



# STATUS OF IMPLEMENTATION the FMD - VIEWPOINT FROM EMVO

Roundtable Falsified Medicines Directive -  
Are We Ready?  
Improving patient safety with the  
FMD in the hospital pharmacy

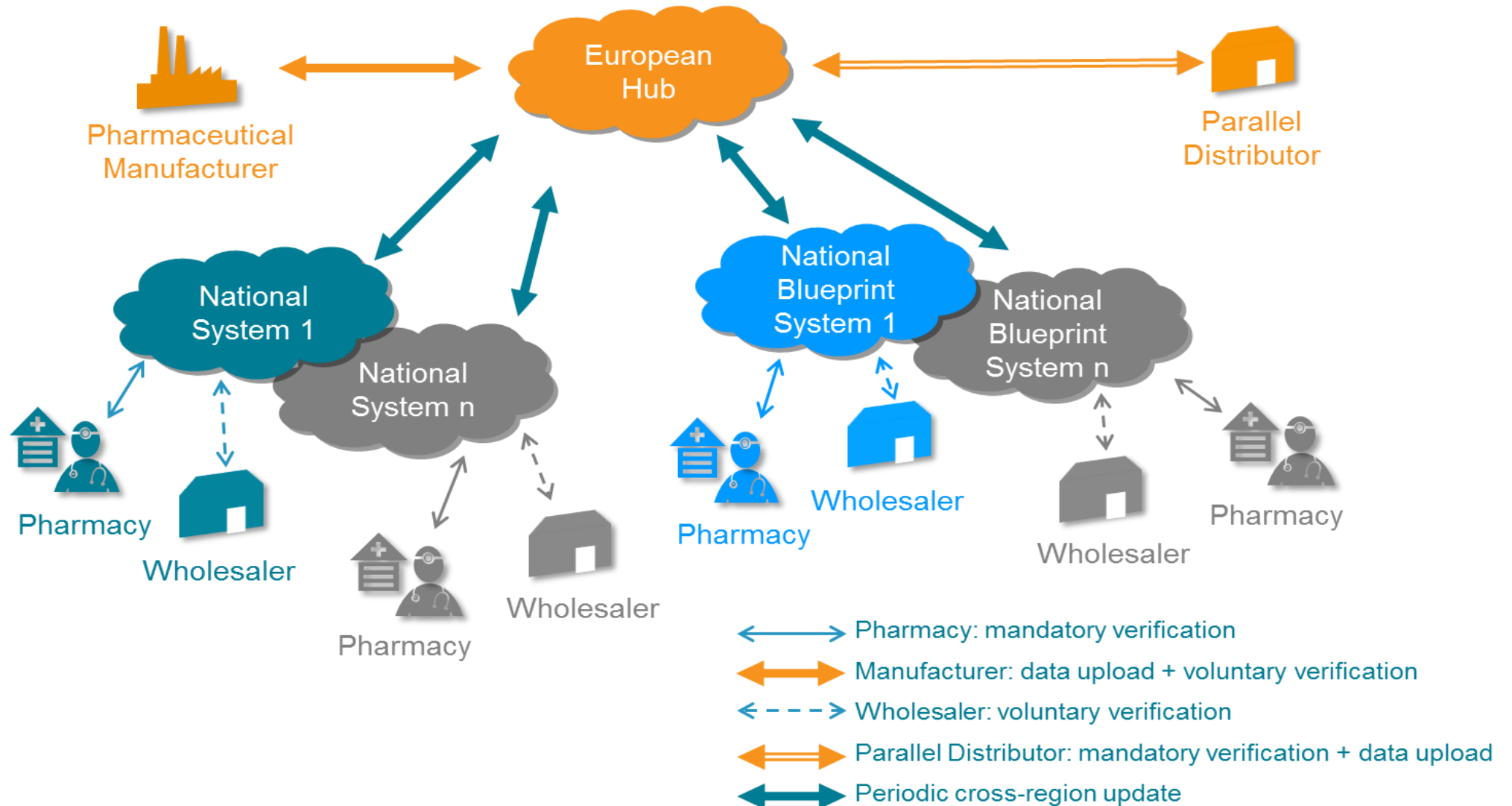
European Parliament, 19<sup>th</sup> February 2019  
Andreas M. WALTER

