

# GS1 Global Healthcare Conference

## EMVO/EMVS – The European State of Play

Andreas M. WALTER  
European Medicines Verification Organisation  
Berlin, 5<sup>th</sup> April 2017

[www.emvo-medicines.eu](http://www.emvo-medicines.eu)  
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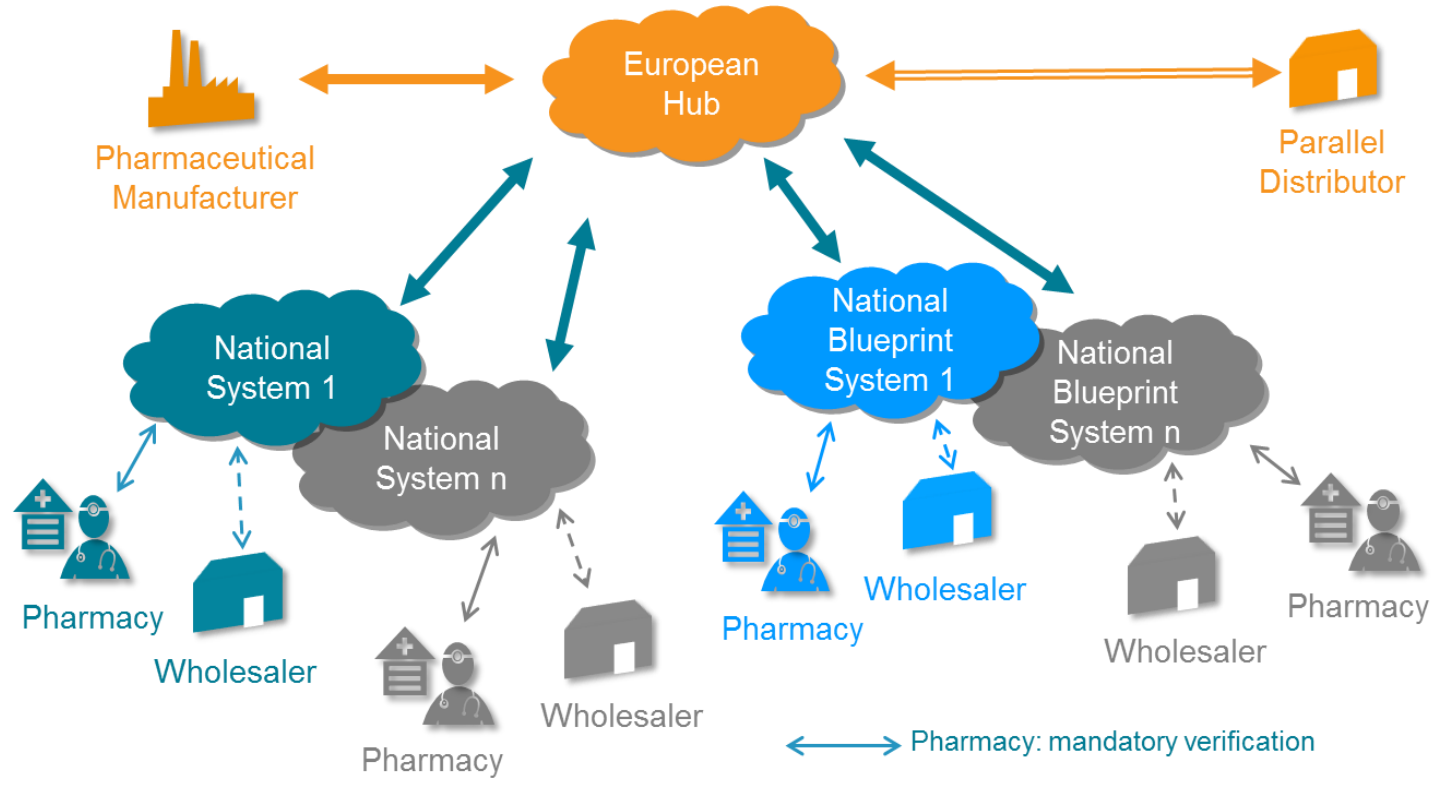
EMVS/EMVO

Manufacturer Onboarding

NMVO Onboarding

FMD Implementation – PMMR & Second Phase Format

# System Landscape



**News:**  
**EU HUB V2 available in June**

# EMVO's stakeholder

EAHP - European Association of Hospital Pharmacists (in discussion)



PHARMACIES

RESEARCH  
BASED  
INDUSTRY



WHOLESALE



GENERICS  
INDUSTRY



PARALLEL  
DISTRIBUTORS



# Organisational chart

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

**General Manager**  
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**Commercial & Partner  
Management**

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Tobias Beer

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**Operations**  
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Willem  
Theunissen

