



European Medicines
Verification Organisation



PGEU GPUE



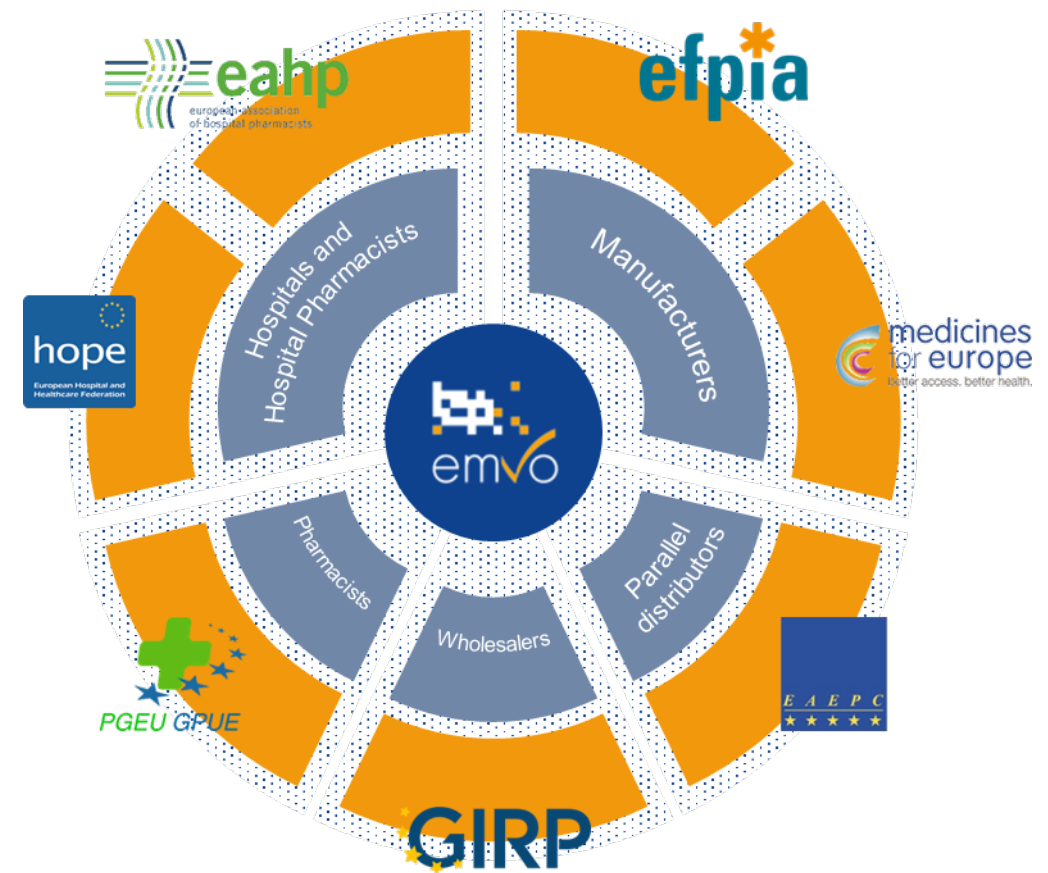
9TH FEBRUARY 2019 AND BEYOND...EU FMD IMPLEMENTATION AT EU AND NATIONAL LEVEL

Global GS1 Healthcare Conference
Plenary Session – Pharmaceutical Traceability

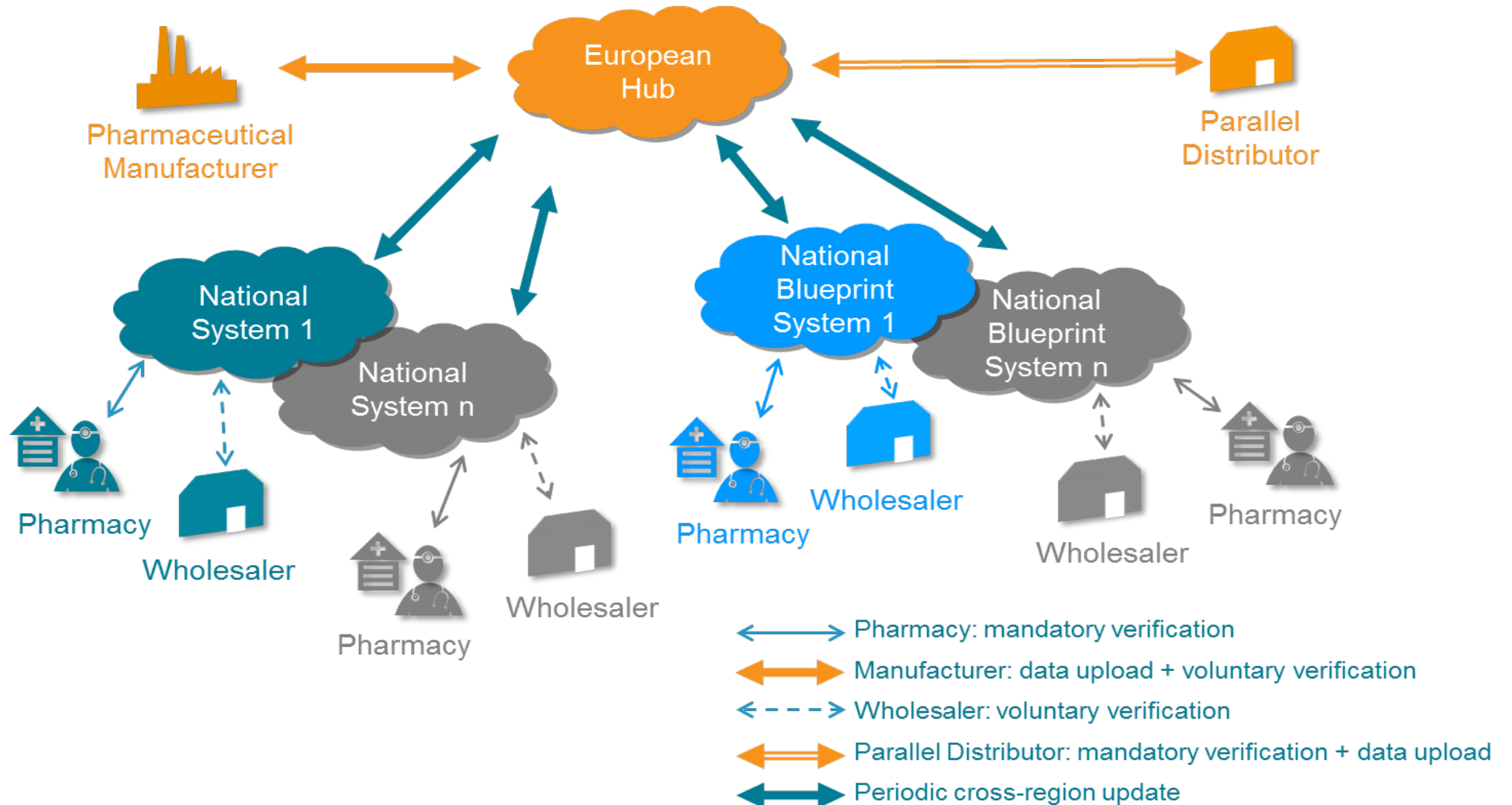
Noordwijk-Amsterdam, 28th March 2019
Andreas M. WALTER