# WHO WE ARE

- European Medicines Verification Organisation(EMVO)
- **Unique collaboration** between supply chain stakeholders comprised of EU medicine manufacturers, parallel distributors, wholesalers, pharmacists, hospitals and hospital pharmacists
- Mandate from stakeholders to:
  - Set up the Hub
  - Connect countries to the Hub
  - Facilitate onboarding of industry/manufacturers to the EU Hub
- EMVO's **driving mission is patient safety**. The safety of patients across Europe is at the centre of our work

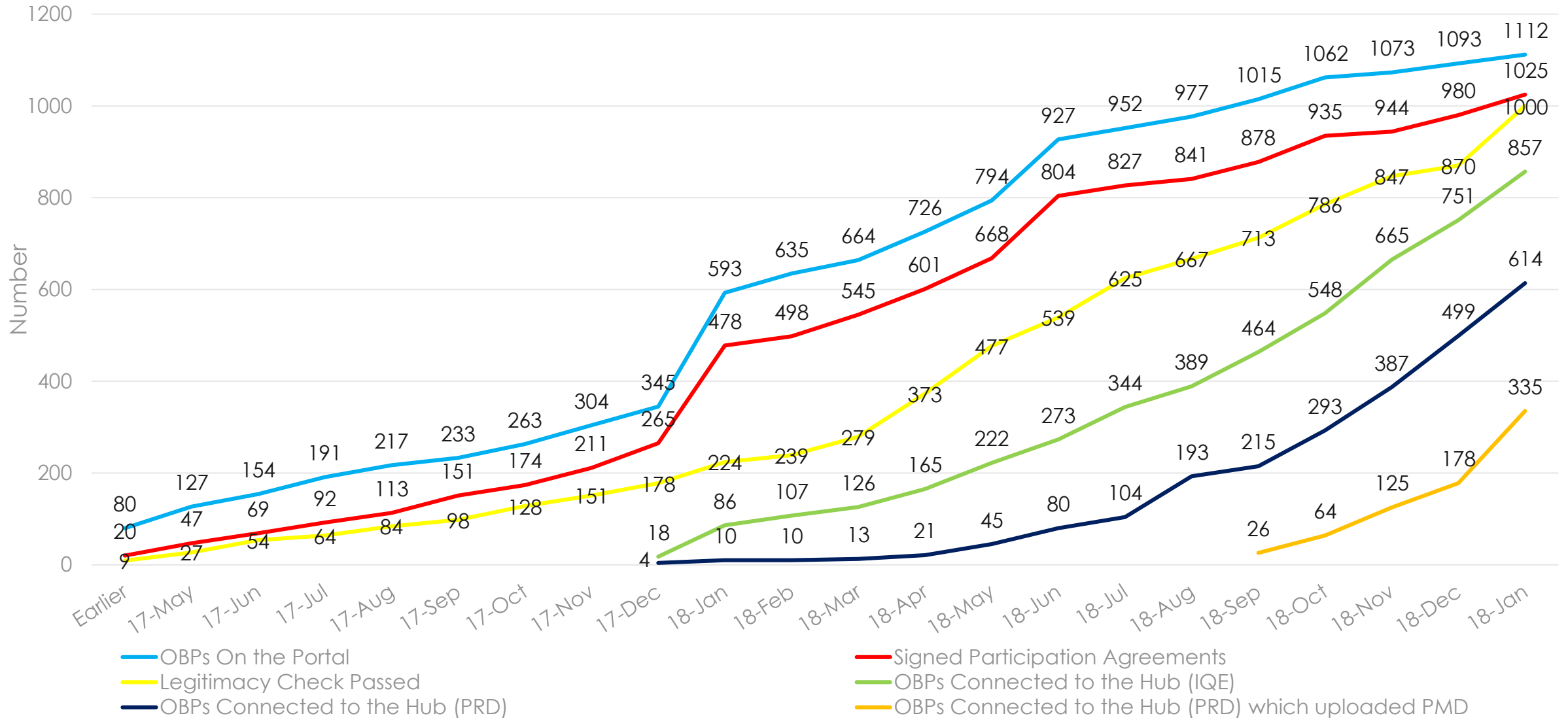


## HOW THE SYSTEM WORKS



# STATUS ON-BOARDING

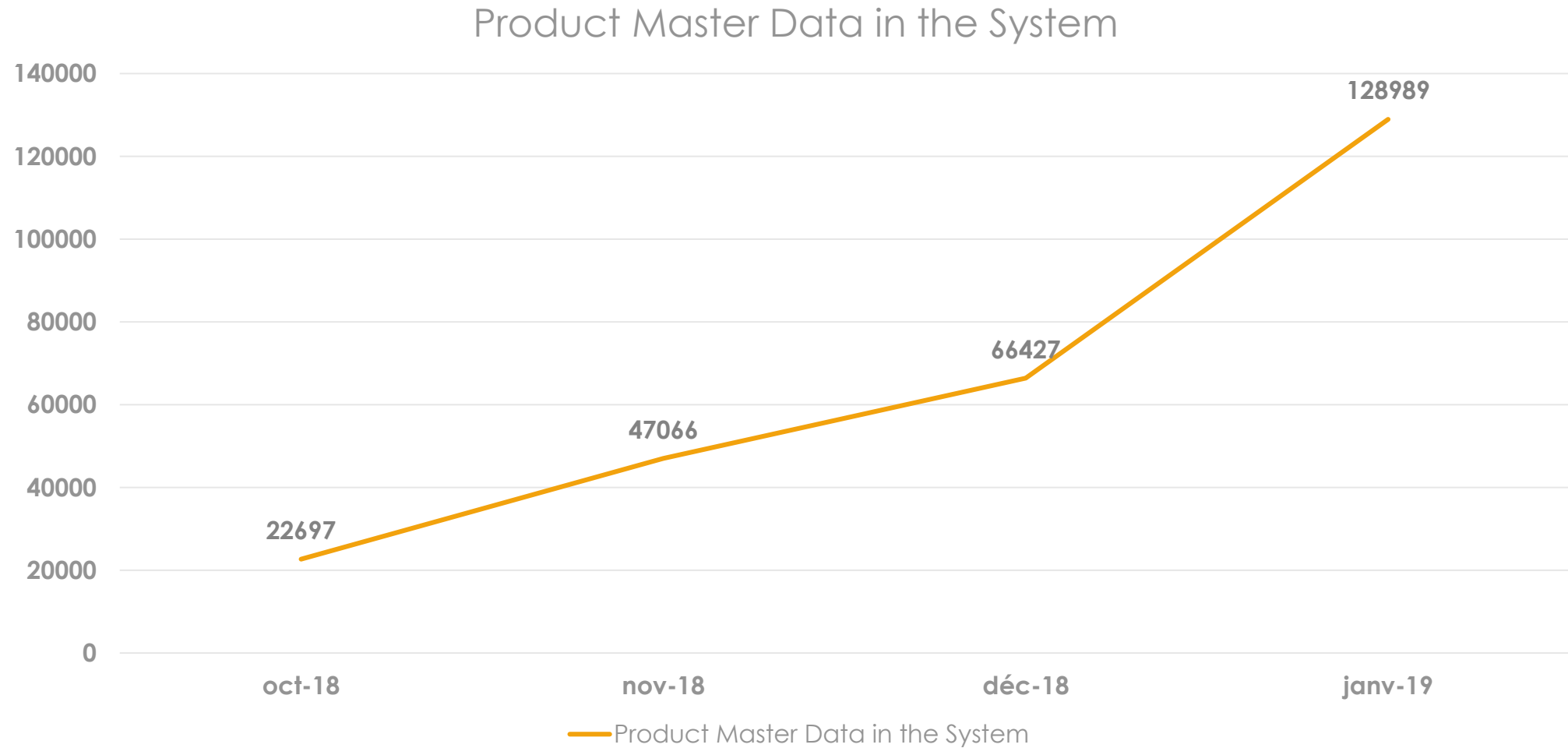
Data collected on  
February 4th 2019



19th February 2019

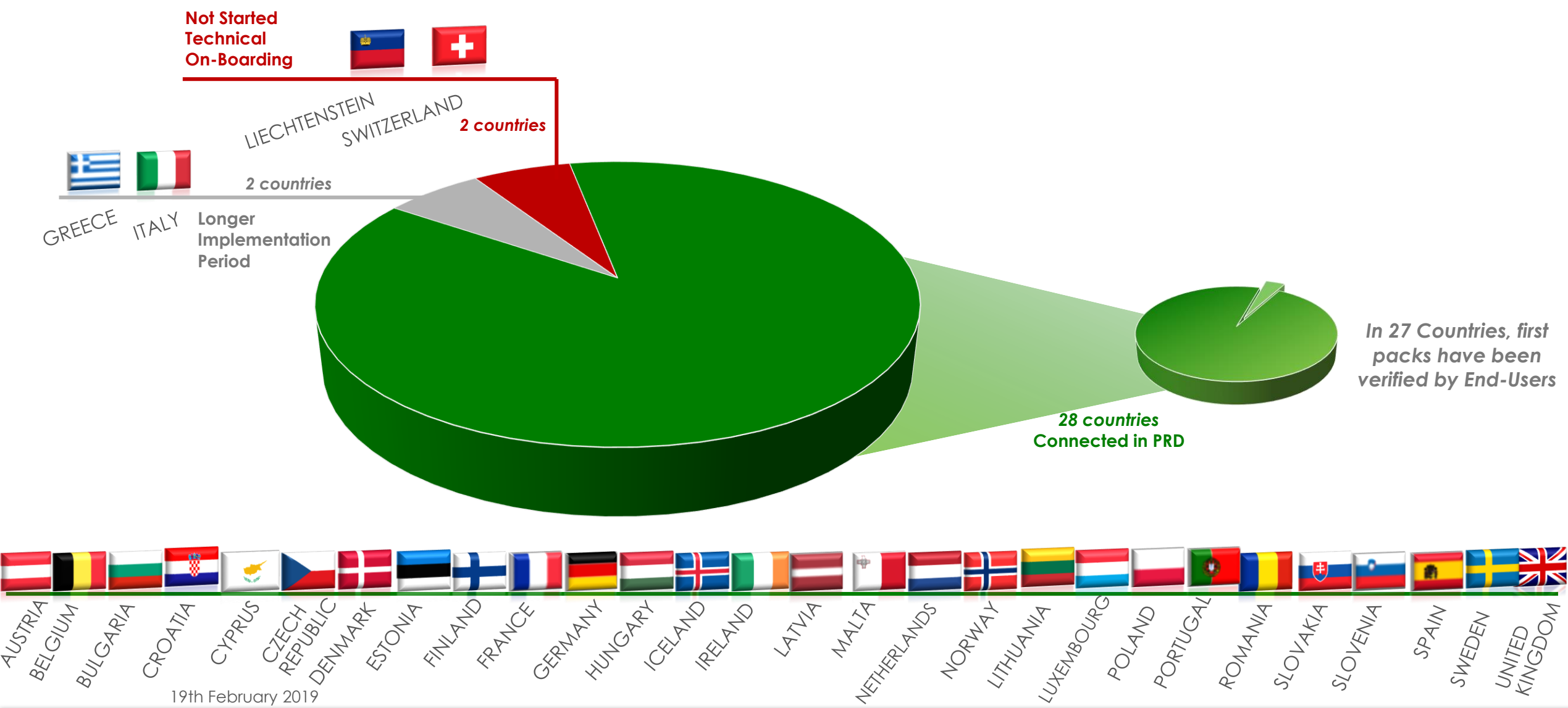
# UPLOADED PRODUCT MASTER DATA

Data collected on  
February 4<sup>th</sup>, 2019



19th February 2019

# NMVO ON-BOARDING - PROGRESS OVERVIEW



19th February 2019

**Full functionality with coming releases**

# EMVS

- European-wide IT project within EU & EEA
- Operational issues and teething problems on European/national level to be expected
- Rapid crisis management in order to maintain trust in the system's added value and to avoid supply chain disruptions
- Data quality/availability a cornerstone for the success
- User compliance and enforcement by NCA are critical (case by case)
- Alert handling in a flexible and smooth way

