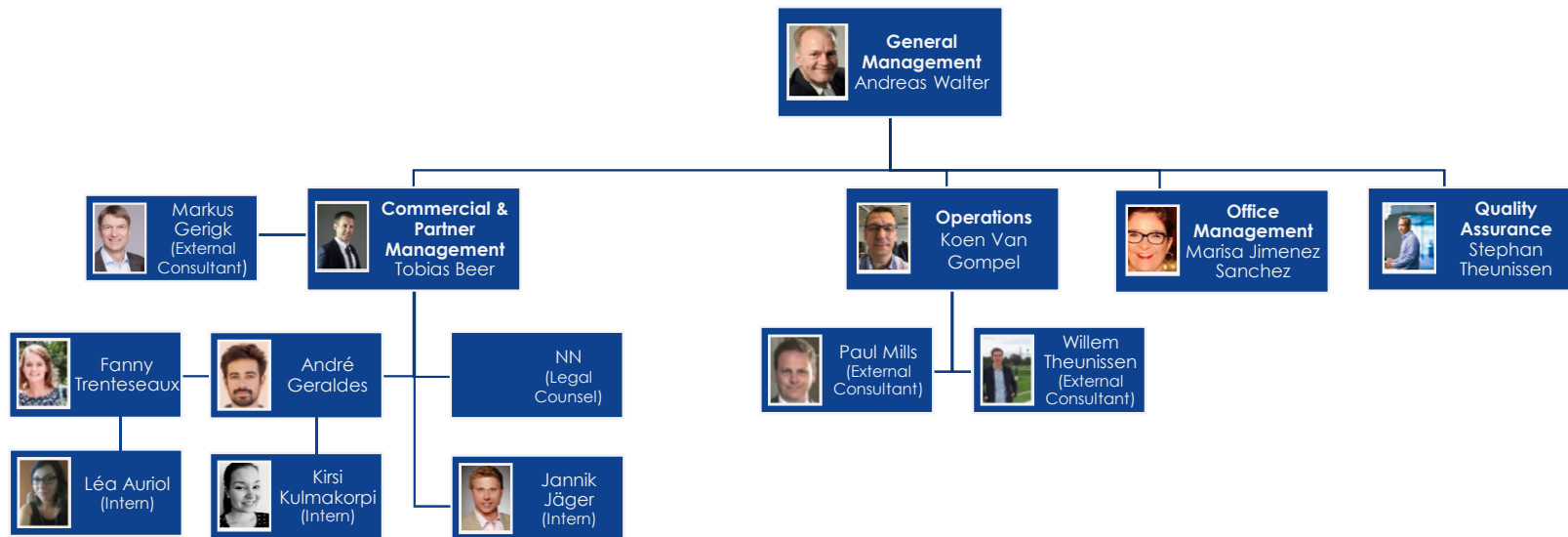
# EMVO MEMBERS



8th November 2017  
 FMD CONFERENCE TALLINN SESSION 1

# ORGANISATIONAL CHART

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



8th November 2017

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# EMVO Service Centre (Tallinn)