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



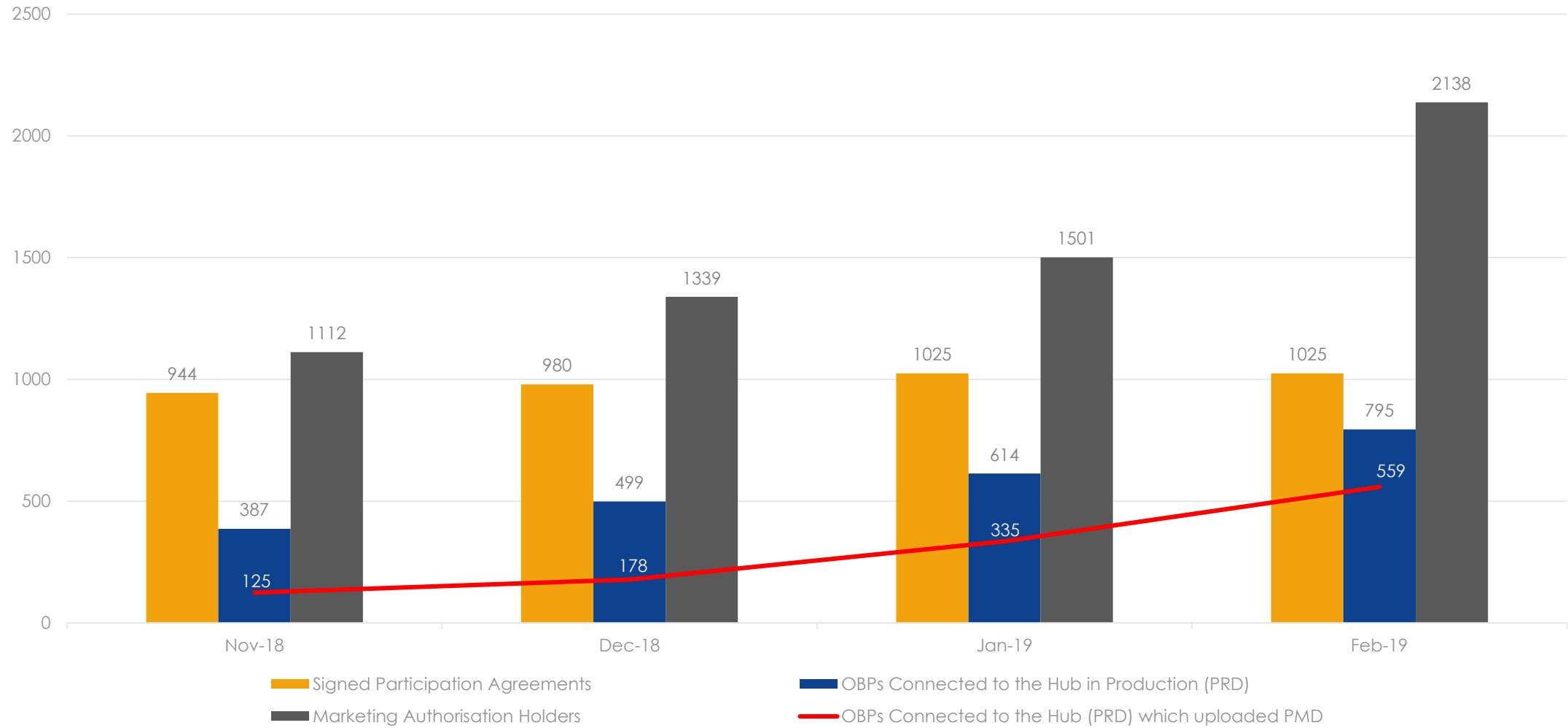
HOW THE SYSTEM WORKS



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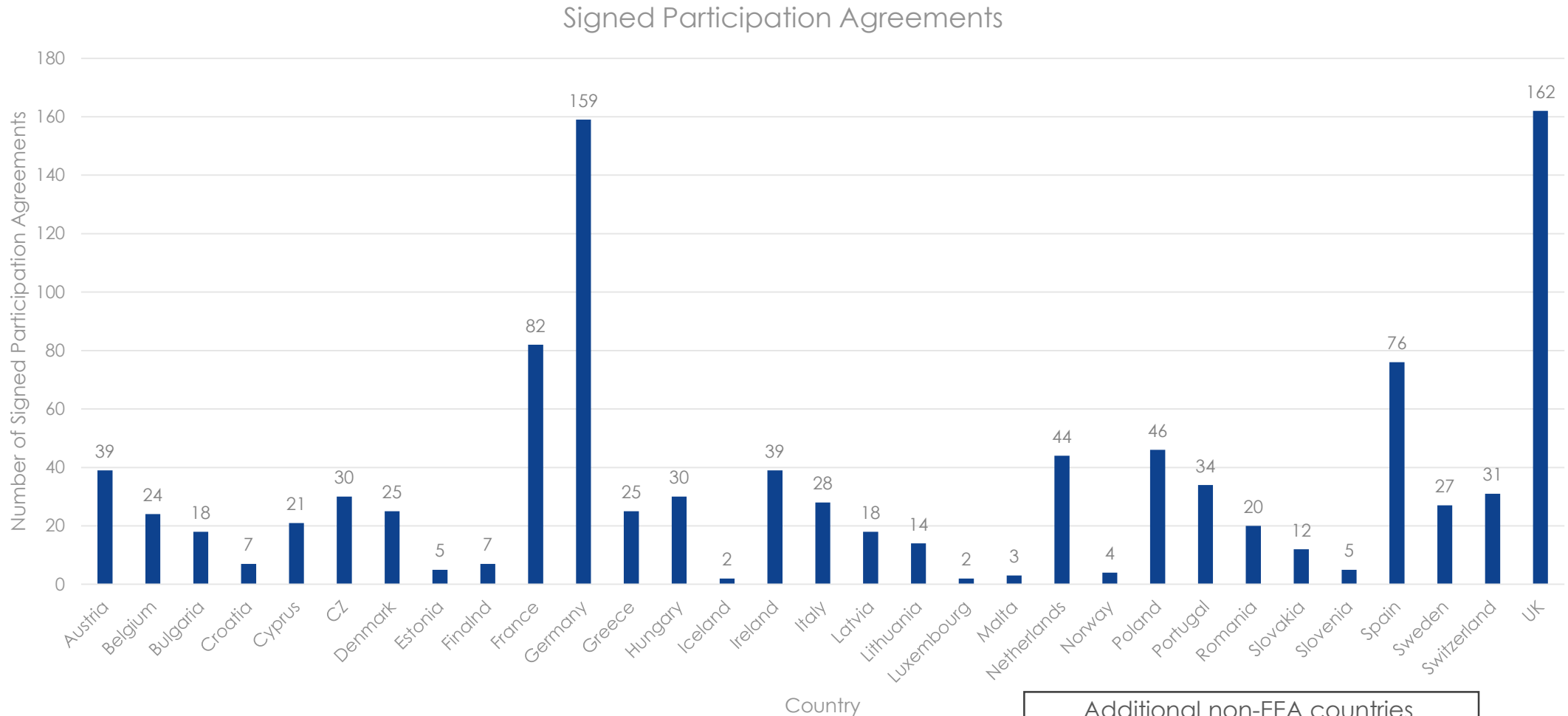
STATUS ON-BOARDING