**Office Manager**  
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**Quality Assurance**  
Stephan Theunissen

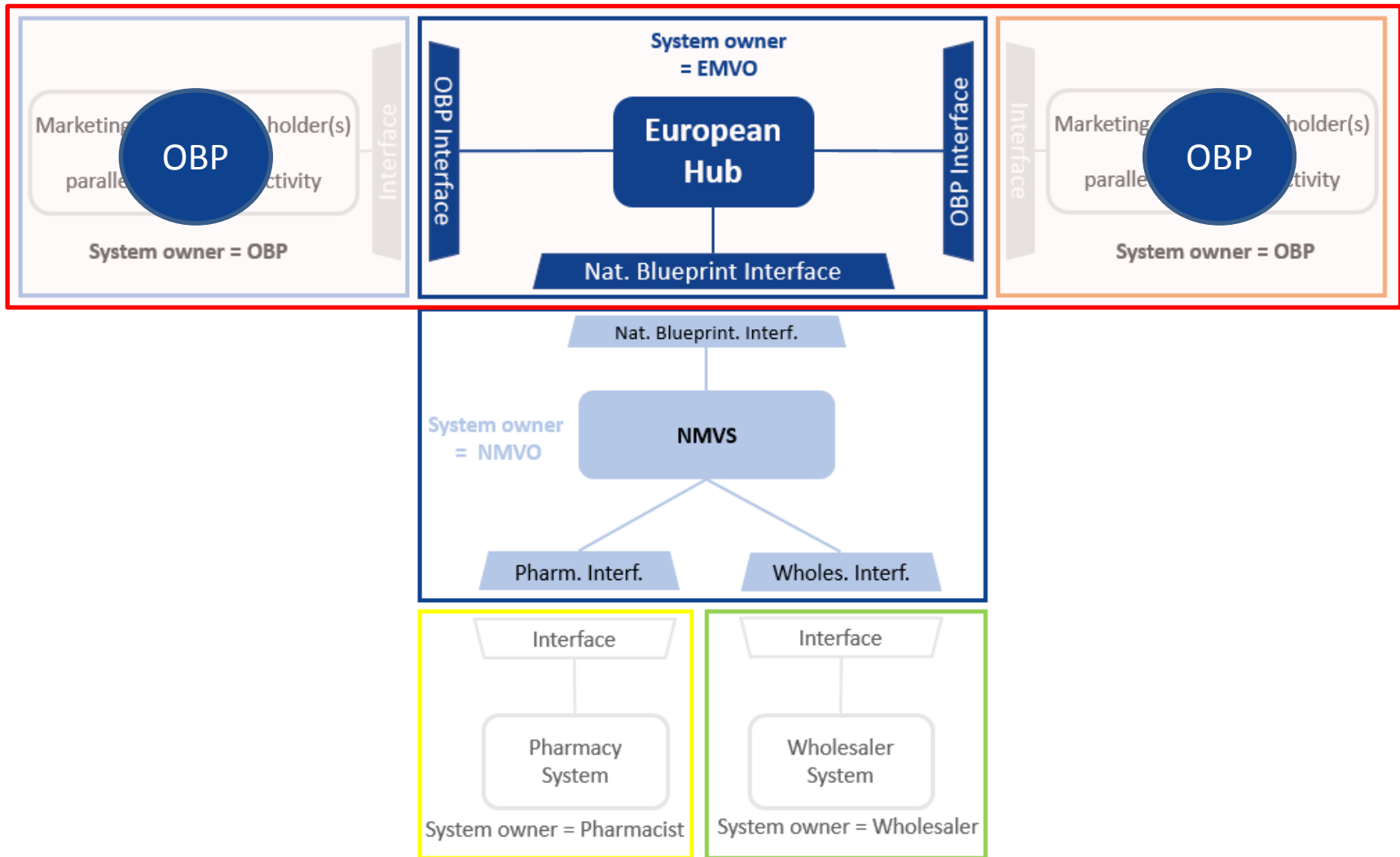
EMVS/EMVO

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# System Landscape



**OBP:** On-boarding Partner

**NMVS:** National Medicines Verification System

**NMVO:** National Medicines Verification Organisation

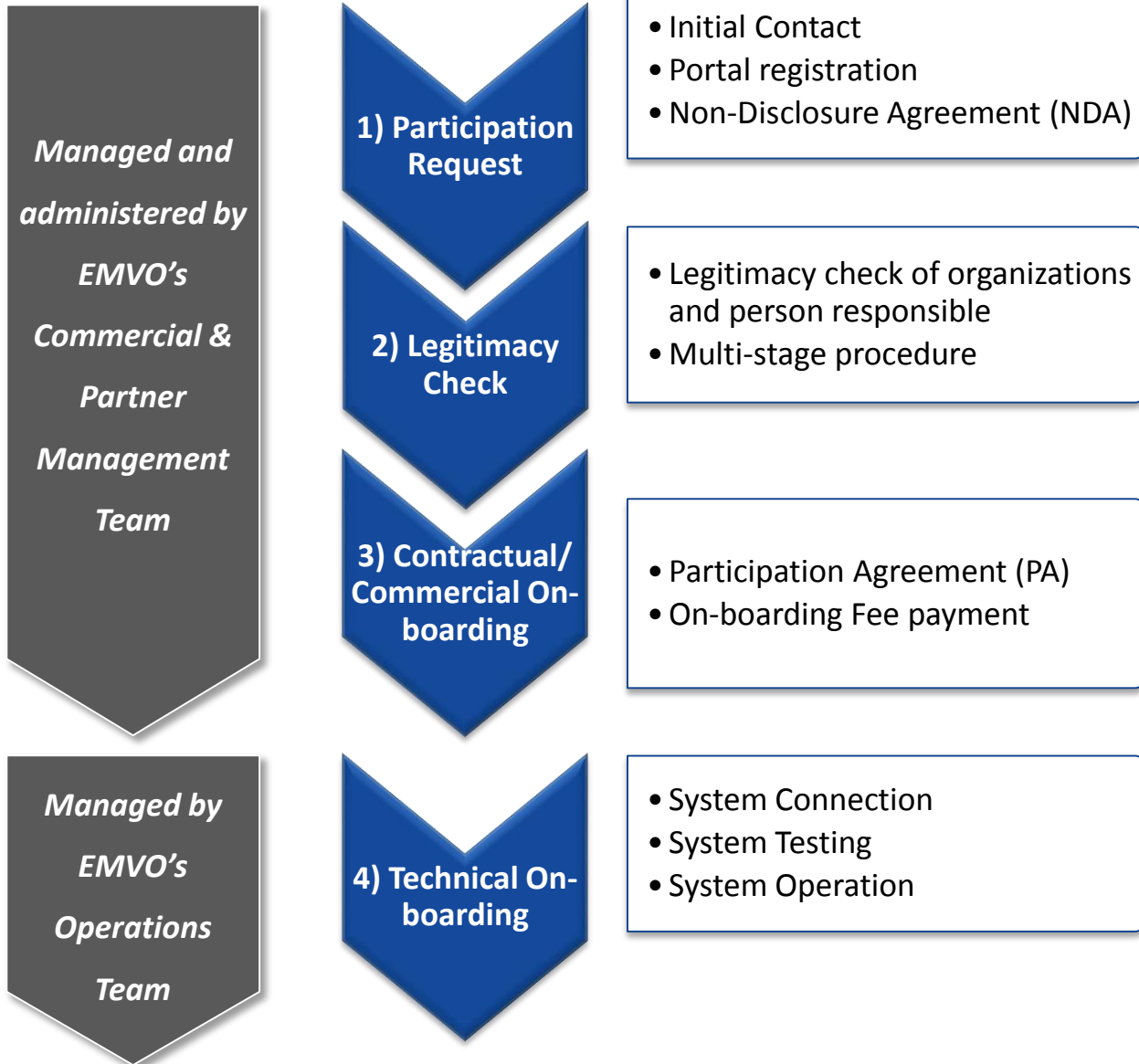
# What is an “OBP”?

- ❑ OBP means On-Boarding Partner and is the contracting party of EMVO and concludes the non-disclosure agreement (NDA) and participation agreement (PA).
- ❑ The OBP is legally authorized to sign on behalf of a MAH/a group of MAHs.
- ❑ The OBP has to be affiliated (\*) to a MAH/a group of MAHs

(\*) Affiliate shall mean, in relation to a Party, any other person affiliated with such Party within the meaning of Article 11 of the Belgian Code of Companies (it being understood, for the avoidance of doubt, that the definition set out in said Article 11 is agreed to also apply to non-Belgian persons).



# On-Boarding Process



# OBP Contracts with EMVO

## 1. Non-Disclosure Agreement (NDA)

- Covers **provision of Confidential Information** by EMVO, e.g. on
  - European Hub
  - Gateway
  - SDK
- Purpose: **Assessment of participation** in the EMVS project

## 2. Participation Agreement (PA)

- Contractual framework for **participation in the On-boarding project**, e.g.
  - Use of Gateway
  - Interface development
  - Connect to the HUB
- Purpose: **Execution of Technical On-Boarding**

## 1. Non-Disclosure Agreement (NDA)

## 2. Participation Agreement (PA)

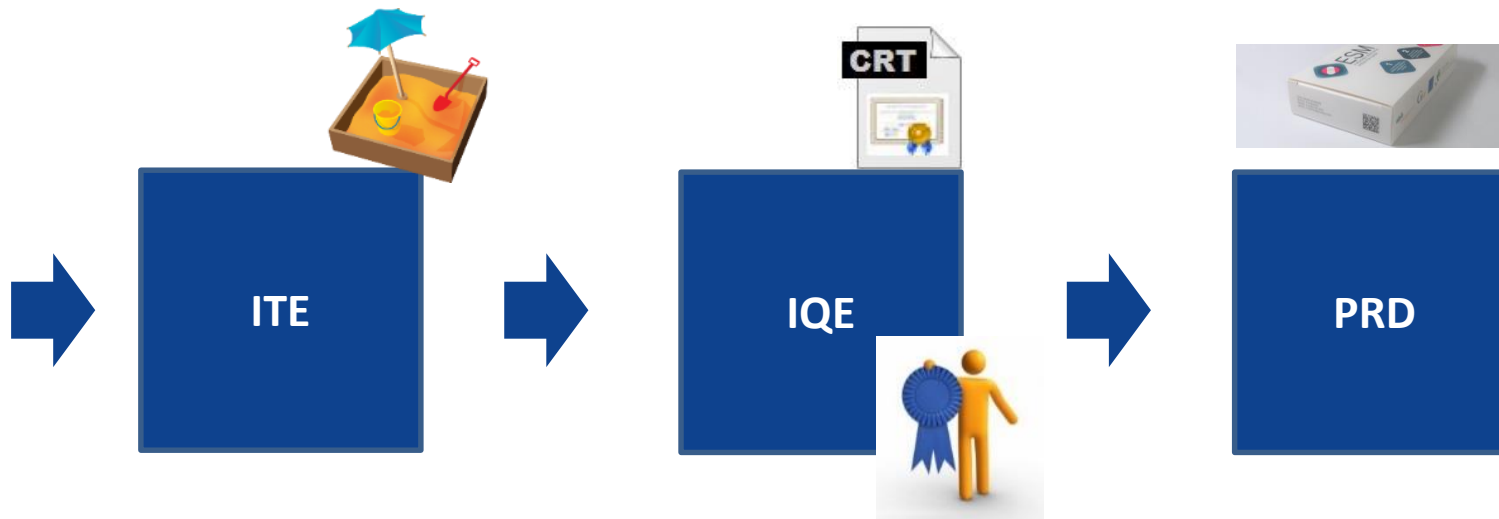
- Covers provisions for Confidentiality and Intellectual Property framework for the On-going EMVO project.
- 
- 
- 
- Public participation project

**No Contract  
Negotiation**

## One-Time Fee per OBP

<b>OBPs with more than 12 MAHs in Europe</b>	20,000 €
<b>OBPs with 6 to 12 MAHs in Europe</b>	10,000 €
<b>OBPs with 3 to 5 MAHs in Europe</b>	8,000 €
<b>OBPs with 2 MAHs in Europe</b>	6,000 €
<b>OBPs with 1 MAH in Europe</b>	3,000 €

- ❑ Starts when Participation Agreement is signed by EMVO
- ❑ OBP will connect his client sequentially to:
  - the ITE environment to develop an interface
  - the IQE environment to certify his interface
  - The PRD environment to use his interface
- ❑ OBP can choose to connect via
  - a Direct connection (data send from client straight to EU Hub)
  - a Gateway connection (Data sent first to a Gateway Provider. The Gateway Provider sends it through to the EU Hub)



## ITE environment

- Integrated Test Environment
- Used as sandbox by multiple OBP's
- Integration testing of OBP's connection

## IQE environment

- Integrated Quality Environment
- Used for Quality- & Certification testing by multiple OBP's
- Validated environment

## PRD environment

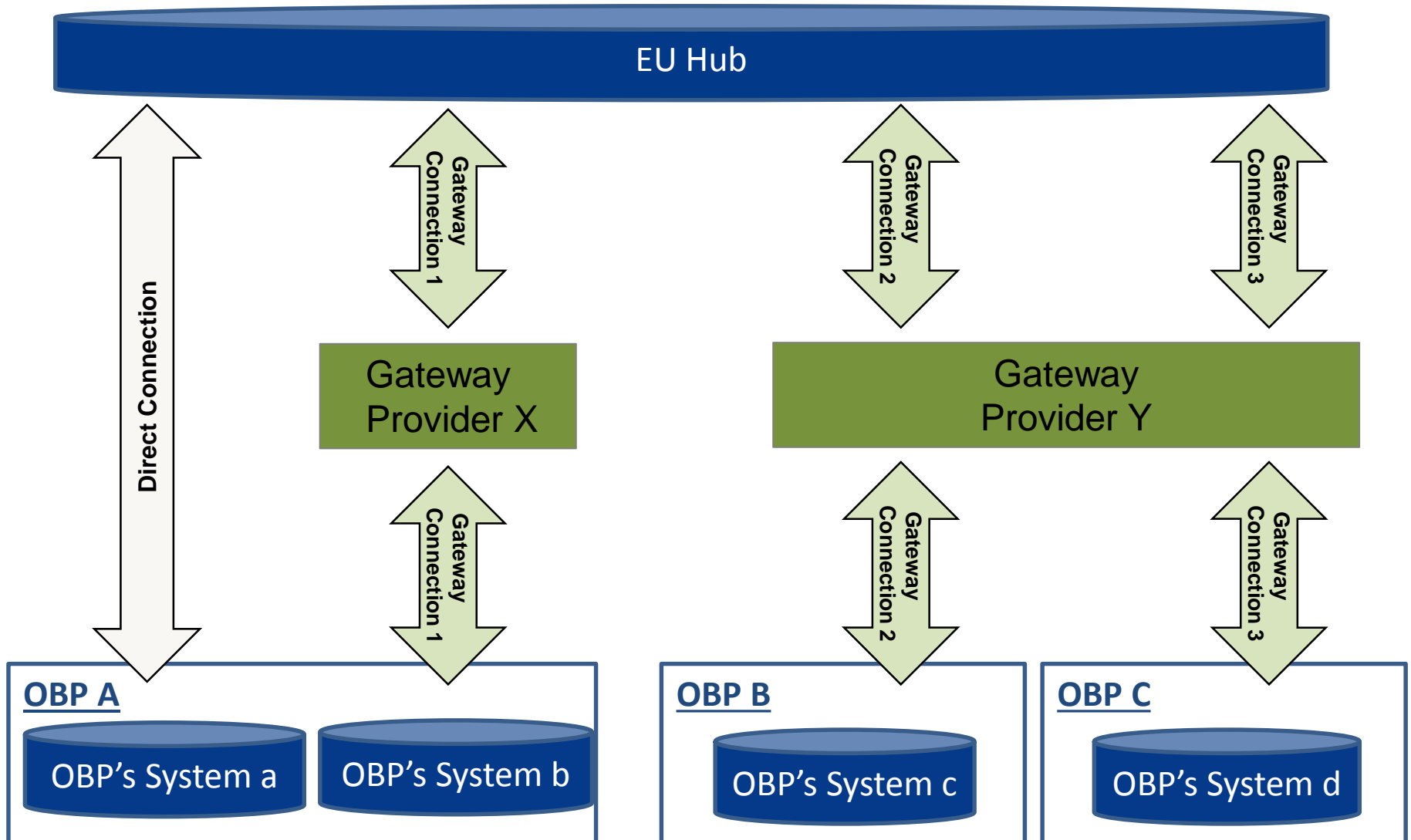
- Productive Environment
- Validated environment