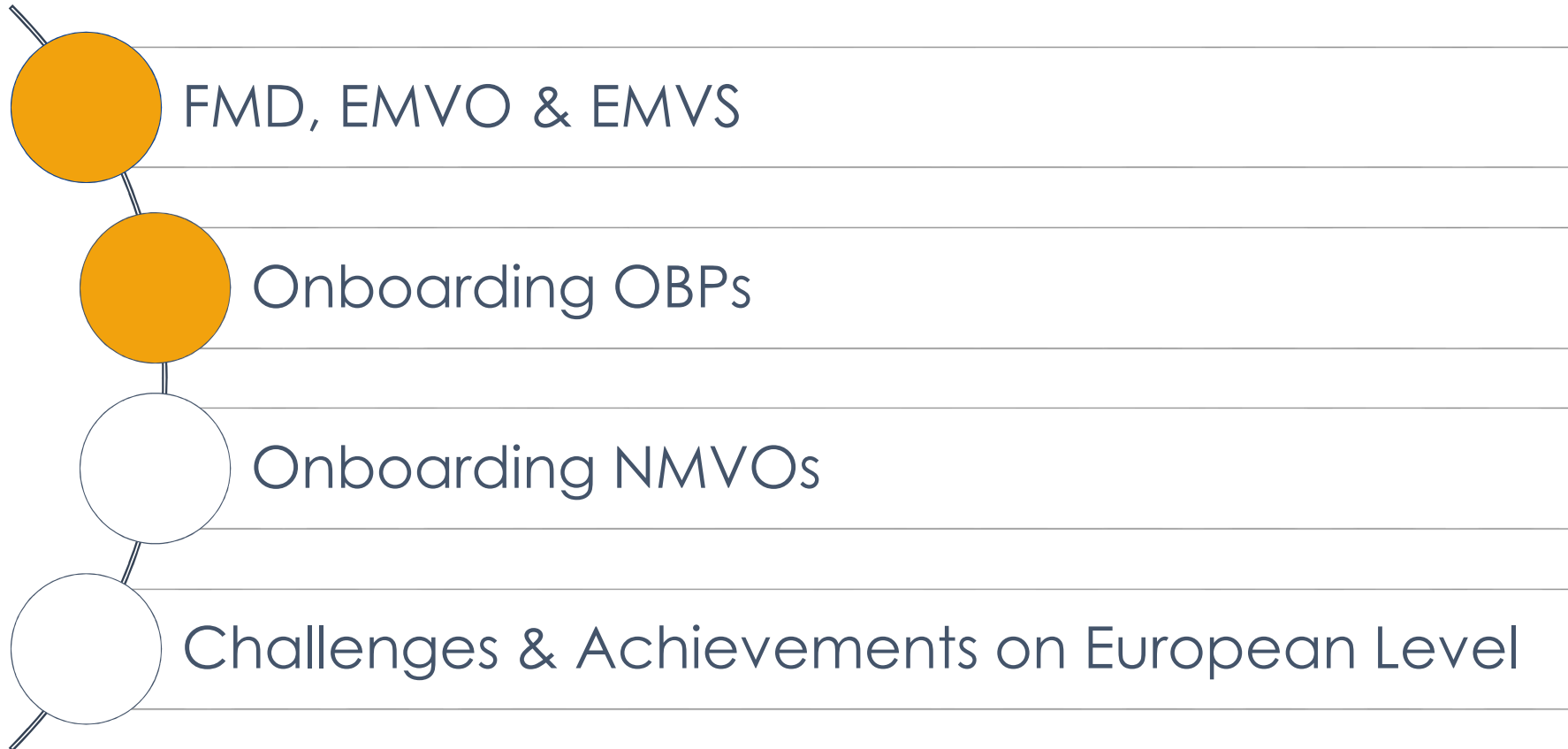
Tel. Helpdesk  
+372 611 90 44



8th November 2017

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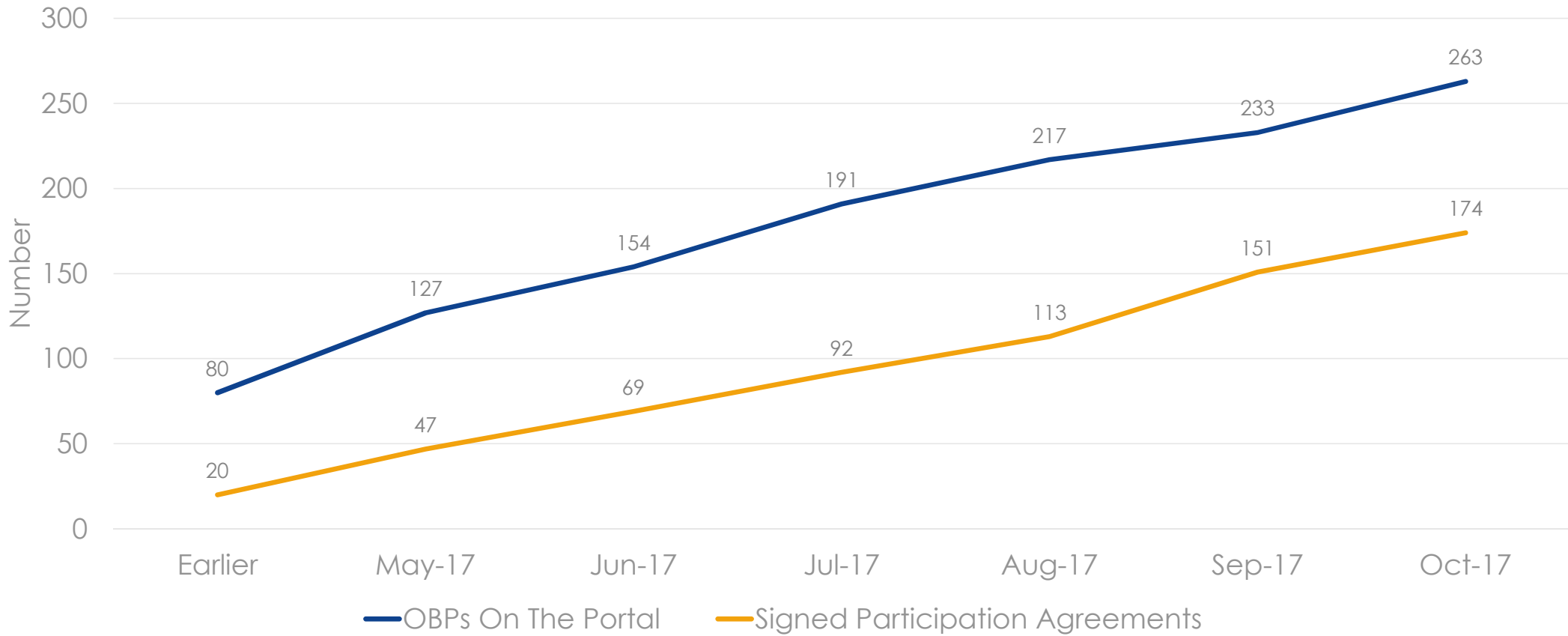
# Agenda



8th November 2017

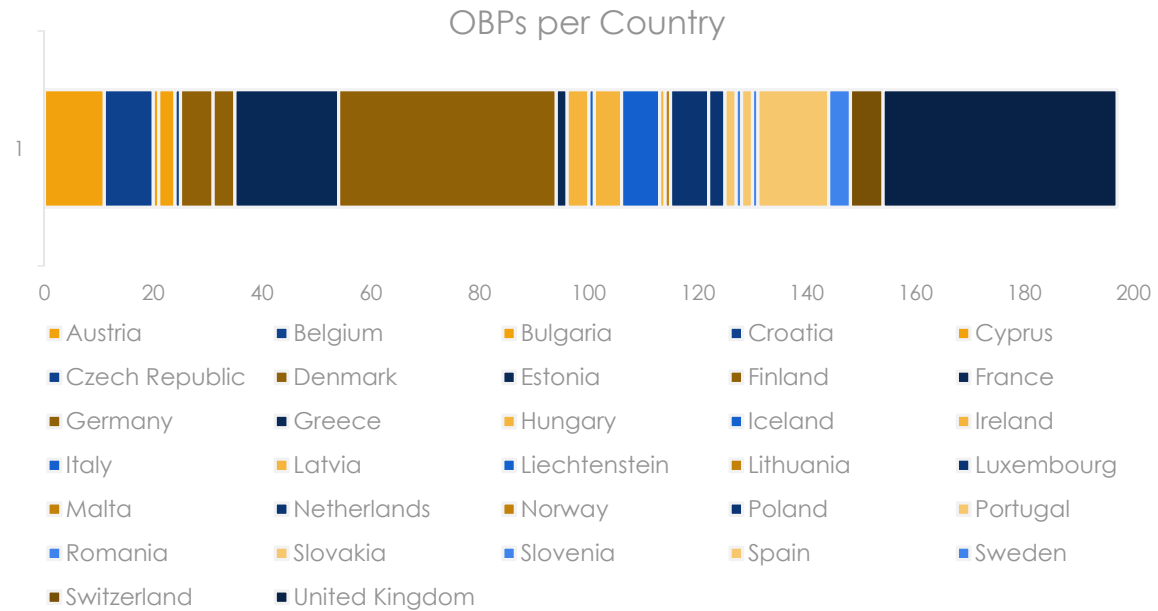
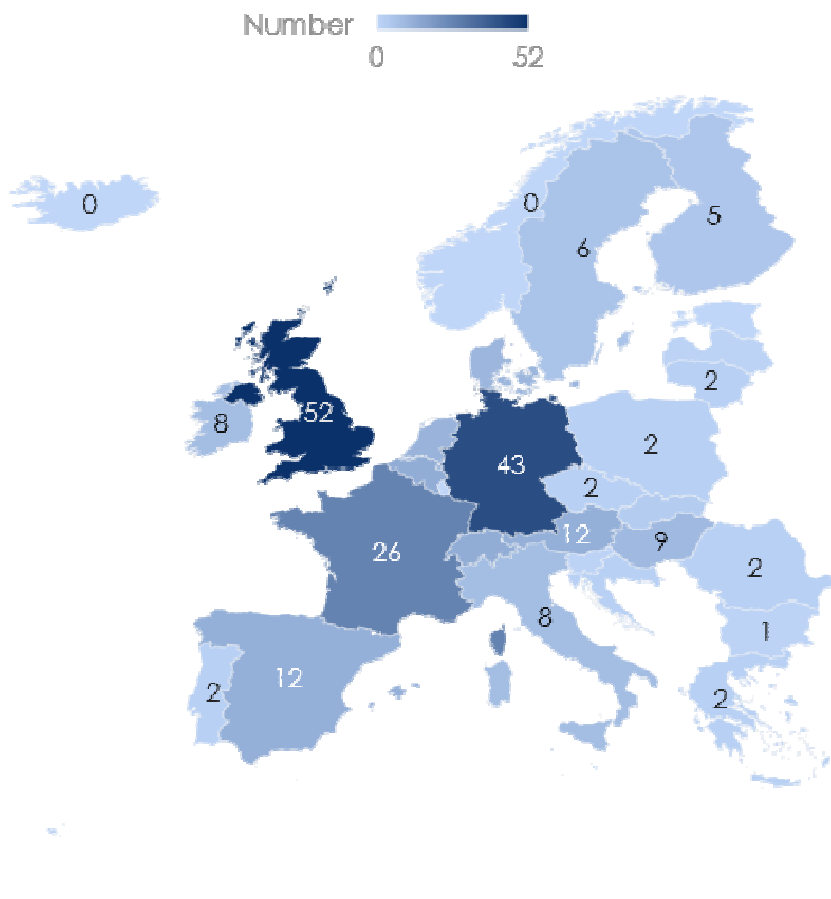
FMD CONFERENCE TALLINN SESSION 1