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SIGNED PARTICIPATION AGREEMENT BY OBPS PER COUNTRY



Additional non-EEA countries

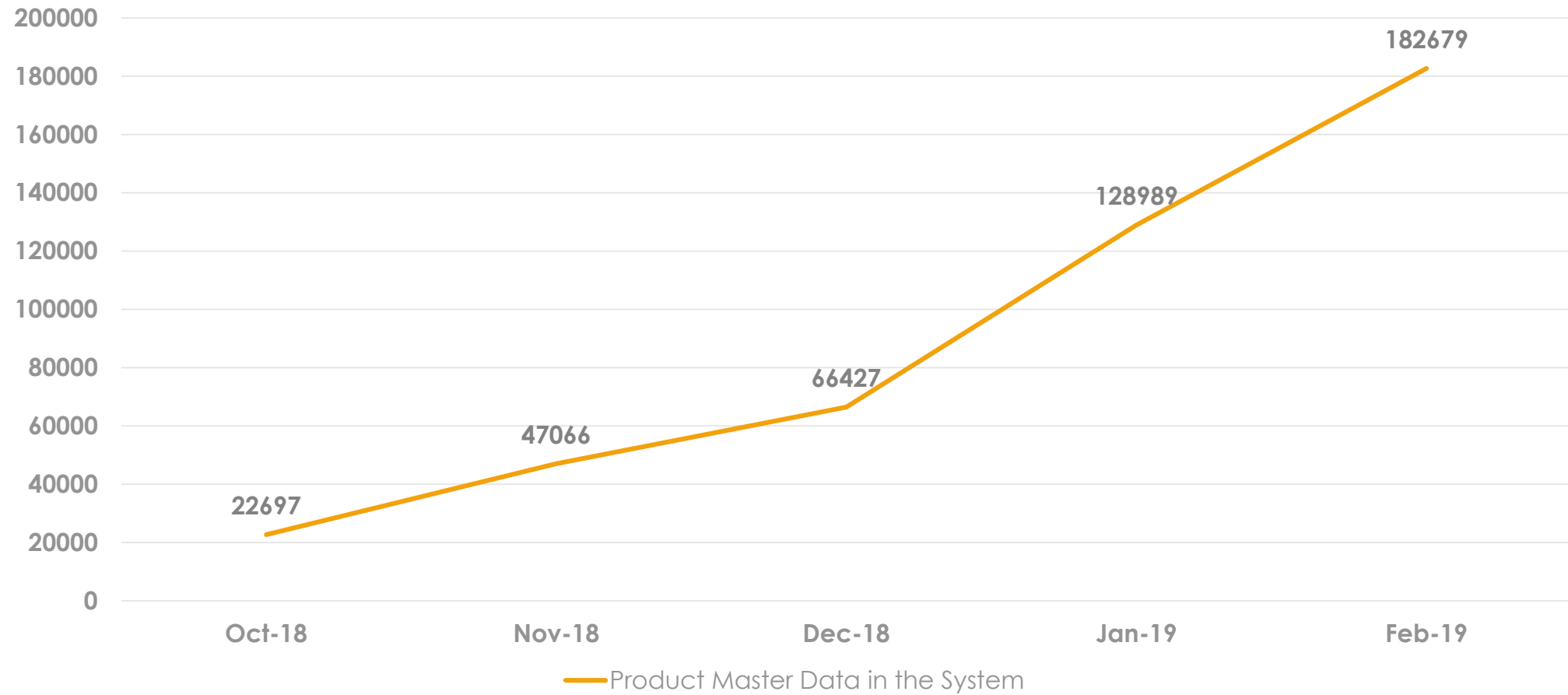
	2 OBPs		1 OBP
	2 OBPs		

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UPLOADED PRODUCT MASTER DATA