**IQE:** Integration Quality Environment

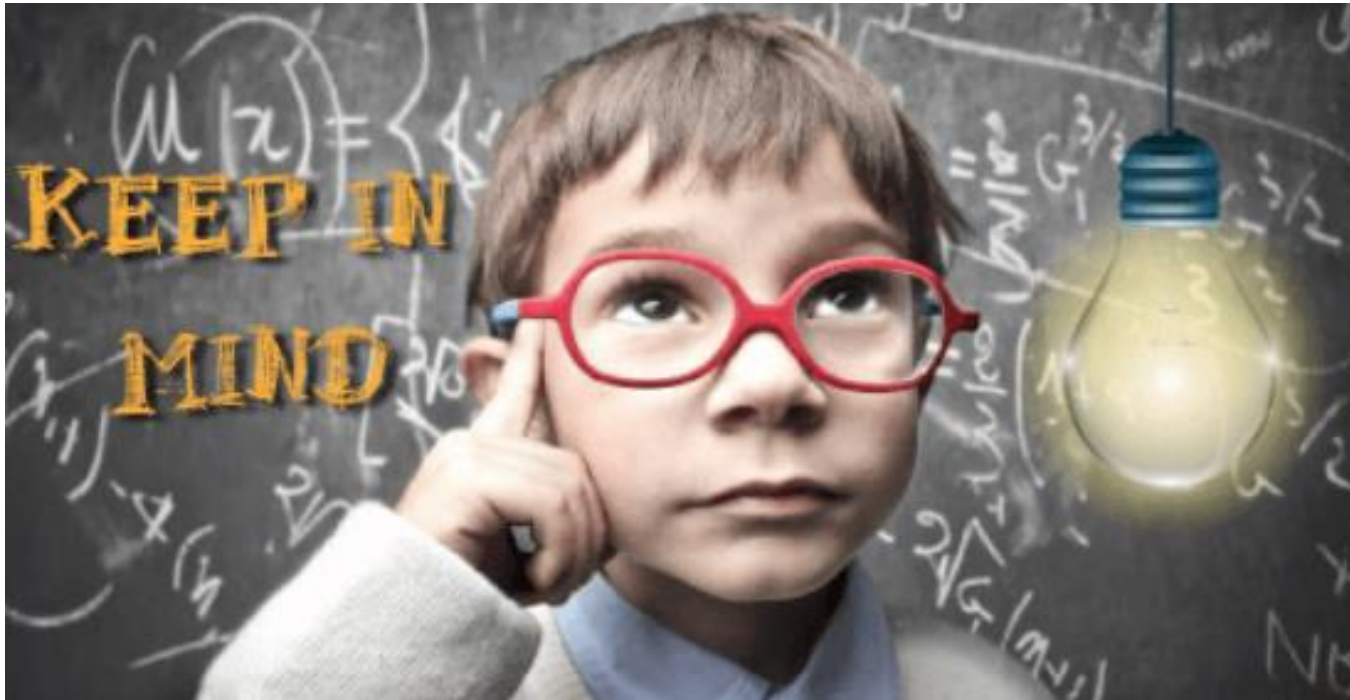
**IQE:** Integration Quality Environment

**PRD:** Productive Environment

# Connection Types

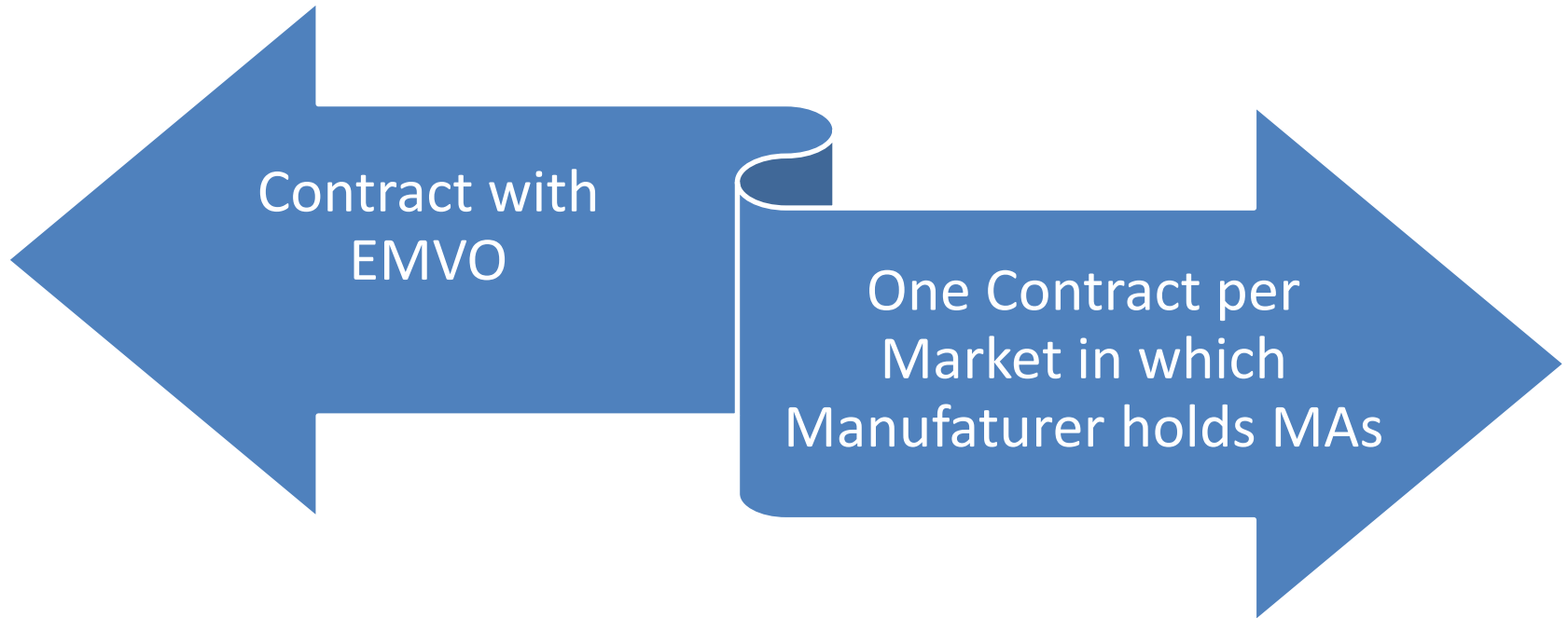


# Keep in mind



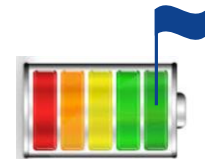
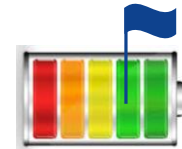


**.....do not forget your Service  
Contract with NMVOs!**



# On-boarding Package

- On-boarding Partner Portal (OBP Portal)
- On-boarding Guideline
- On-boarding Contracts
- On-boarding PPT





Prerequisite to on-board  
> 2.500 MAHs/Parallel Distributors



User-friendly  
web-based portal



Decrease EMVO's  
response time



Starting point/ trigger  
for legitimacy check

Step 1: Provide initial information

Complete










Step 2: Non-disclosure agreement

Complete



Step 3: Detailed information and participation agreement



			Time to complete	Status
3.1	General info pack 	<a href="#">Open</a>		Available
3.2	Single point of contact information 	<a href="#">Modify</a>	5-7 min	Complete
3.3	Participation Agreement 	<a href="#">View Download</a>	1 min	Available
3.4	Upload Signed Participation Agreement 	<a href="#">Upload PDF</a>	1 min	Awaiting approval
3.5	Invoicing information 	<a href="#">Add</a>	5-7 min	Not Started
3.6	Additional company information 	<a href="#">Add</a>	5-7 min	Not started
3.7	MAH and product information 	<a href="#">Add</a>	60 min	Not started

Step 4: Approvals

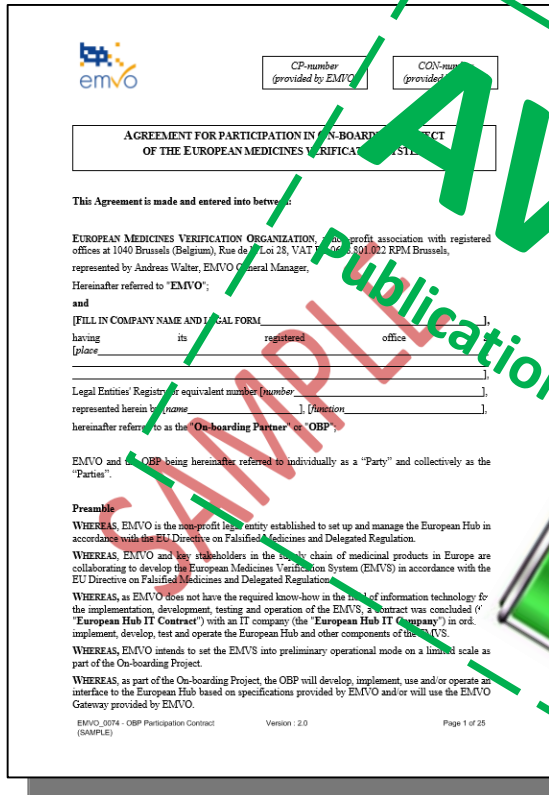


Step 5: Technical onboarding



## Non-disclosure agreement (NDA)

## Participation Agreement (PA)



CP-number (provided by EMVO)      COV-number (provided by EMVO)

**AGREEMENT FOR PARTICIPATION IN ON-BOARDING PROJECT OF THE EUROPEAN MEDICINES VERIFICATION SYSTEM**

This Agreement is made and entered into between:

**EUROPEAN MEDICINES VERIFICATION ORGANIZATION**, a non-profit association with registered offices at 1049 Brussels (Belgium), Rue de la Loi 28, VAT BE 08.801.022 RPM Brussels, represented by Andreas Walter, EMVO General Manager, Hereinafter referred to "EMVO";

and

[FILL IN COMPANY NAME AND LEGAL FORM], having its registered office at [place], [address], [country], [postal code], [city], hereinafter referred to as the "On-boarding Partner" or "OBP";

EMVO and the OBP being hereinafter referred to individually as a "Party" and collectively as the "Parties".