# STATUS CONTRACTUAL ON-BOARDING





# ON-BOARDING PARTNER (OBP) PER COUNTRY

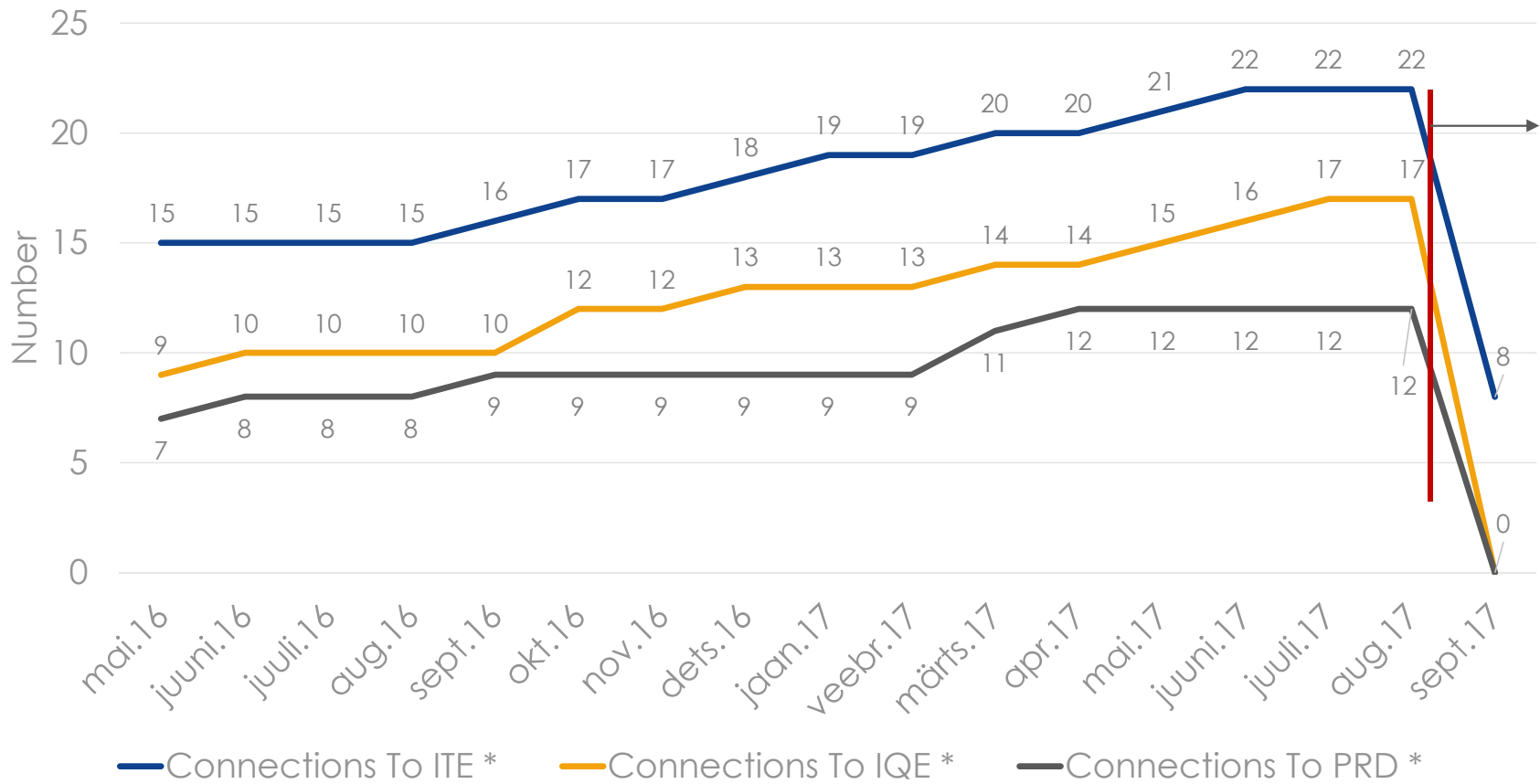


Additional non-european countries:



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# STATUS TECHNICAL ON-BOARDING



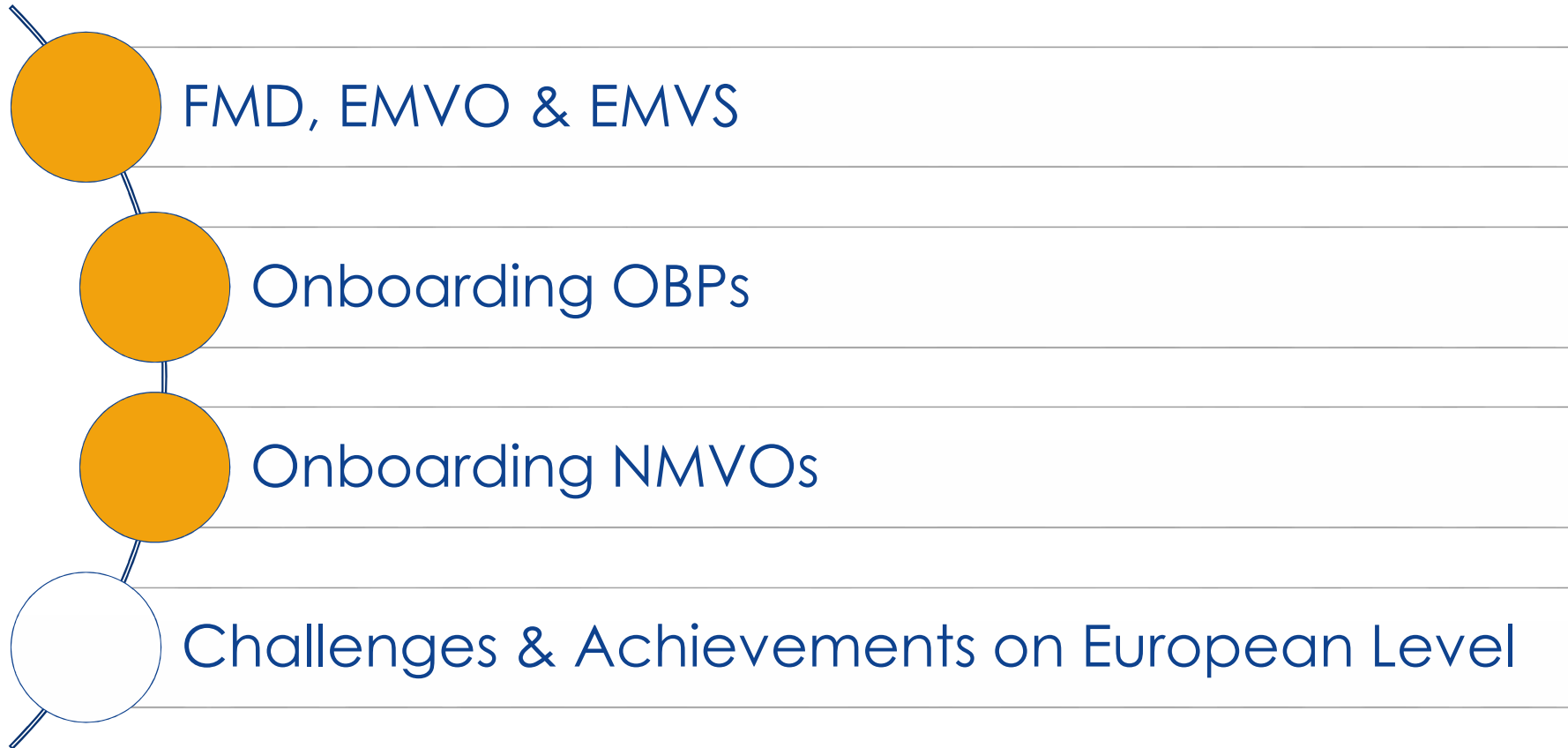
HUB 2.0  
GO-Live

8th November 2017  
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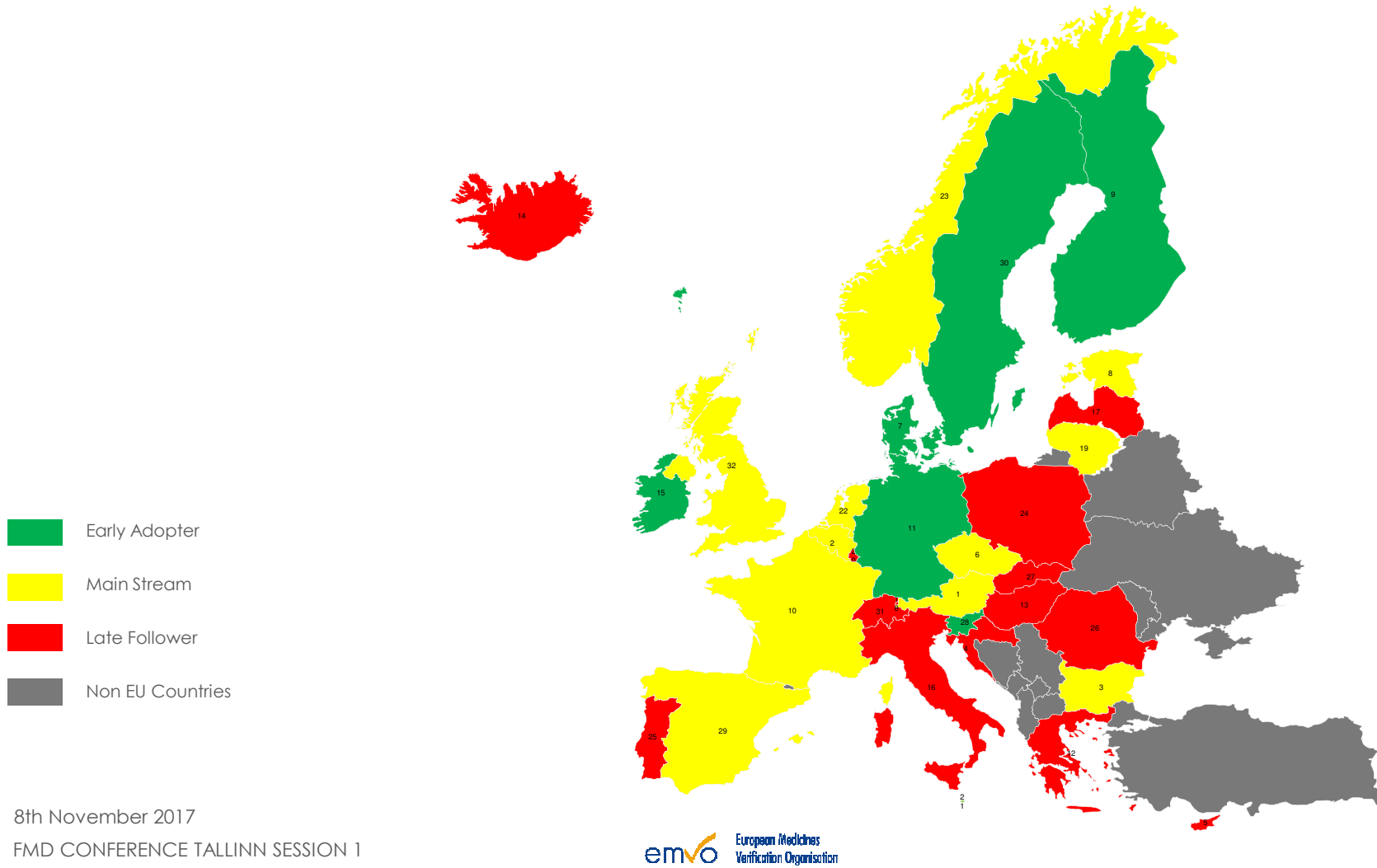