Product Master Data in the System



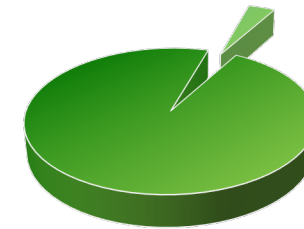
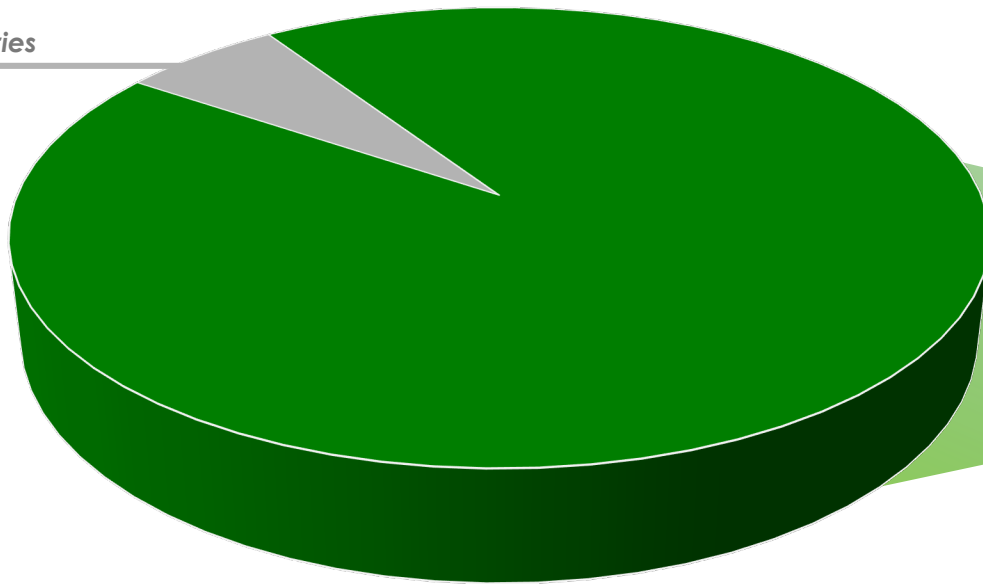
NMVO ON-BOARDING - PROGRESS OVERVIEW



 2 countries

 GRECE ITALY

 Longer Implementation Period



In 28 Countries, first packs have been verified by End-Users

30 countries Connected in PRD

-  AUSTRIA
-  BELGIUM
-  BULGARIA
-  CROATIA
-  CYPRUS
-  CZECH REPUBLIC
-  DENMARK
-  ESTONIA
-  FINLAND
-  FRANCE
-  GERMANY
-  HUNGARY
-  ICELAND
-  IRELAND
-  LATVIA
-  MALTA
-  NETHERLANDS
-  NORWAY
-  LITHUANIA
-  LUXEMBOURG
-  POLAND
-  PORTUGAL
-  ROMANIA
-  SLOVAKIA
-  SLOVENIA
-  SPAIN
-  SWEDEN
-  UNITED KINGDOM