**Preamble**

WHEREAS, EMVO is the non-profit legal entity established to set up and manage the European Hub in accordance with the EU Directive on Falsified Medicines and Delegated Regulation.

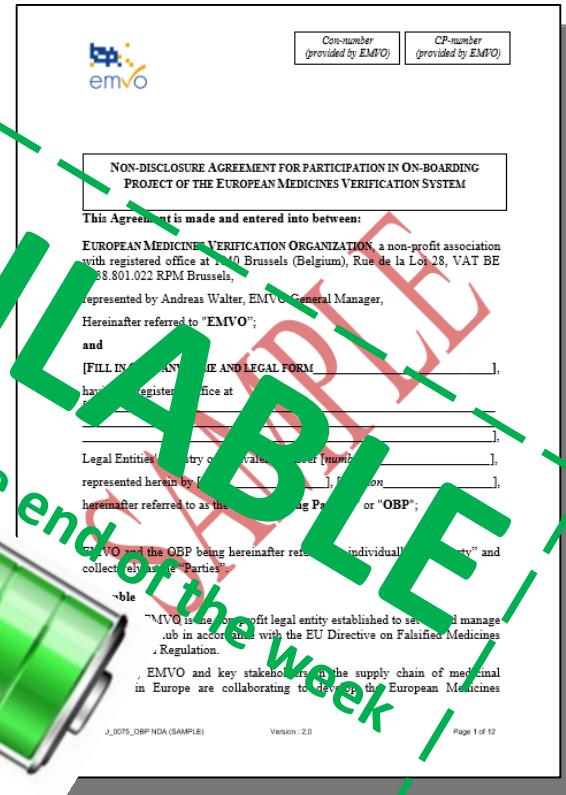
WHEREAS, EMVO and key stakeholders in the supply chain of medicinal products in Europe are collaborating to develop the European Medicines Verification System (EMVS) in accordance with the EU Directive on Falsified Medicines and Delegated Regulation.

WHEREAS, as EMVO does not have the required know-how in the field of information technology for the implementation, development, testing and operation of the EMVS, a contract was concluded ("European Hub IT Contract") with an IT company (the "European Hub IT Company") in order to implement, develop, test and operate the European Hub and other components of the EMVS.

WHEREAS, EMVO intends to set the EMVS into preliminary operational mode on a limited scale as part of the On-boarding Project.

WHEREAS, as part of the On-boarding Project, the OBP will develop, implement, use and/or operate an interface to the European Hub based on specifications provided by EMVO and/or will use the EMVO Gateway provided by EMVO.

EMVO\_0074 - OBP Participation Contract      Version : 2.0      Page 1 of 25 (SAMPLE)



CP-number (provided by EMVO)

**NON-DISCLOSURE AGREEMENT FOR PARTICIPATION IN ON-BOARDING PROJECT OF THE EUROPEAN MEDICINES VERIFICATION SYSTEM**

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J\_0075\_OBP NDA (SAMPLE)      Version : 2.0      Page 1 of 12

Please check <https://www.emvo-medicines.eu/> for the latest version of this presentation and the On-boarding Guideline.



European Medicines  
Verification Organisation



## EMVO On-boarding How to connect to the EU Hub?

European Medicines Verification Organisation (EMVO)  
[www.emvo-medicines.eu](http://www.emvo-medicines.eu)  
[helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)

Please check  
<https://www.emvo-medicines.eu>  
for the latest version of this presentation and the On-boarding Guideline.



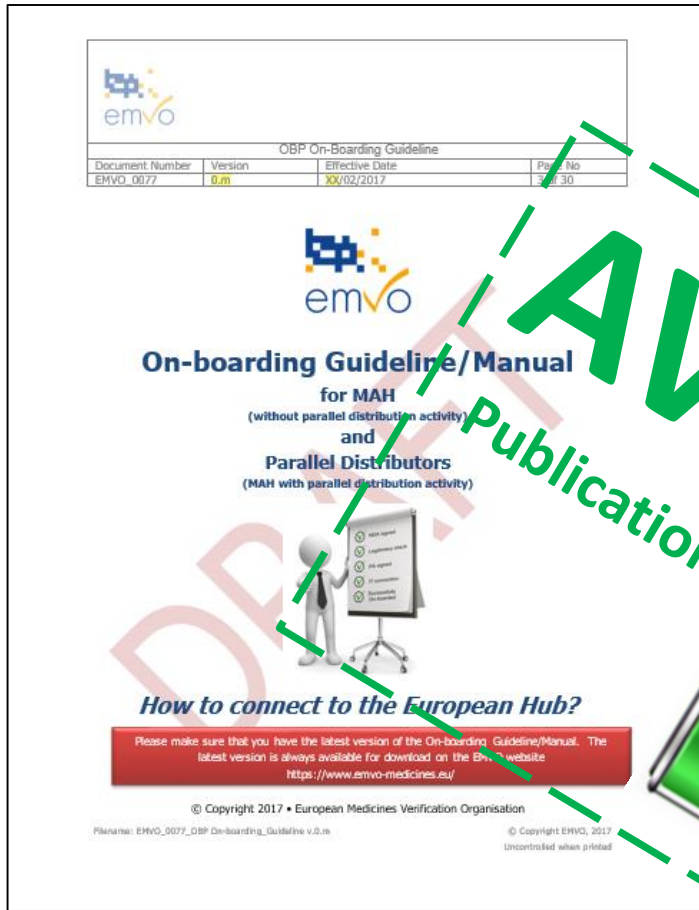
EAEPCE  
European Association of  
Euro-Pharmaceutical  
Companies

medicines  
for europe  
better access. better health.

IRP  
vital link in healthcare

GPUE  
European Group of  
Development Pharmacies of the European Union

Please check <https://www.emvo-medicines.eu/>  
for the latest version of this presentation and the On-boarding Guideline.



emvo


OBP On-Boarding Guideline

Document Number	Version	Effective Date	Page No
EMVO_0077	0.0m	XX/02/2017	4 of 30

emvo

## On-boarding Guideline/Manual

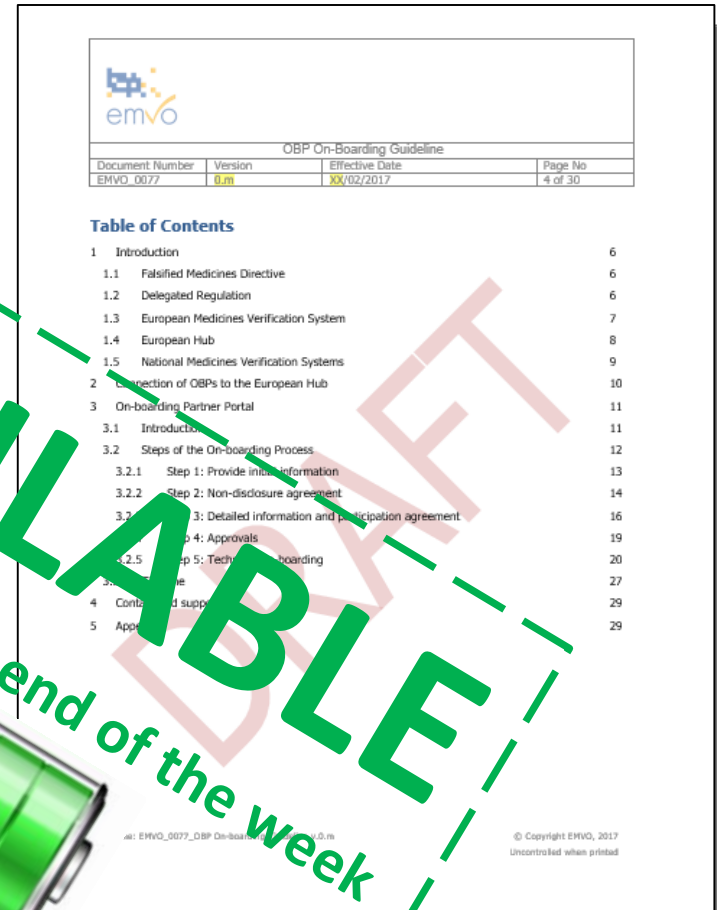
for MAH  
(without parallel distribution activity)  
and  
Parallel Distributors  
(MAH with parallel distribution activity)



### How to connect to the European Hub?

Please make sure that you have the latest version of the On-boarding Guideline/Manual. The latest version is always available for download on the EMVO website <https://www.emvo-medicines.eu/>

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OBP On-Boarding Guideline

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EMVO_0077	0.0m	XX/02/2017	4 of 30

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for the latest version of this presentation and the On-boarding Guideline.

EMVS/EMVO

Manufacturer Onboarding

NMVO Onboarding

FMD Implementation – PMMR & Second Phase Format



# Organisational Requirements

NMVS must be governed and managed by a national stakeholder organisation (NMVO), i.e.