\* ITE: Integrated Test Environment  
\* IQE: Integrated Quality Environment  
\* PRD: Production Environment Hub V1

# AGENDA



# EXECUTIVE SUMMARY COUNTRY READINESS



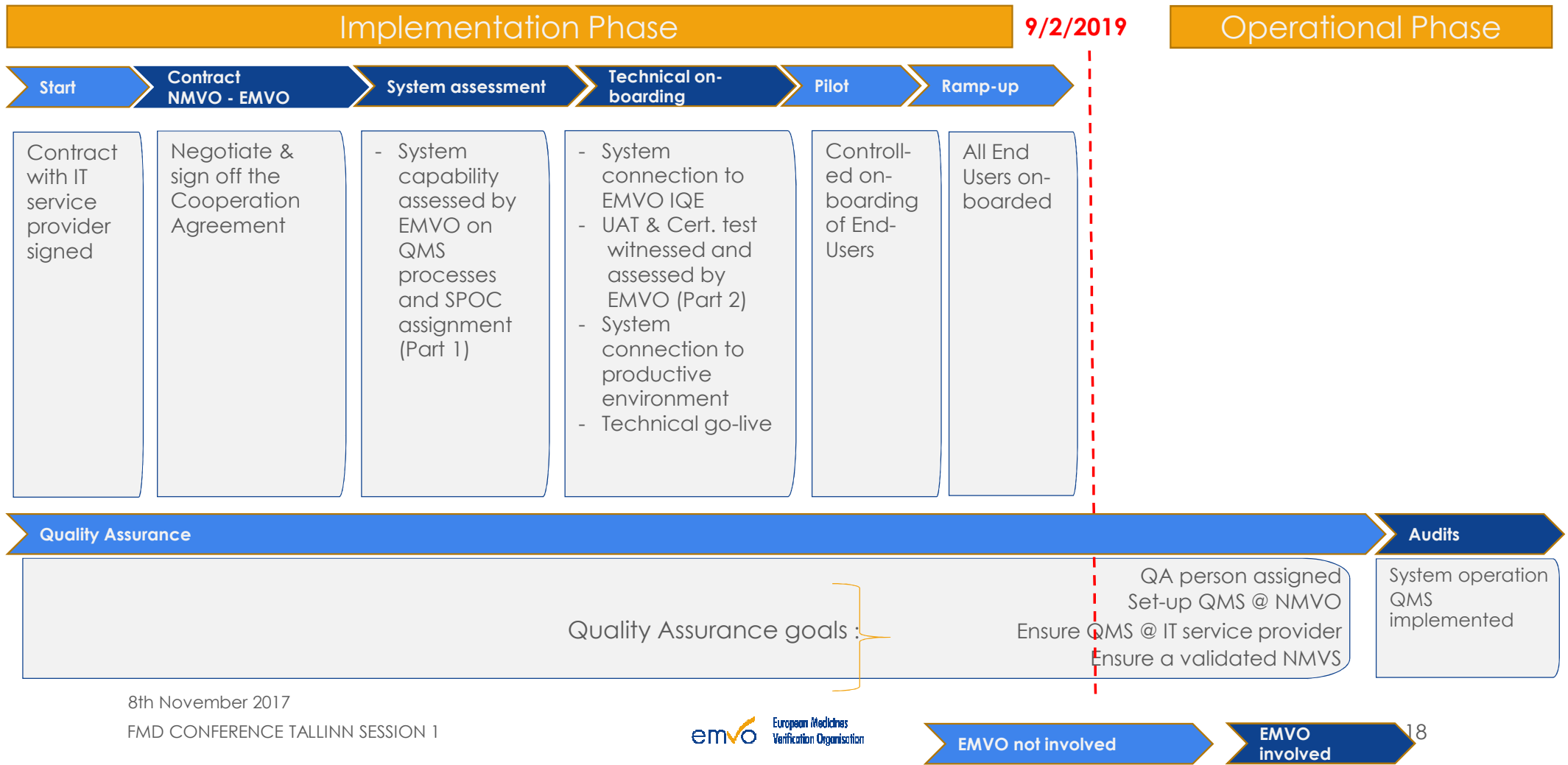
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# REFERENCE SCHEDULE FOR NMVOS, MANUFACTURERS AND END USERS

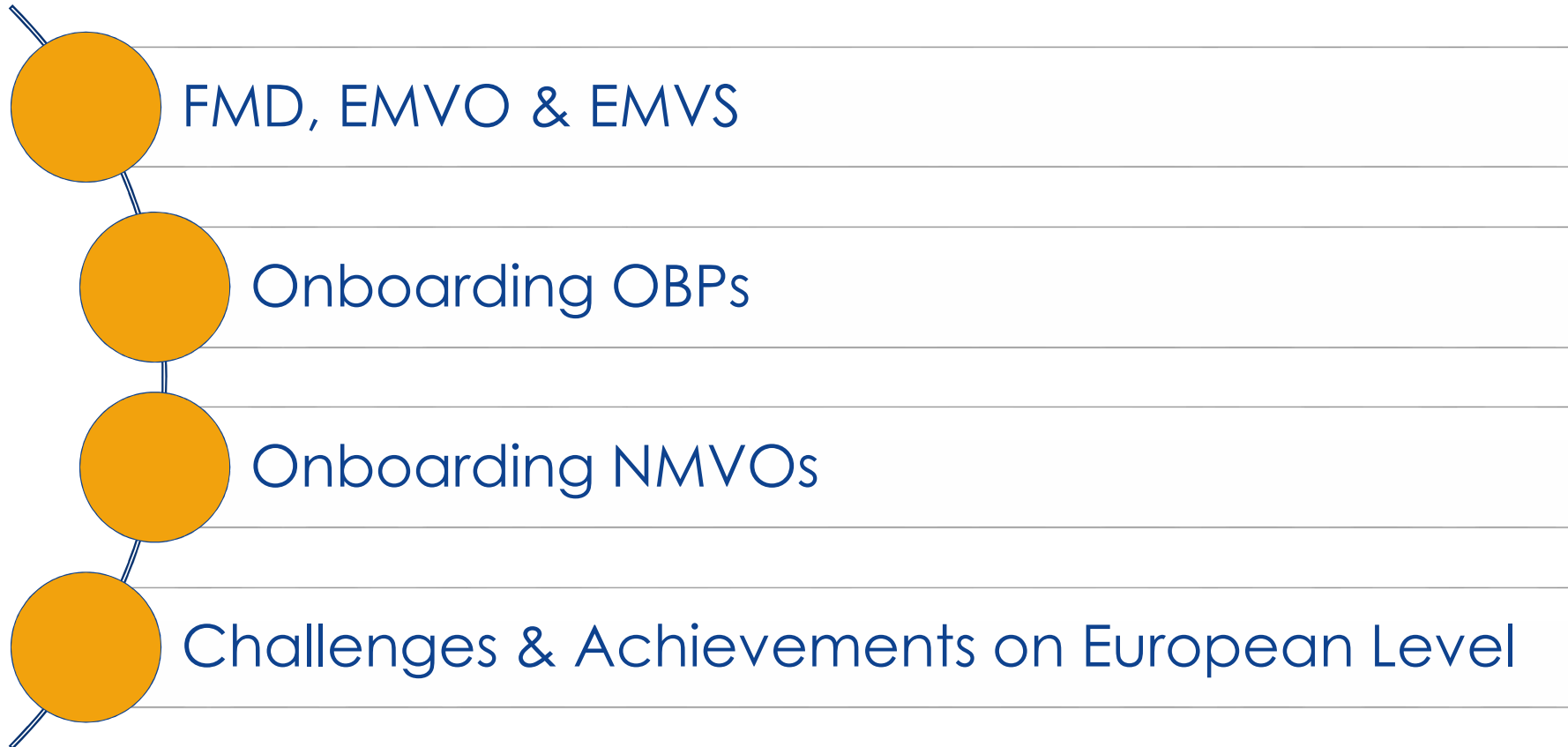
Year	2017	Q 2	Q 3	Q 4	2018	Q 2	Q 3	Q 4	2019
<b>MAH On-boarding</b>									
1	Connected to HUB (CH)	25%	50%	75%	100%				
2	Products serialized + uploaded (PS)	For Pilot			25%	50%	75%	100%	
<b>NMVO Operation</b>									
1	Funding secured (Funding)								
2	Team implemented (Team)								
3	Initial Tasks completed (Tasks)								
<b>National Pilot</b>									
1	Technical Implementation started (TIS)								
2	Prerequisites + Pilot defined (PD)								
3	First Products verified (FP)								
4	Pilot successfully completed (PC)								
<b>National Ramp Up</b>									
1	End User Systems connected + live (SY)	For Pilot		25%	50%	75%	100%		
2	End Users connected + live (EC)				25%	50%	75%	100%	