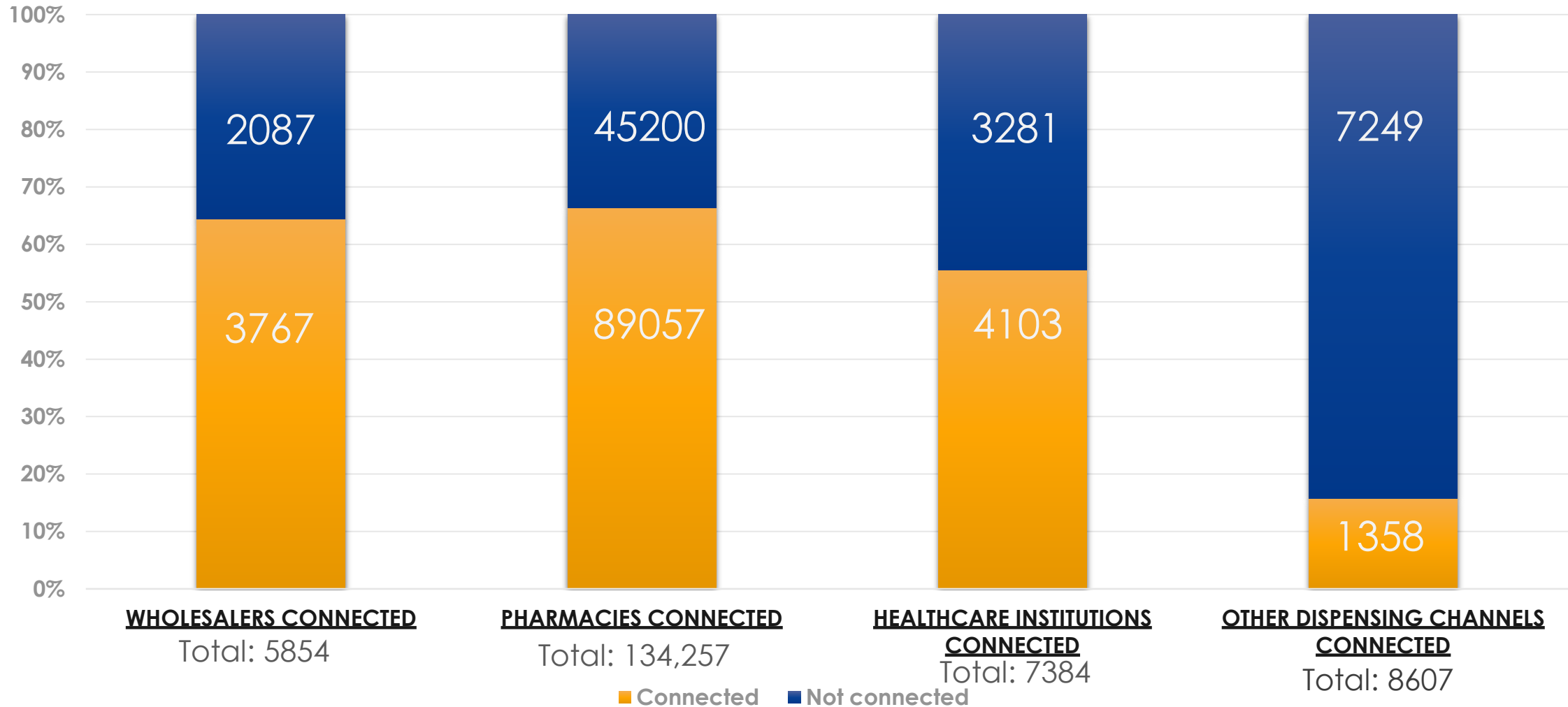
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Full functionality with coming releases

END-USER CONNECTION OVERVIEW

This data represents all End-Users in all countries



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EMVS – SYSTEM STABILIZATION

- European-wide IT project within EU & EEA
- Operational issues and teething problems on European/national level were 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

STABILIZATION PERIOD – SYSTEM ISSUES (I)