- Alignment between all stakeholders
  - NMVO Statutes agreed
  - NMVO established
- non-profit legal entity compliant with DR Article 31(1)

NMVO to implement fundamentals of QMS (Quality Management System)\*

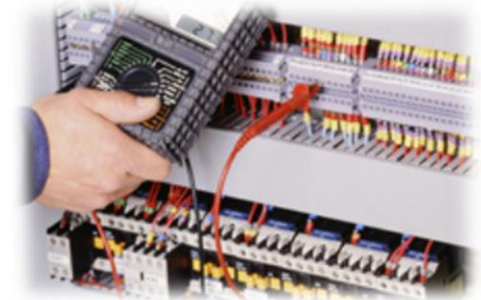
**NMVS:** National Medicines Verification System  
**NMVO:** National Medicines Verification Organisation  
**DR:** Delegated Regulation

\* May be supported by EMVO



NMVS have to meet the following criteria:

- IT service provider selected  
(Blueprint or Standalone)
- Contract with IT service provider signed
- Interface with EU Hub developed according to EMVS specification (EMVS URS & SDK)
- Secure protection of the computerized system to ensure adequately and securely protected data
- NMVO to approve Validation Plan and Validation Report



**URS:** User Requirement Specification  
**SDK:** Software Development Kit

Audit will focus, inter alia, on:

- URS compliance with DR
- System design and architecture compliance with DR
- Interface with EU Hub developed according to EMVS specification (EMVS URS & SDK)
- Data integrity, access and ownership
- Compliance of NMVO to Article 31 of the DR
- Financial Stability NMVO
- QMS of NMVO, inter alia:
  - On-boarding procedure for end-users (to ensure compliance with DR Article 37(b) :
  - Legitimacy check of end-users & potentially manufacturers (if applicable)



Green text: Potentially not to be audited as of 2<sup>nd</sup> Blueprint System of the same supplier (EMVO to decide)

# Cooperation Agreement – Principles

- Template Approach (not negotiable)
- Valid for BPS and Standalone systems
- Country specifics to be laid down in « side letters »
- Recommendations for NMVO-end user relationship (annex 4)
- Valid only in Implementation Phase

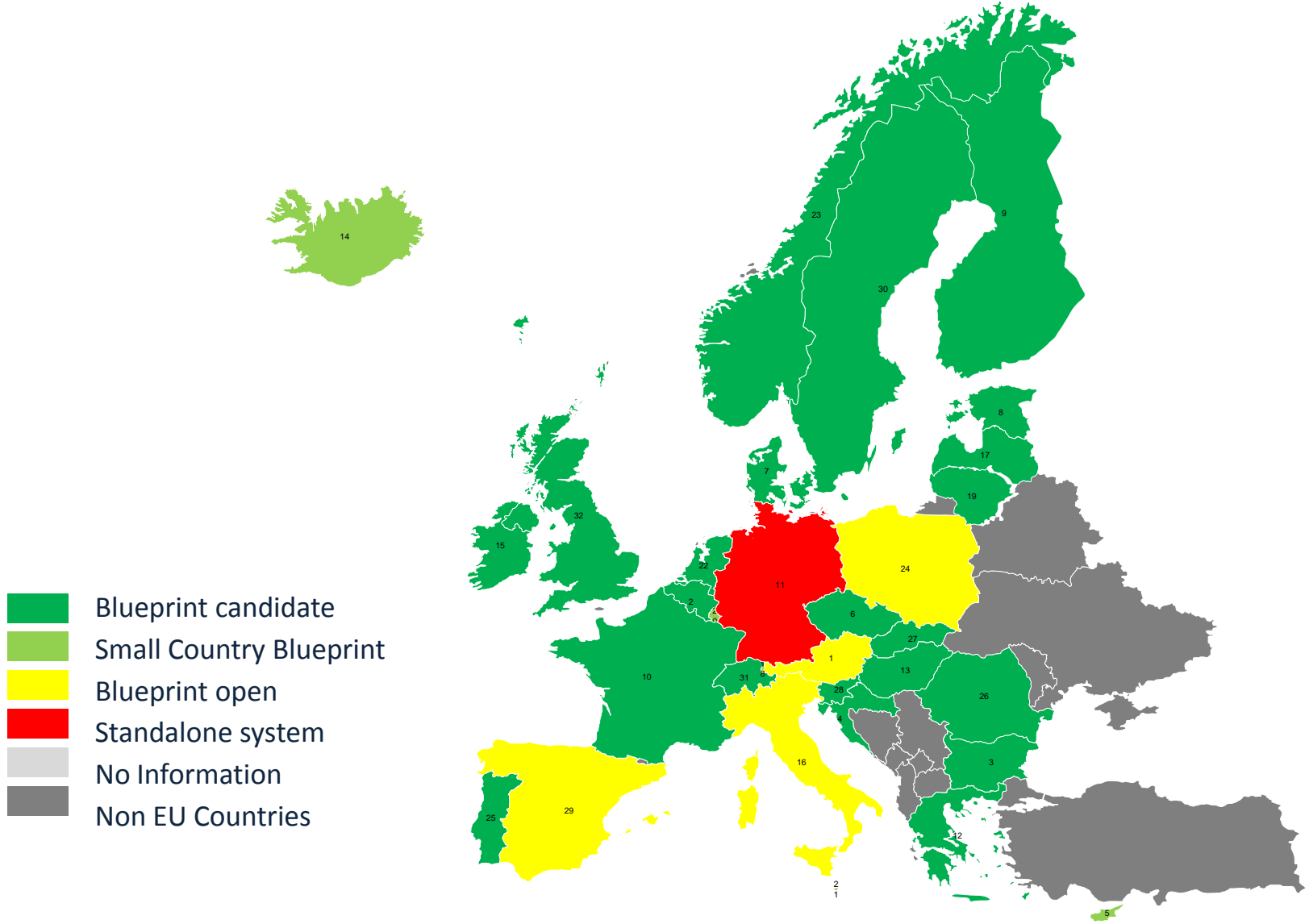
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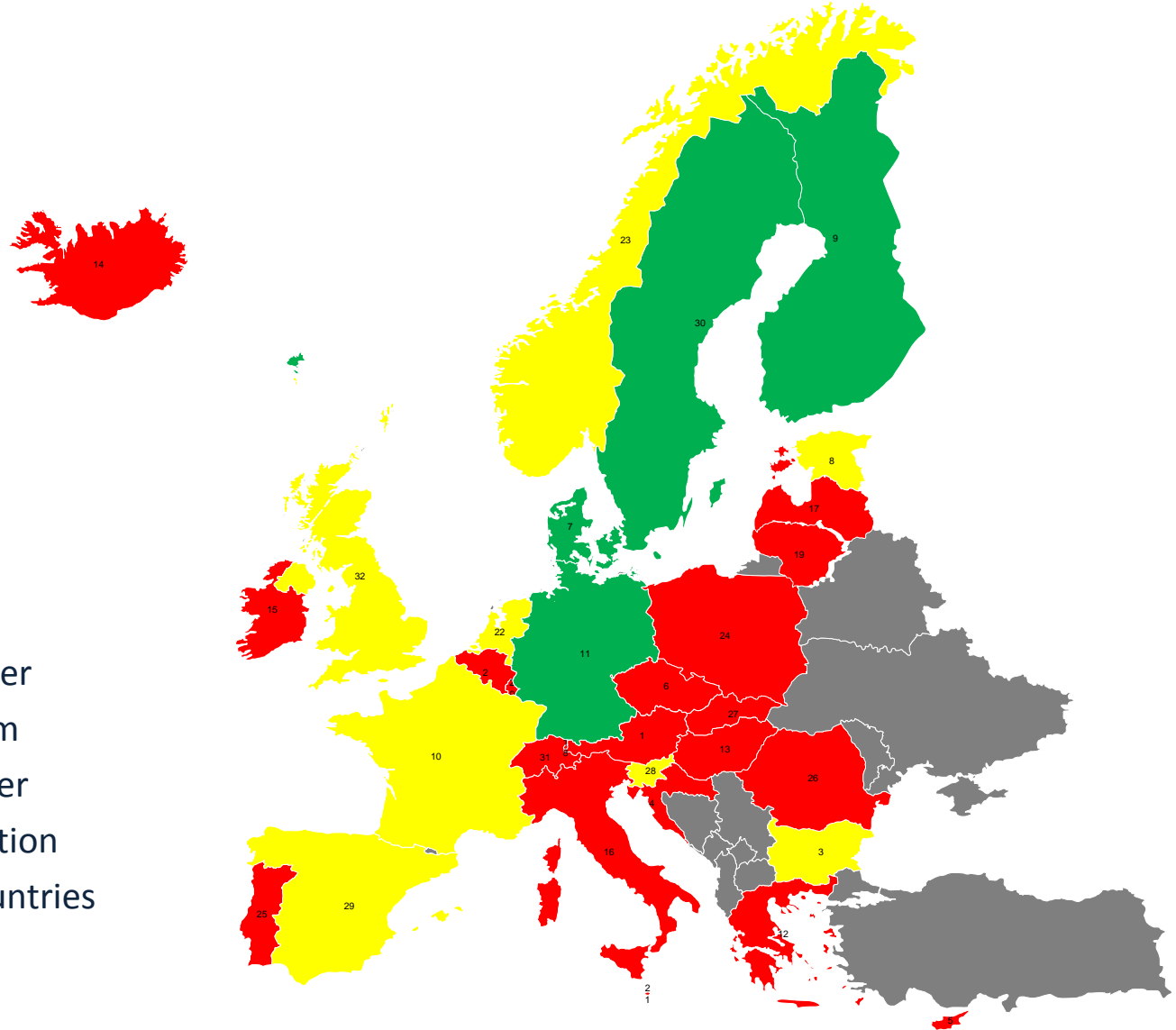
# Executive Summary Blueprint Tendency



# Executive Summary

## Country Readiness

- Early Adopter
- Main Stream
- Late Follower
- No Information
- Non EU Countries



## □ Program Progress

- 16 NMVOs (50%) founded, 4 Contracts Signed
- Majority of Countries progress and aim for Provider Contract in Q1 2017
- Countries decide for Blueprint, only 4 remain open

## □ To be improved

- 2/3 of Countries are still behind Schedule
- Still 4 Countries did not start Technical Work Stream
- Stakeholder alignment in MOU and Statutes not complete in a few Countries (e.g. Pharmacies and Wholesalers not integrated in NMVO set up)



## Outcome of the Expert Group Meeting 28 March

- Progress with setting up **NMVOs** and **signature of IT providers**
- **12 Member States reported significant issues with the proposed cost allocation model**
  - Lack of consideration for small low turnover MAHs
- **ATD: most of Member States consider voluntary use** (e.g. if in place to retain), some MS to extend to all OTC
- Importance of use of **aggregated codes** particularly within the **hospital** setting
- Difficulties to involve hospital pharmacists within NMVO