8th November 2017

# NMVO ON-BOARDING PROCESS



# AGENDA



# CHALLENGES & ACHIEVEMENTS ON EUROPEAN LEVEL

## 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 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.





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# THANK YOU

Contact for On Boarding and general topics:  
[helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)



IRISH  
MEDICINES  
VERIFICATION  
ORGANISATION

# European and National Medicines Verification Organizations – state of play

SAFER EUROPE WITHOUT FALSIFIED MEDICINES CONFERENCE

LEONIE CLARKE – IMVO PROJECT MANAGER

8<sup>TH</sup> NOVEMBER 2017

# Delegated Regulation\* - setting the brief for NMVOs

- ▶ Every MS must be served by national or supranational repository based in EU
- ▶ Repository to be set up & managed by non-profit entity established by marketing authorisation holders (MAHs) & manufacturers of products with safety features
- ▶ Cost of repository system to be borne by manufacturers
- ▶ Wholesalers, persons authorised/entitled to supply medicines (e.g. pharmacists) to public & national competent authority to be consulted when setting up
- ▶ Wholesalers & pharmacists may participate in legal entity on voluntary basis at no cost

\* *Commission Delegated Regulation (EU) 2016/161 – Chapter VII*

*NMVO: national medicines verification organisation*

# IMVO's role

- ▶ Set up and manage repository of unique identifiers for Ireland
- ▶ Interface with EMVO to ensure full interconnectivity of national repository with European Hub
- ▶ Verify credentials of & grant access to system users in Ireland
- ▶ Levy fees on MA holders
- ▶ Monitor system and manage & investigate alerts



# Who's involved in IMVO?

- ▶ **Founding members** as per EMVO model:



Parallel  
Distributors



Research  
based industry



Community  
pharmacists



Generics /  
biosimilars  
industry



Wholesalers

- ▶ **Affiliate membership** open to other organisations, individual wholesalers, pharmacists, pharma companies, etc.
- ▶ **Independent chairperson** – Professor Pat O'Mahony
- ▶ Extensive engagement with **hospital sector**

# Key Tasks

- ▶ Setting up a brand new organisation
- ▶ Setting up repository system
- ▶ Communications & awareness building





# Setting up organisation

## ▶ Legalities

- ▶ Agreeing company constitution – very time consuming
- ▶ IMVO set up as non-profit company in April 2017
- ▶ Structures to ensure good corporate governance



## ▶ Funding

- ▶ Two categories of cost – repository & organisation
- ▶ Financial projections for 2017-2020 drawn up at start
- ▶ Require cash flow to meet financial commitments **but** must be cost-efficient
- ▶ Long-term, IMVO will be funded by annual membership subscriptions & MAH user fees
- ▶ In set-up period, costs covered by loans from IMVO members & one-off MAH registration fees



# Setting up organisation (ctd)

## ▶ Workplan

- ▶ Defining tasks and what needs to be done and when
- ▶ What resources are required to deliver this?

## ▶ Organisational ramp-up

### ▶ *Staff*

- ▶ Currently operating 'virtually' with 2 contractors – will expand in 2018
- ▶ IMVO members providing considerable support & resources

- ▶ **Systems & procedures** to support repository – quality management system, access management, invoicing etc.





# Setting up repository system

- ▶ Pilot will start in Q1 2018 & full ramp up from July 2018
- ▶ Collaborating with other NMVOs using our IT supplier on matters such as system testing & supplier audits

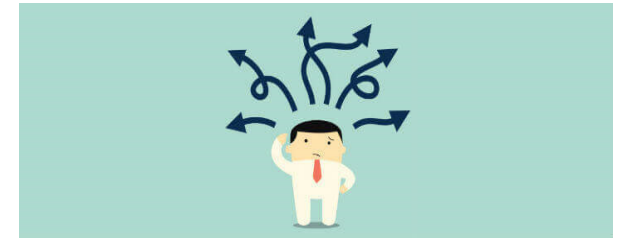


# Communications & awareness building

- ▶ Extensive outreach since early 2016 to raise awareness of new requirements and Feb 2019 deadline
- ▶ Continual dialogue with national authorities
- ▶ Minister for Health attended IMVO launch in July 2017
- ▶ Close co-operation with EMVO & other NMVOs



# The challenges ...



# The successes ...





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ORGANISATION

[www.imvo.ie](http://www.imvo.ie)