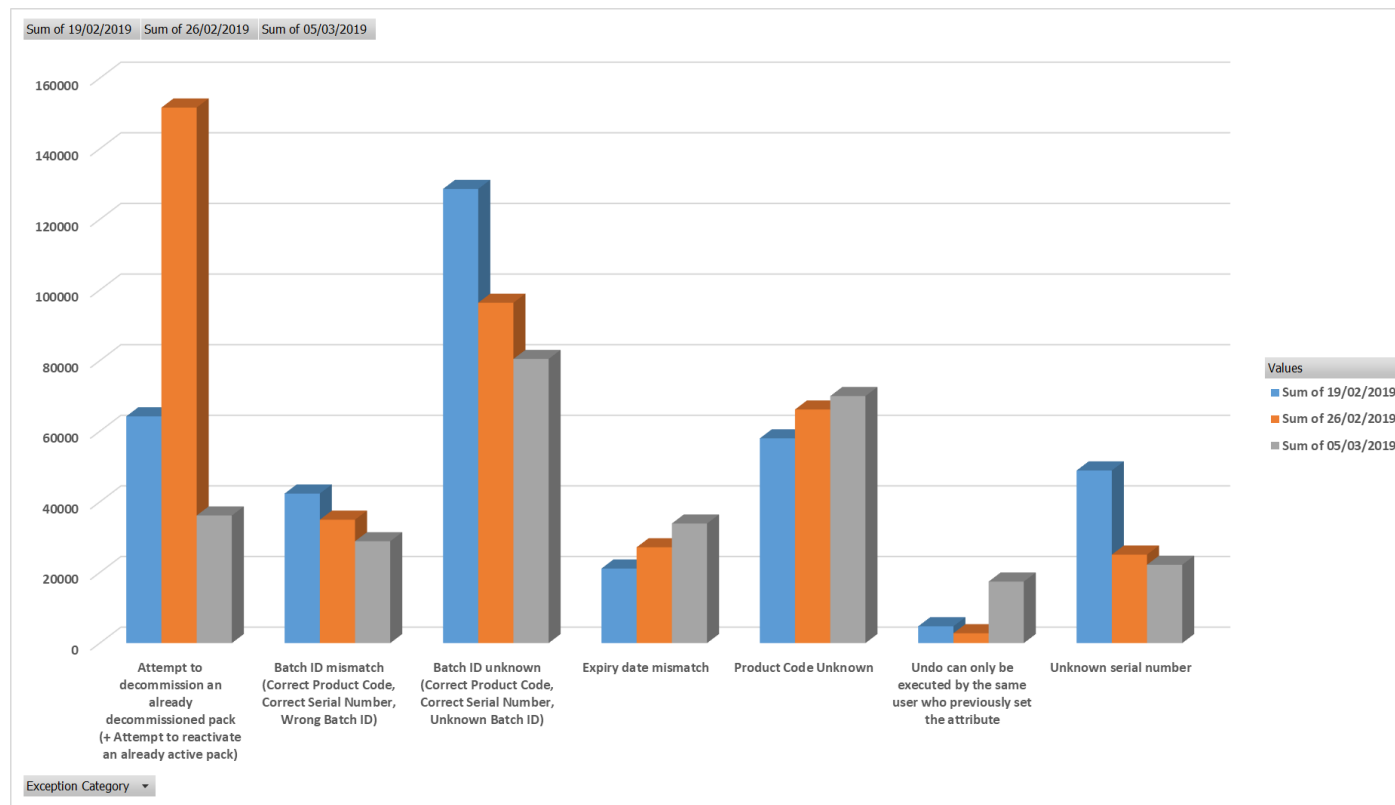
- Missing Call-Backs
 - 3 bugs have been fixed
 - Stabilized
- O1 Messages (“system not available”)
 - Work around available : Under control after a few hours (0 instances at 2 PM)
 - Stabilized
- Product Master Data
 - The version number increment algorithm is not correct
 - Stabalized
 - Final fix – 19 March
- Emulated markets missing in IQE (2018 schema only)
 - OBP may not be able to test all functionalities
 - Final fix end of March