## Outcome of the Expert Group Meeting 28 March

- Multi country pack codes – support from MS to avoid using a National Number providing that:
  - **A correlation table between GTIN and National code can be established e.g. BE**
  - **No reallocation of stock which leads to a shortage risk**
- **Important to have access to the Conformity Assessment Report performed by EDQM to feed the workstream on the Supervision of the Repository Systems**

# Questions?





**Thank you very much!**

*Andreas M. WALTER  
General Manager*

*Contact for On Boarding and general topics:*

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



BULGARIAN MEDICINES  
VERIFICATION ORGANISATION

# Implementation of FMD in Bulgaria Establishment of BgMVO

*Illiana Paunova  
Berlin, 05.04.2017*

# FMD is about ...

## Patient Safety



- Delivering patient confidence in medicines
- Protecting patients against counterfeit products

## Regulatory Compliance



- Ensuring compliance deadlines defined by regulators and governments are met

## Supply Chain Security



- Improving visibility and efficiency across the supply chain

## Value Through Standardisation



- Working with GS1 to optimise the way healthcare is delivered globally
- Defining standard processes, solutions and equipment for GMS to maximise investment and control complexity

# The Impact of Counterfeit



- In some developing areas of Asia, Africa and Latin America up-to 30% counterfeit sales
- 50% of illegal sales on the internet
- Recent study of EUIPO shows 4.4% counterfeit-medicines sales in Europe (this means 440 million packs per year)

# Can you tell the difference



**Geniune**



**Falsified**

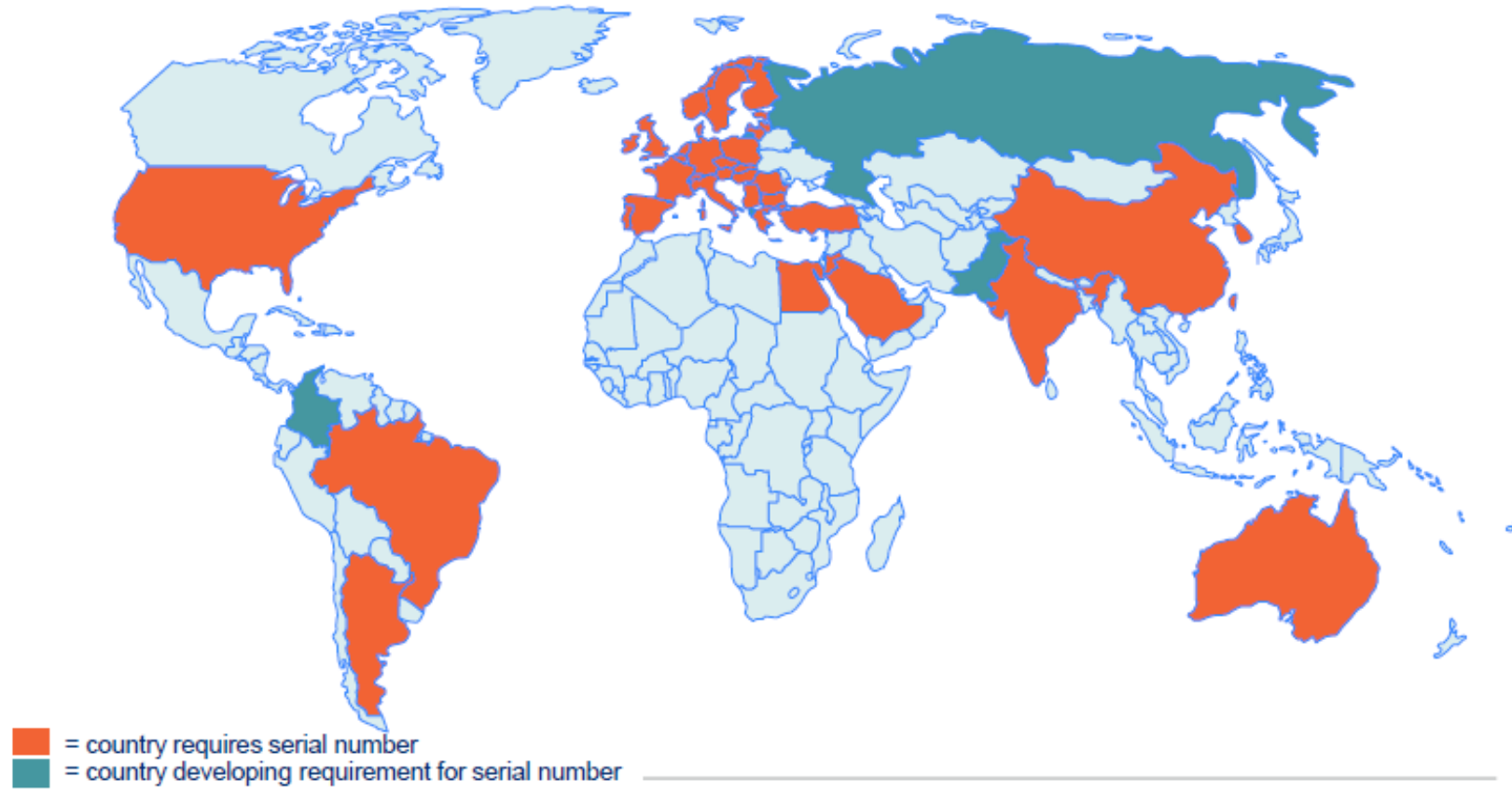
- According to Interpol more than 1 million people die each year from counterfeit drugs
- The mortality of HIV/AIDS in 2015 was 1,1 million people (WHO, The Top 10 causes of death, Jan. 2017)
- Road injuries killed 1.3 million people in 2015 and this is the 10<sup>th</sup> leading cause of death (WHO, The Top 10 causes of death, Jan. 2017)



Falsifiers do not spend money on GMP,  
but invest in packaging equipment  
**Profits: 500 times higher than investments**



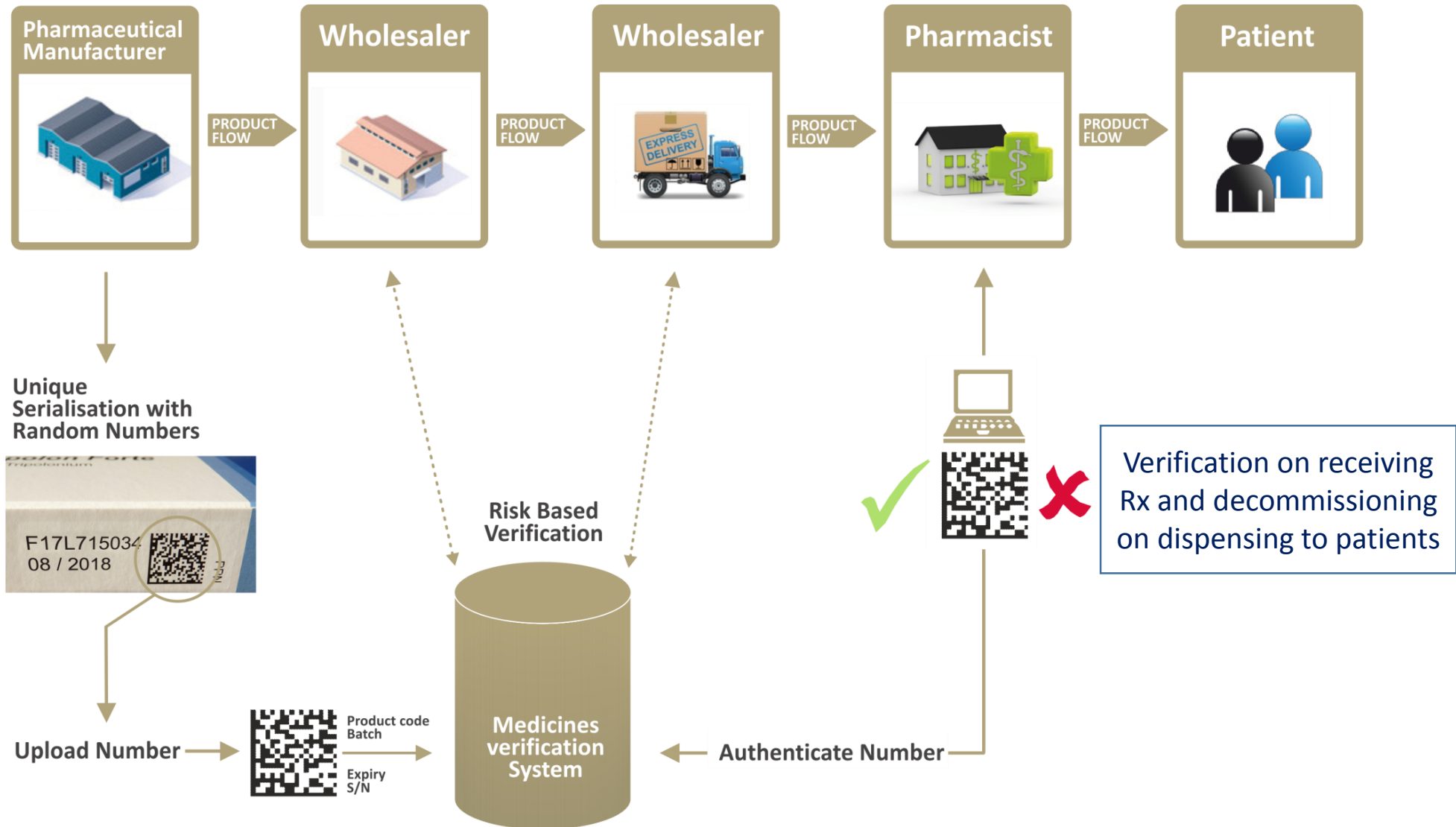
# Serialization map of pharmaceuticals



# BgMVO Vision in the Memorandum of Understanding signed July 2015

- **Model**
  - Mandatory decommissioning at the point of dispense
  - Verification on receiving Rx in the pharmacy
  - GTIN coding with the 2D code
  - Rx products according to the FMD, tender Vx verification at WH
- **Governance**
  - Non profit organisation of 5 stakeholders
  - Equal rights of all stakeholders, full consent for important issues
  - Flat fee principle (equal membership fees and verification fees)
  - Collaboration and consultations with Authorities (BDA, MoH)
- **System**
  - Single pan European system
  - Blueprint model to be followed
  - Support to local Onboarding Partners
- **Benefits**
  - Meets all requirements of the Directive
  - Minimised complexity
  - Cost efficiency
  - Foundation for other functionalities