# Safer Europe without Falsified Medicines

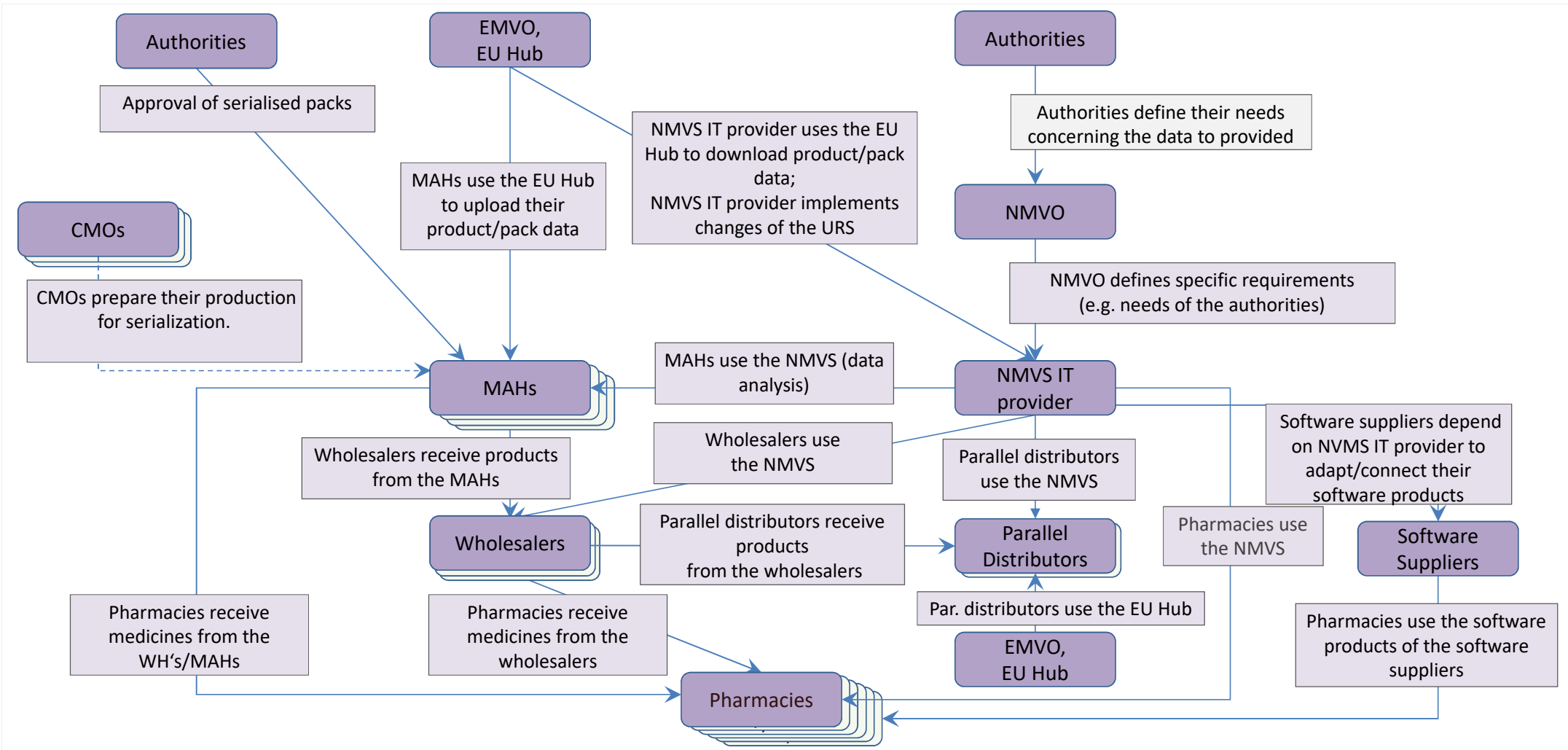
European and National Medicines Verification Organisations -  
State of Play

Maija Gohlke-Kokkonen  
General Manager, Finnish Medicines Verification Organisation  
FiMVO





# It's all about dependencies!



# The Finnish Experience?



NCA  
(National Competent  
Authority)

**Sharing  
information is the key!**

Pharma Industry

Wholesalers

- All stakeholders involved?
- It's all about cooperation and compromise!

FiMVO

- Contracting takes time!
- National requirements – blueprint?

System IT provider

- Who's an MAH in Finland?
- How to reach them?
- Contracting!
- Invoicing!

Pharma Industry

- National requirements?
- Handling of product information – GTIN!

Wholesalers



GTIN®

Global Trade  
Item Number®

- IT-providers key in setting up the system!
- Who's the contracting partner?

Pharmacies



- Who needs to be involved?
- IT-providers key!
- Who's the contracting partner?

Hospital pharmacies & dispensaries



- The tie that binds!
- Be active – it's not a national project!
- Share information!
- Ask questions

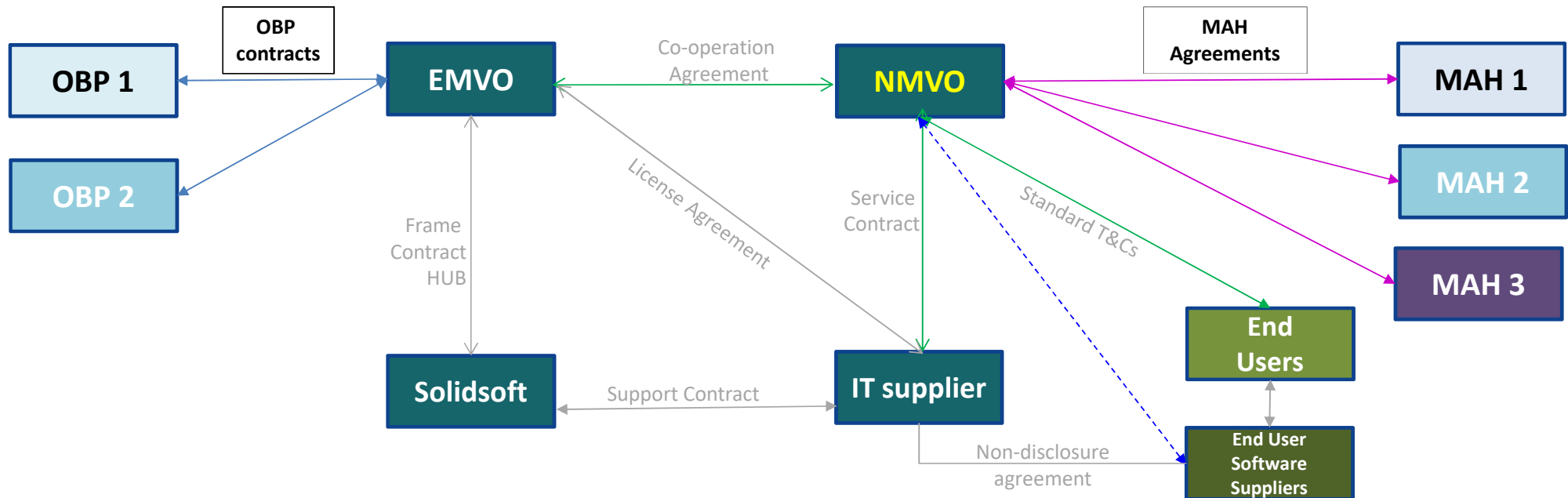
EMVO

Other NVMO's

- Be active!
- National requirements?

NCA  
(National Competent  
Authority)

# EMVS Contract Landscape



- OBP:** Onboarding Partner is the pharmaceutical corporation that contracts with EMVO to create connection to EU Hub
- Solidsoft:** IT Service Provider for implementation and operation of European HUB
- NMVO:** National Medicines Verification Organisation
- IT Supplier:** IT Service Supplier for national system
- End Users:** Pharmacies, wholesalers, healthcare institutions

# Successes and challenges in Finland

- Excellent cooperation amongst stakeholders
- Cooperation with EMVO
- Simple distribution chain – most stakeholders are easily on-boarded
- Cooperation with NVMS system provider

- Public health care sector
  - Reaching all stakeholders
- Communication – why are we doing this?
- It's all new to everyone – a huge learning curve

# **European and National Medicines Verification Organisations - Bulgaria**

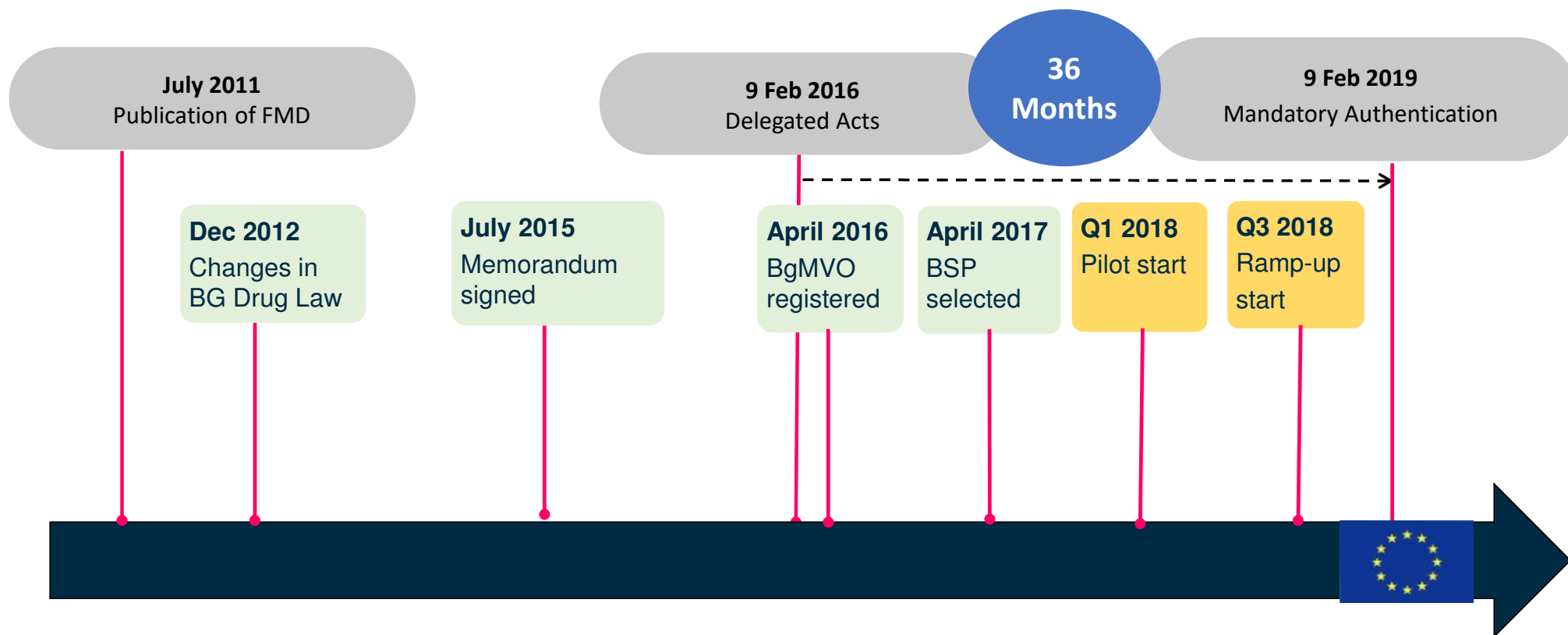
Safer Europe without Falsified Medicines