STABILIZATION PERIOD – SYSTEM ISSUES (II)

- Creation Pack Disclosure Report
 - Available end of March
- Product Pack Verification status issue
 - Batch Expired/Recalled, Product Withdrawn
 - Change request planned
- Recent issues – under investigation
 - Creation of alert end points
 - Timestamp of the alerts sent to the OBPs - character omitted

ALERT REPORTING & ALERT MANAGEMENT (I)

- **First milestone:** EMVO undertook to identify the scale and categories of false alerts being generated.



ALERT REPORTING & ALERT MANAGEMENT (II)

- **Second milestone:** EMVO is establishing weekly reporting together with the Blueprint providers and NMVOs. We will collect the number of packs scanned and the number of alerts generated; to allow a sense of perspective.
- **Third milestone:** EMVO will establish preventative action for each identified alert category, in close collaboration with the Blueprint providers and NMVOs.

ALERT REPORTING & ALERT MANAGEMENT: ACTIONS ALREADY TAKEN BY EMVO (I)

- Shared advice and guidance documents with 3000 – 4000 End User Providers via the contact channels of the Blueprint Providers
 - Advice was that there should be no interpretation of the elements encoded in the DMC: The information sent to the NMVS MUST remain as encoded in the DMC.
 - Guidance documents:
 - EU FMD Barcode & Software Configuration Issues (PPT provided by EFPIA)
 - European Pack Coding Guidelines
 - A simple set of exemplar DataMatrix codes in a pdf file which could be used to test the scanner and software set up. (work in progress by EFPIA)
- Working in close cooperation with OBPs, NMVOs and Blueprint Providers, EMVO has assisted in identifying false alerts. EMVO also addresses these false alerts – via the Blueprint Providers – with the relevant End-User Provider.

ALERT REPORTING & ALERT MANAGEMENT: ACTIONS ALREADY TAKEN BY EMVO (II)