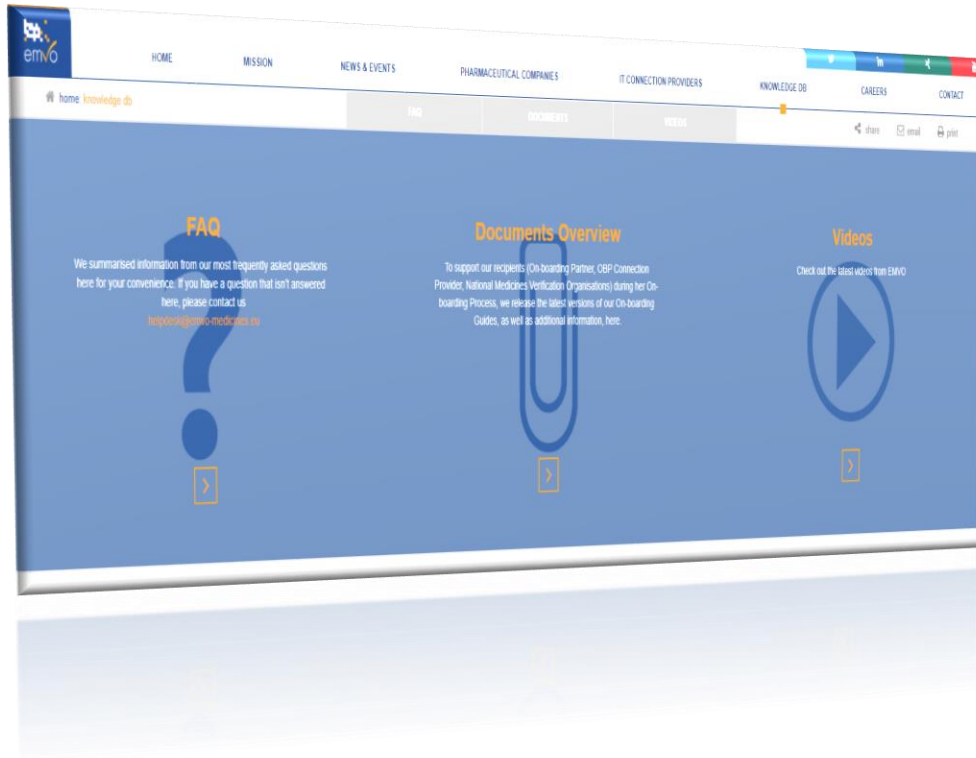
# CONCLUSION: CALL FOR “STABILIZATION PERIOD” WHILE MAINTAINING PATIENT SAFETY

Period to ensure a controlled application of the NMVS and an uninterrupted medicines supply (to be negotiated with NCA), i.e.

- Flexible alert handling (in cooperation with NCA);
- Enforcement and inspections only on a case by case basis;
- Increase of EMVS stability/performance, i.e.
  - Well performing EU Hub and NMVS (data quantity & data quality of utmost importance)
  - Well performing IT systems of On-Boarding Partners (OBPs)
  - Well performing IT systems of End-Users
- Completion of serialization, OBP & end-user onboarding;
- Staged implementation of NCA reporting;
- Improve crisis management and maintain trust in the system's added value



# ADDITIONAL INFORMATION



## ○ EMVO Website

- Article 23 Implementation  
<https://emvo-medicines.eu/newdoc/european-commission-article-23-implementation/>
- Knowledge Database & Documents Overview  
<https://emvo-medicines.eu/knowledge-database/>

## ○ Documentation

- Q&As V13.0  
[https://emvo-medicines.eu/new/wp-content/uploads/qa\\_safetyfeature\\_en\\_V13.pdf](https://emvo-medicines.eu/new/wp-content/uploads/qa_safetyfeature_en_V13.pdf)
- OBP On-boarding Guideline  
[https://emvo-medicines.eu/new/wp-content/uploads/EMVO\\_0077\\_OBP-Onboarding\\_Guideline-4.pdf](https://emvo-medicines.eu/new/wp-content/uploads/EMVO_0077_OBP-Onboarding_Guideline-4.pdf)

# Questions?