# Concept: point of dispense verification



# Coding recommendations: GTIN and 4 elements

## Data Matrix – Coding proposal derived from GS1 standards (EAN 128 syntax with Application Identifiers; Data matrix ECC200)

Manufacturer Product Code (GTIN)  
Unique Serial Number (randomized)  
Expiry Date (in Bulgarian)  
Batch Number (in Bulgarian)

14 digits  
up to 20 alpha-numeric characters  
6 digits (YYMMDD)  
up to 20 alpha-numeric characters

+ minimum requirements on quality of randomisation

### Example:

PC: GTIN (01) 07046261398572

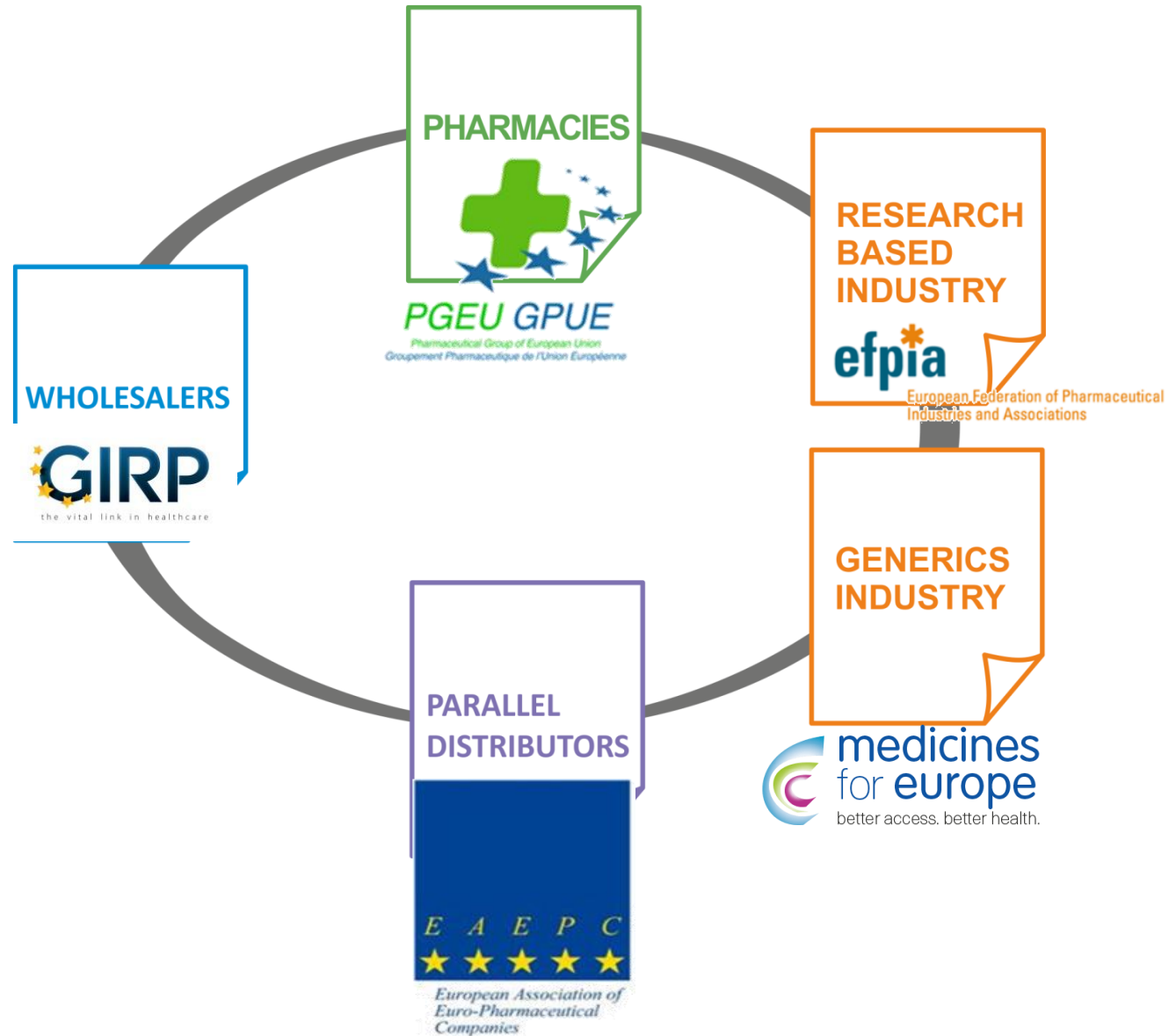
Парт. №: (10) TEST5632

Годен до: (17) 23021

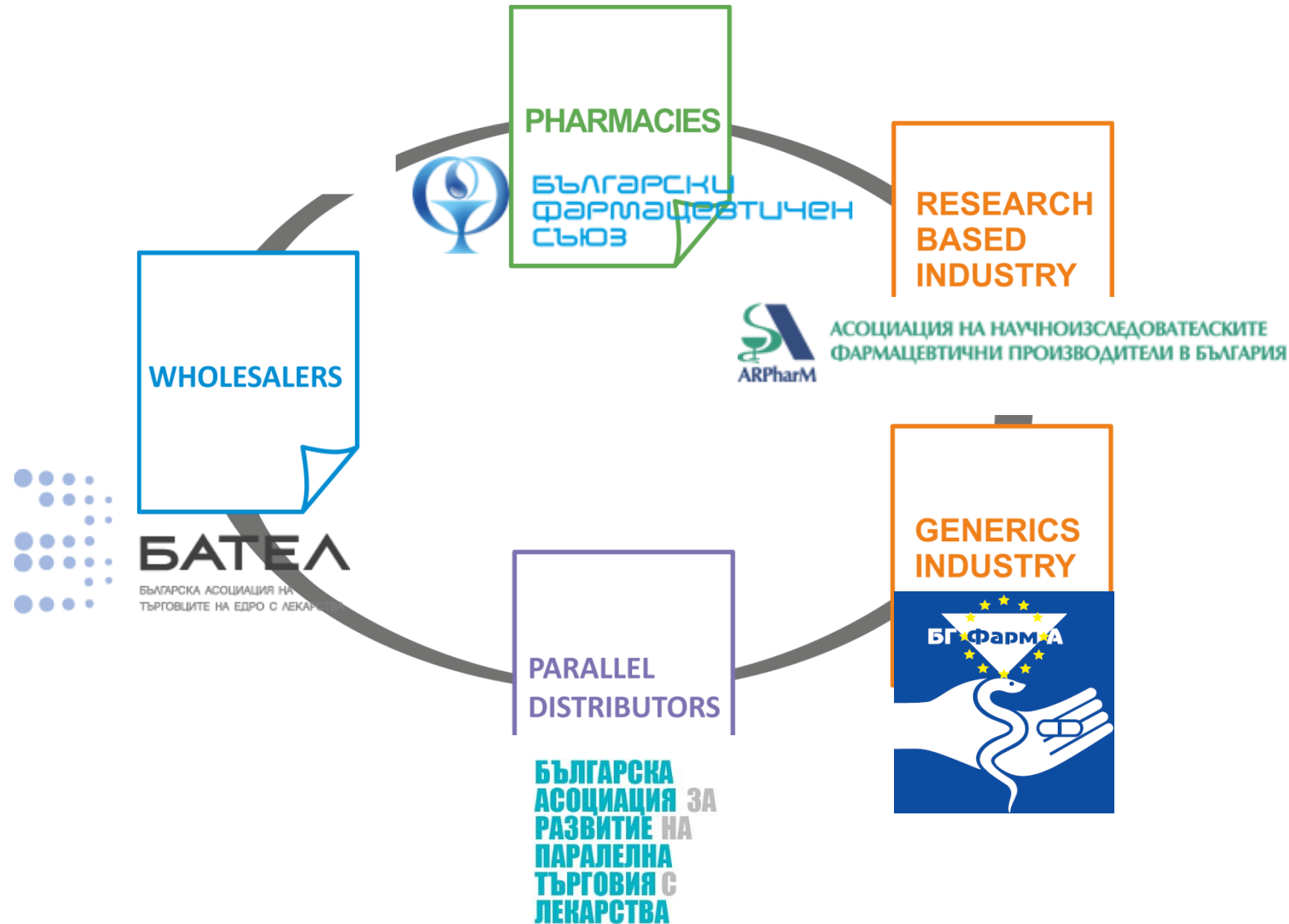
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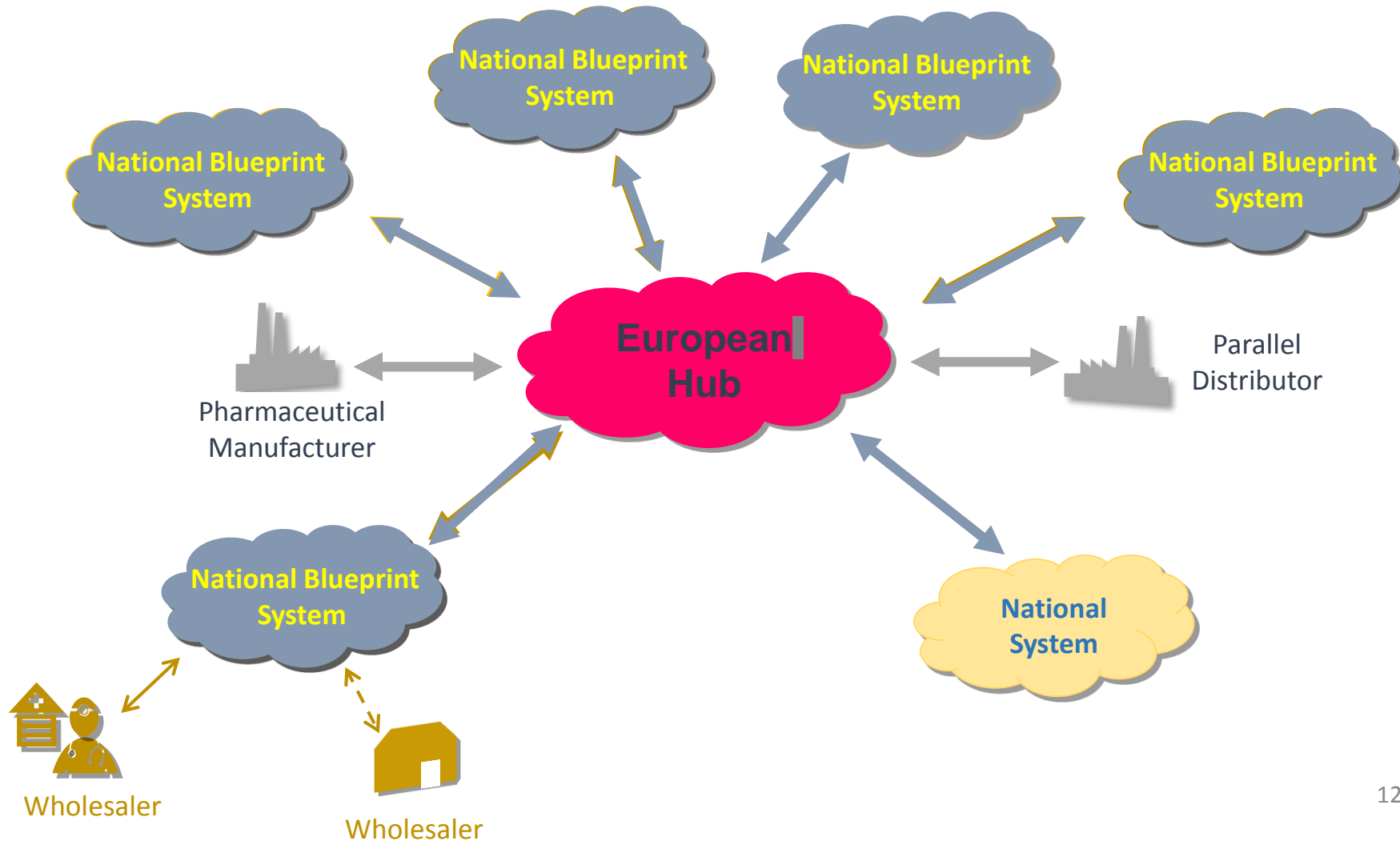
# EMVO constituency members