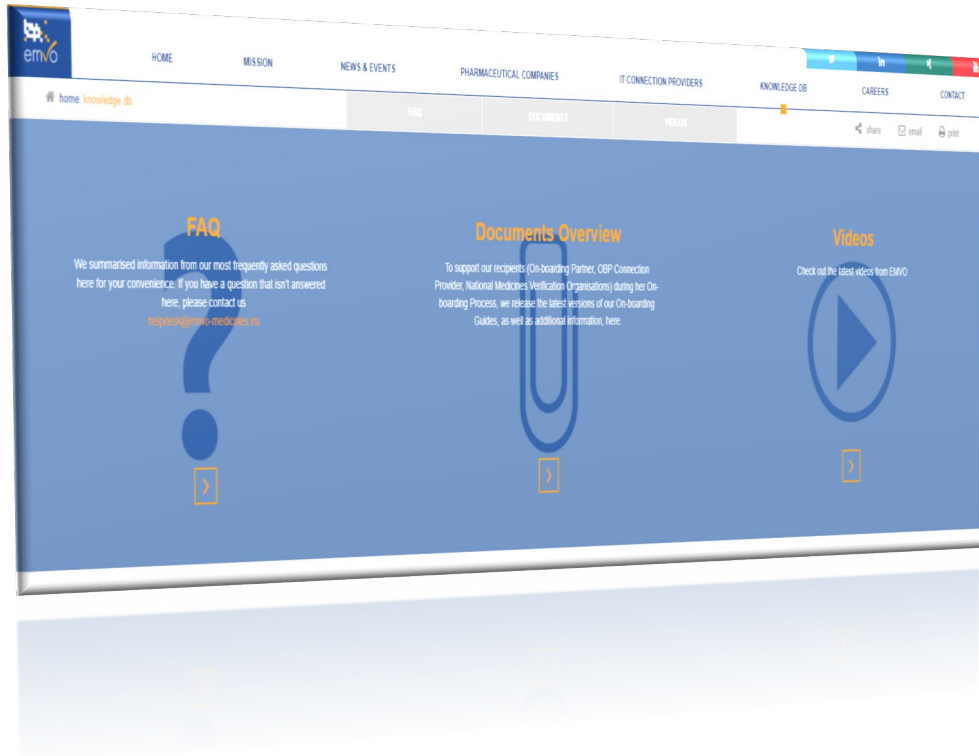
- Establishment of an alternate, centralised alert management system integrated in the EMVS, governed under existing stakeholder framework and agreements;
 - The system will be an EMVS system, accessible for all markets;
 - The solution shall be delivered in operational steps – staged implementation (September/December 2019)

CONCLUSION: “STABILIZATION PERIOD” WAS NECESSARY WHILE ALWAYS MAINTAINING PATIENT SAFETY

Period to ensure a controlled application of the NMVS and an uninterrupted medicines supply (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
- OBP On-boarding Guideline
https://emvo-medicines.eu/new/wp-content/uploads/EMVO_0077_OBP-On-boarding_Guideline-4.pdf

EVI – EUROPEAN MEDICINES VERIFICATION SYSTEM INFORMATION

- **Background and Development:**

The EVI has been developed as the tool to provide OBPs with the most up-to-date and accurate information on Known Issues or Downtimes of the systems of the EMVS.

- **Publication of entries:**

EMVO is responsible for adding entries for the EU Hub, EMVO Gateway and OBP Portal. Each NMVO is responsible for entries related to their own system, with BluePrint suppliers being nominated for adding entries on behalf of the NMVOs.

- **Further development:**

The EVI now has almost 1000 subscribers, and EMVO is encouraging all interested parties to subscribe. It is the primary means EMVO will use to communicate with OBPs during the Operational Phase of the EMVS.

EVI SCREENSHOTS – SYSTEM HOMEPAGE

FILTER INFORMATION

Type (of Interruption):

ALL TYPE (OF INTERRUPTION)

Notification Status:

ALL NOTIFICATION STATUS

System:

ALL SYSTEM

Type:

ALL TYPE

Country:

ALL COUNTRY

Start date:

End date:

CLEAR FILTERS

DOWNLOAD CSV

DOWNLOAD PDF

Type (of Interruption)	System	Impacted Env.	Country	Build N°	Type	Start date	End date	Publication date	Notification Status	Reason (if available)	Contact
Known Issue	NMVS	IQE	Spain	Reporting release 1.01.001	Planned	2019-03-04 15:00 PM CET	2019-03-04 20:00 PM CET	March 4, 2019	● Active	Deployment of the NMVS Reporting release 1.01.001 on IQE	support@nmvs.eu
Known Issue	EU Hub	PRD	All	N/A	Forced	2019-02-25 08:00 AM CET	2019-02-25 23:00 PM CET	February 26, 2019	● Active	Receiving O1 errors. For further information, please click here.	helpdesk@emvo-medicines.eu

28/03/2019

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EVI SCREENSHOTS – SUBSCRIPTION PAGE

SUBSCRIBE TO EVI NEWSLETTER

First Name *

Last Name *

Email *

Environment *

- PRD
- IQE
- ITE

System *

- EU Hub
- OBP Portal
- NMVS
- EMVO Gateway

Country *

- Austria
- Belgium/Luxembourg
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- France
- Germany
- Hungary
- Finland
- Ireland
- Latvia
- Liechtenstein
- Iceland
- Lithuania
- Malta
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- United Kingdom

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Questions?