Estonia, Tallinn, 8-9 November, 2017

Illiana Paunova, Executive Director BgMVO



# Implementation of the FMD in Bulgaria



# Bulgaria: Strengths and Weaknesses

## ACHIEVEMENTS

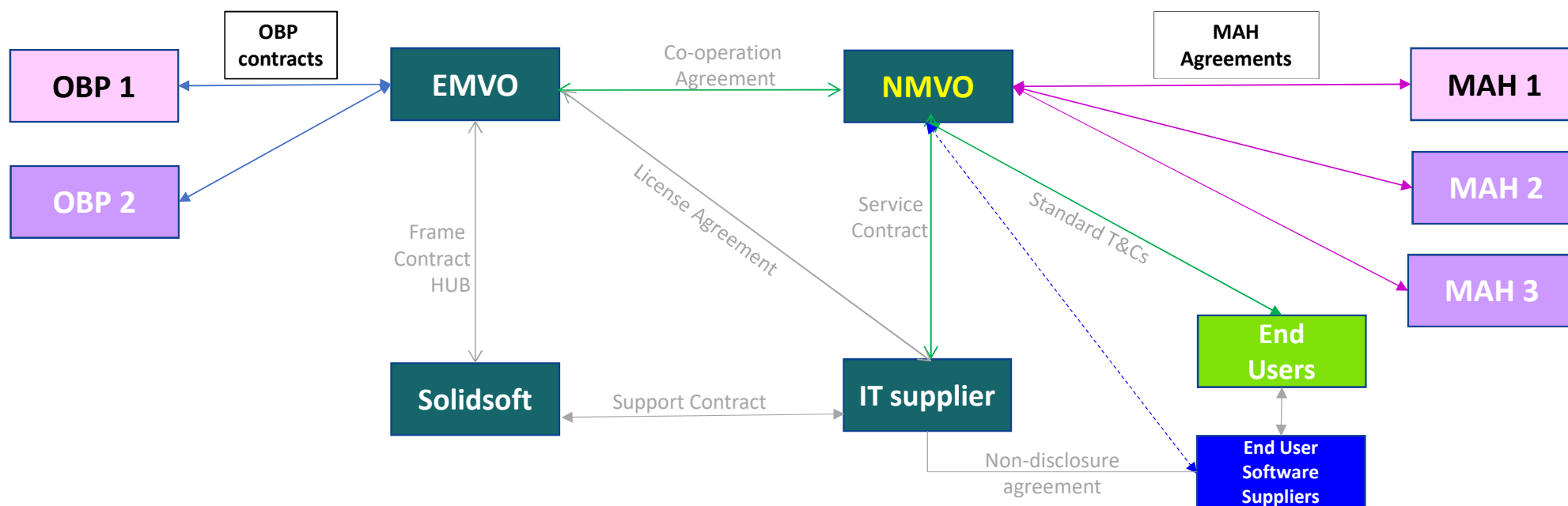
- Early set-up of the BgMVO
- Alignment of stakeholders
- Harmonization with the blueprint model
- Good collaboration with NCA
- Wide communication plan

## CHALLENGES

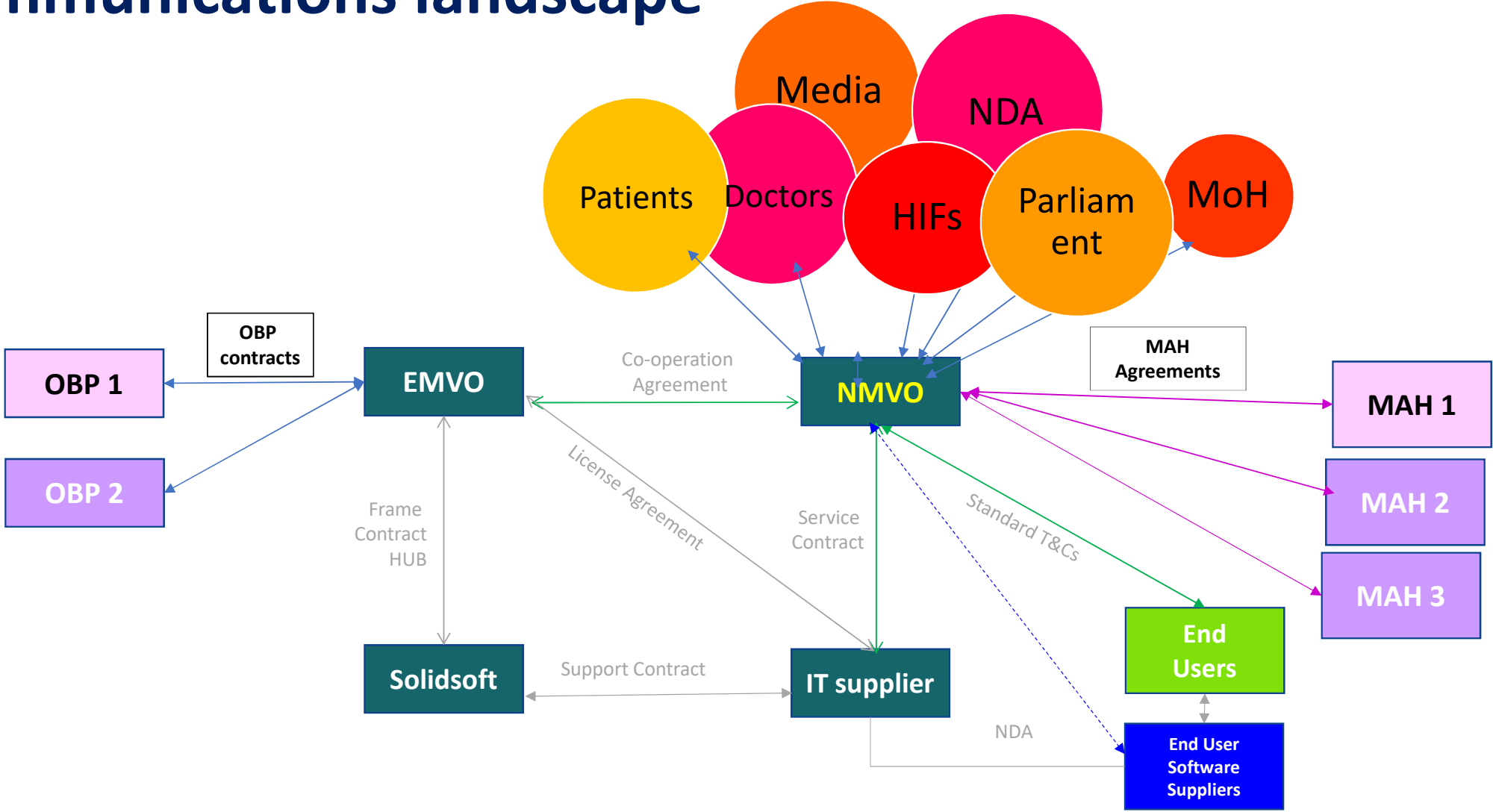
- Engagement of local IT providers
- Shortage of resources
- MAH, Pharmacy and WH registries to pass legitimacy check
- Internet access of rural end-users