# BgMVO members match the EMVO constituency members

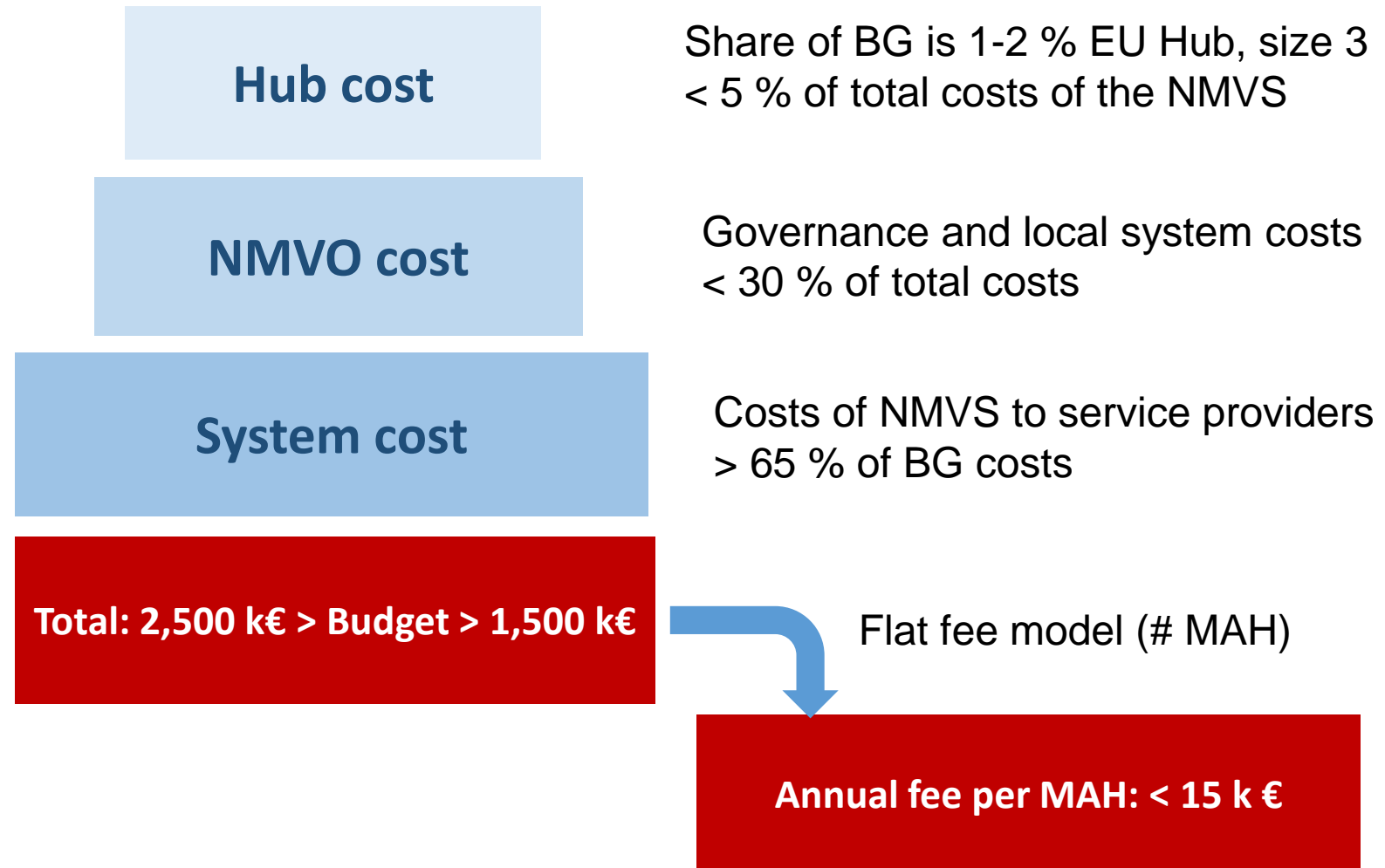


# The blueprint model: a standardised national system with all necessary functionality

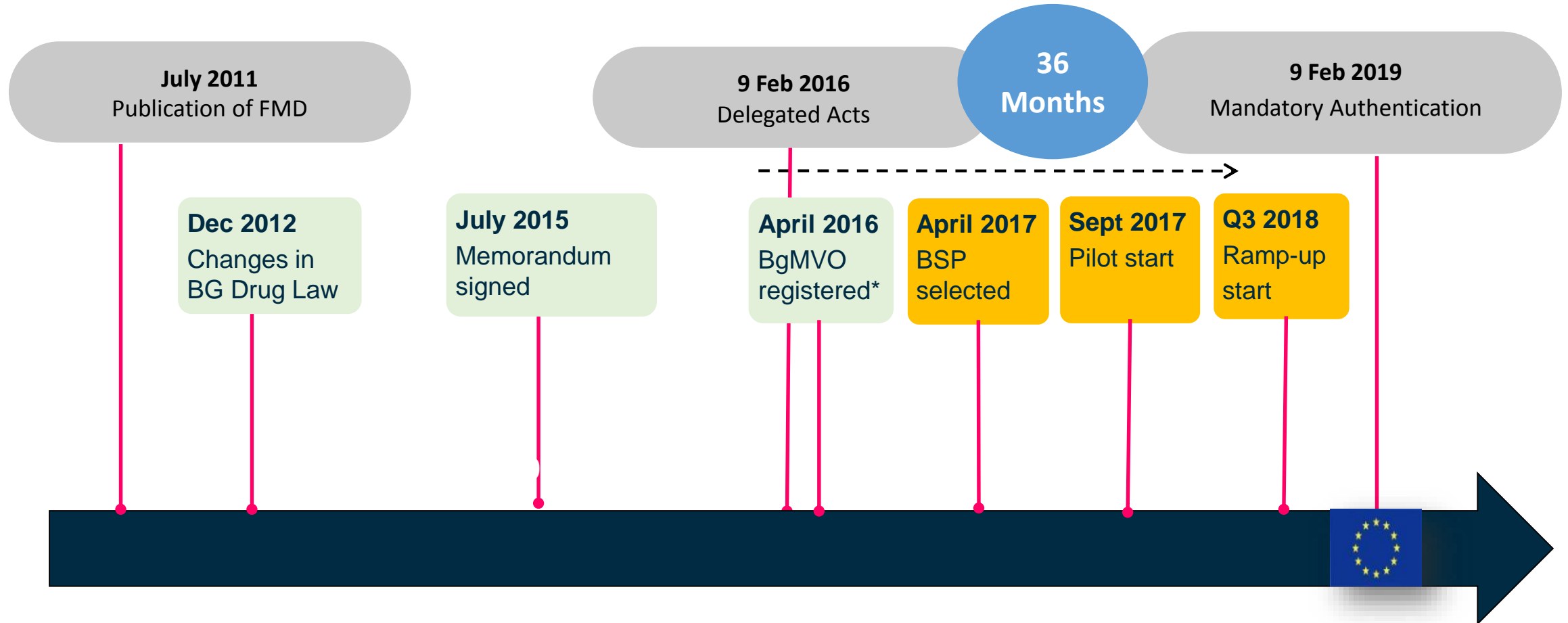




# Flat Fee Model: annual costs for full operation



# Implementation of the FMD in Bulgaria



# Priorities of BgMVO in 2017/2018

- **System:**

- Selection of IT provider Q2/2017
- Cooperation with GS1 Bulgaria about Product Code (GTIN)
- Support to local Onboarding Partners
- Engagement of local IT providers
- Pilot phase in Q4/2017 and Ramp-up in Q3/2018



- **Governance:**

- BgMVO incorporation
- Office organisation
- Funding of the organisation: local contracts; verification fees
- Staff, roles and responsibilities
- QMS and SOPs for the office and for the verification system



- **Communications:**

- Meetings with authorities: implementation of safety features
- Training of pharmacists
- Positive PR campaign to the public in Q4/2018
- Drafts of local legislation in consultations with authorities





BULGARIAN MEDICINES  
VERIFICATION ORGANISATION

**THANK YOU**  
**Q&A**



*Божолудже*