**One of the biggest Public-private partnerships in Europe**

# EMVS-NMVS contract landscape



# Communications landscape



# Channels of Communication

Credibility

Relevance

Convenience

Reach

Clarity

F2F MEETINGS & CALLS

CONFERENCES

EMAIL COMMUNICATION

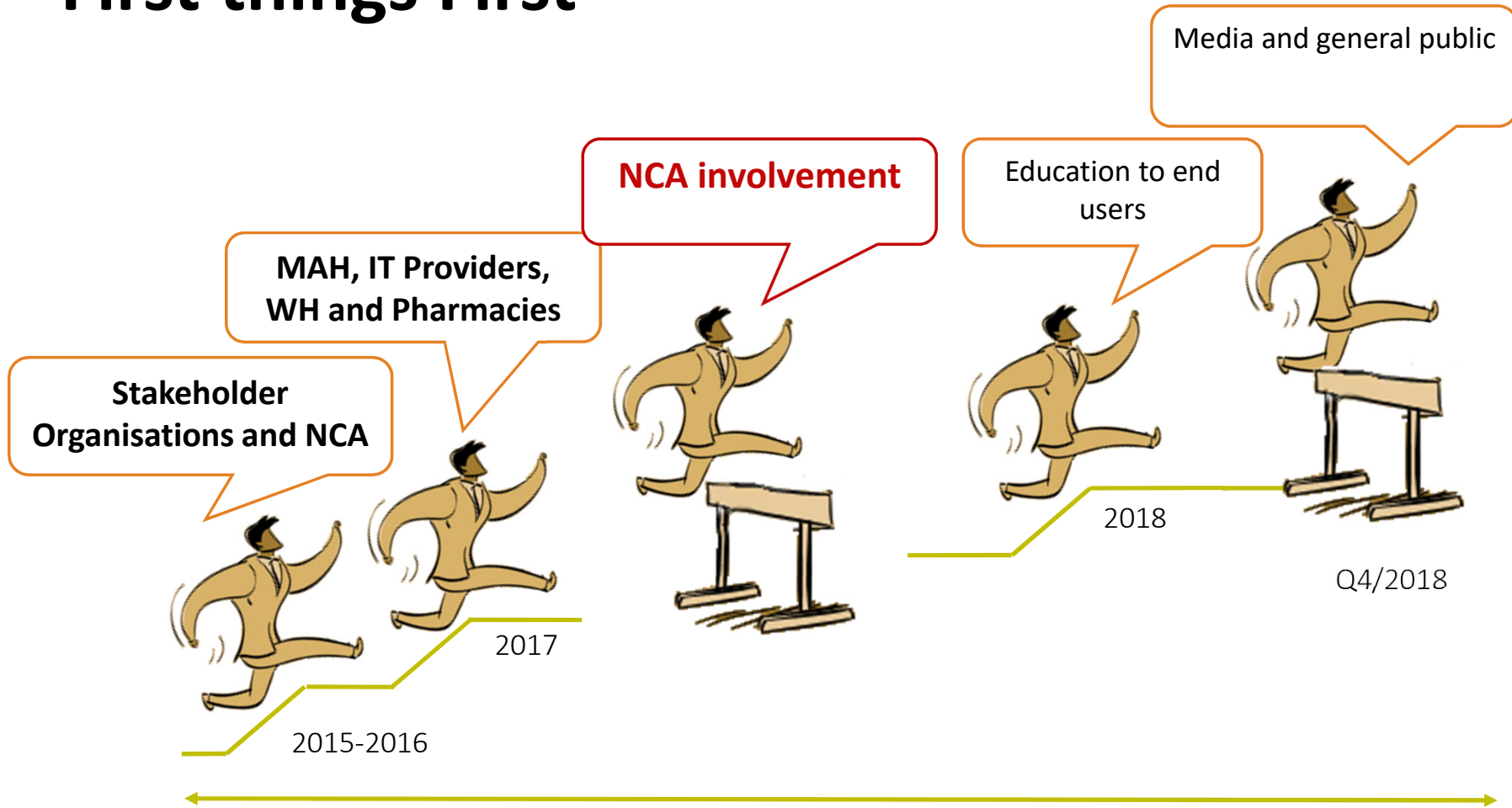
ONLINE EDUCATIONAL PLATFORMS

MEDIA

WEBSITES



# First things First



# Objectives and Role of NCA

- **Directive 118 a)** Shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive; the penalties must be effective, proportionate and dissuasive
- **Directive 118 b)** Member States shall organise meetings involving patients' organisations
- **Directive 118 c)** Cooperation between competent authorities for medicinal products and customs authorities
- **DR art 18, art.24, art. 30)** When the product may not be authentic the manufacturer, the wholesaler, the pharmacy shall not supply the product and shall immediately inform the relevant competent authorities
- **DR art. 23)** Regulate the particular cases on their territory, when a wholesaler verifies the safety features and decommissions the unique identifier
- **DR art. 44)** Supervision of the repositories system
- **DR art. 46)** Notifications to the Commission













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# Estonian Medicines Verification Organization

Raul Mill, 8/11/2017, Chief Executive





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## Estonia



2016

GDP (per capita) – 16 000 €

GDP - 20 bn €

- 495 pharmacies
- 61 wholesalers (2 covers about 2/3 of the market size)
- 37 manufacturers (or representations)
- About 450 MAH
- About 2000 pharmacists



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# Implementing stakeholders model

- **NMVO Estonia – REKS**
  - Manufacturers
  - Wholesalers
  - Pharmacies
  - Hospital pharmacies
- **Differences** – parallel distributors are not presented in association level





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## Engagement of partners

- **Authorities – the role of the state**
- **Patients and other end users**
- **Software developers**





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## Small country ...

### Strengths

- Small territory
- Internet access all over the country
  - All pharmacies are connected to the internet
- 100% implemented digital prescription
- Involving all stakeholders
- Good communication
- Small number of local IT providers
- Implemented authentication method (ID-card, Mobile-ID)

### Challenges

- Limited resources
- Financial model – all MAH will taken part of sharing costs
- Motivation of all market players
- Changes in work processes and wholesalers logistics
- Tight schedule



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Marketing Authorization Holder  
(MAH)



*EF*

## Role of the MAH...

- About 450 MAH - only 4 are local
  - About 1/2 are not Estonian juridical persons
- Contracts and payments with foreign partners
  - Flat fee and free riders
- Falcificatons handling process
- Implementing the NMVS



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# Success factors and risk management

- **Financing model and equal treatment of stakeholders**
- **Awareness and interests – what motivates market players?**
- **Sustainability and co-operation**
- **Communication - partners+stakeholders**
- **Engagement of partners**







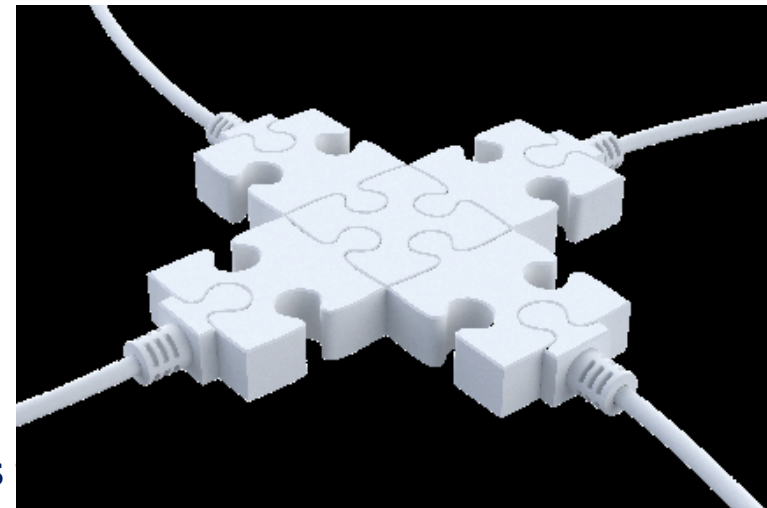
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## After 9<sup>th</sup> of February 2019 ...

- **Quality management**
- **User management**
- **Communication**
- **Co-operation model**
- **Sustainable finance model on equal bases**





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Thank you!

Raul Mill, 8/11/2017, Chief Executive, [raul.mill@reks.ee](mailto:raul.mill@reks.ee)

