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1993 EFPIA - Executive for Administration and Finance.

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European Medicines  
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European Federation of Pharmaceutical  
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PGEU GPUE

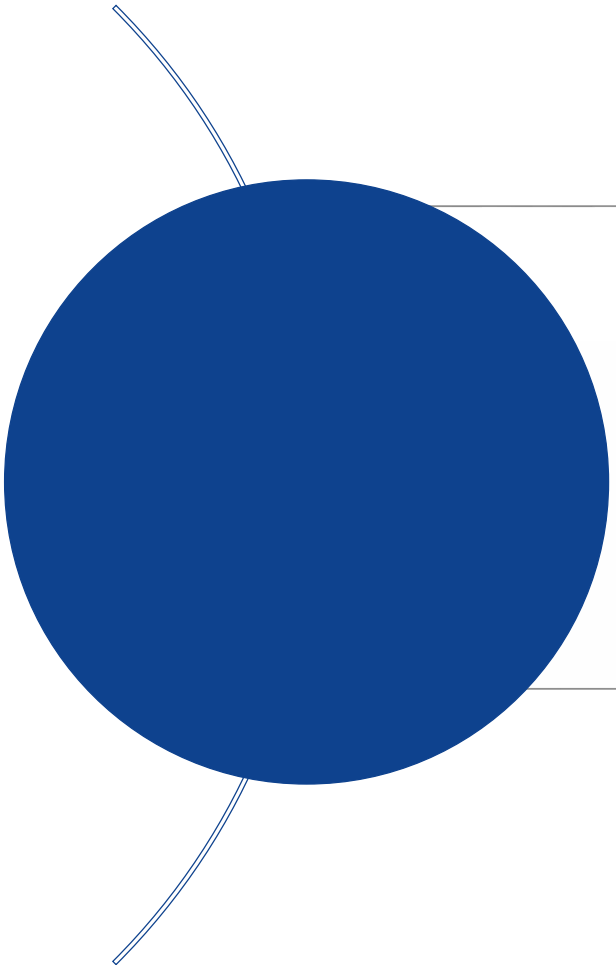


# THE IMPLEMENTATION OF THE EU FALSIFIED MEDICINES DIRECTIVE

36<sup>th</sup> GS1 Global Healthcare Conference  
5<sup>th</sup> November 2019, New Delhi, India

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# INTRODUCTION



European Medicines Verification System (EMVS)/European Medicines Verification Organization (EMVO) & Falsified Medicines Directive (FMD)

# FMD – What is it about? 1/2



## EU Legislation against Falsified Medicines

Directive 2011/62/EU (the FMD)

### 4 Pillars

#### 1. Safety features

Mandatory identification and authentication of individual medicine packs. **Feb 2019**

#### 3. Active substances

Tougher rules on importation of APIs; reinforced controls and inspections of API manufacturers. ✓

#### 2. Reinforcing the distribution chain

Strengthened GDP and requirements for wholesale distributors ✓

#### 4. Internet sales

A common, EU-wide logo to identify legal online pharmacies. ✓



# FMD – What is it about? 2/2

- A 2D data matrix on the side of packages carrying the **Unique Identifier (UI)**
- It allows all those involved across the supply chain to verify the medicine using specifically designed software to scan the data matrix to check its authenticity
- The **tamper verification feature** also provides a physical barrier against falsified medicines
- Before dispensing the medicines to a patient, the UI will be **verified and then decommissioned** from the EMVS



# Who we are: EMVO

- 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 EU Hub
  - Connect countries to the EU 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**



# Who we are:

## European Medicines Verification System (EMVS)

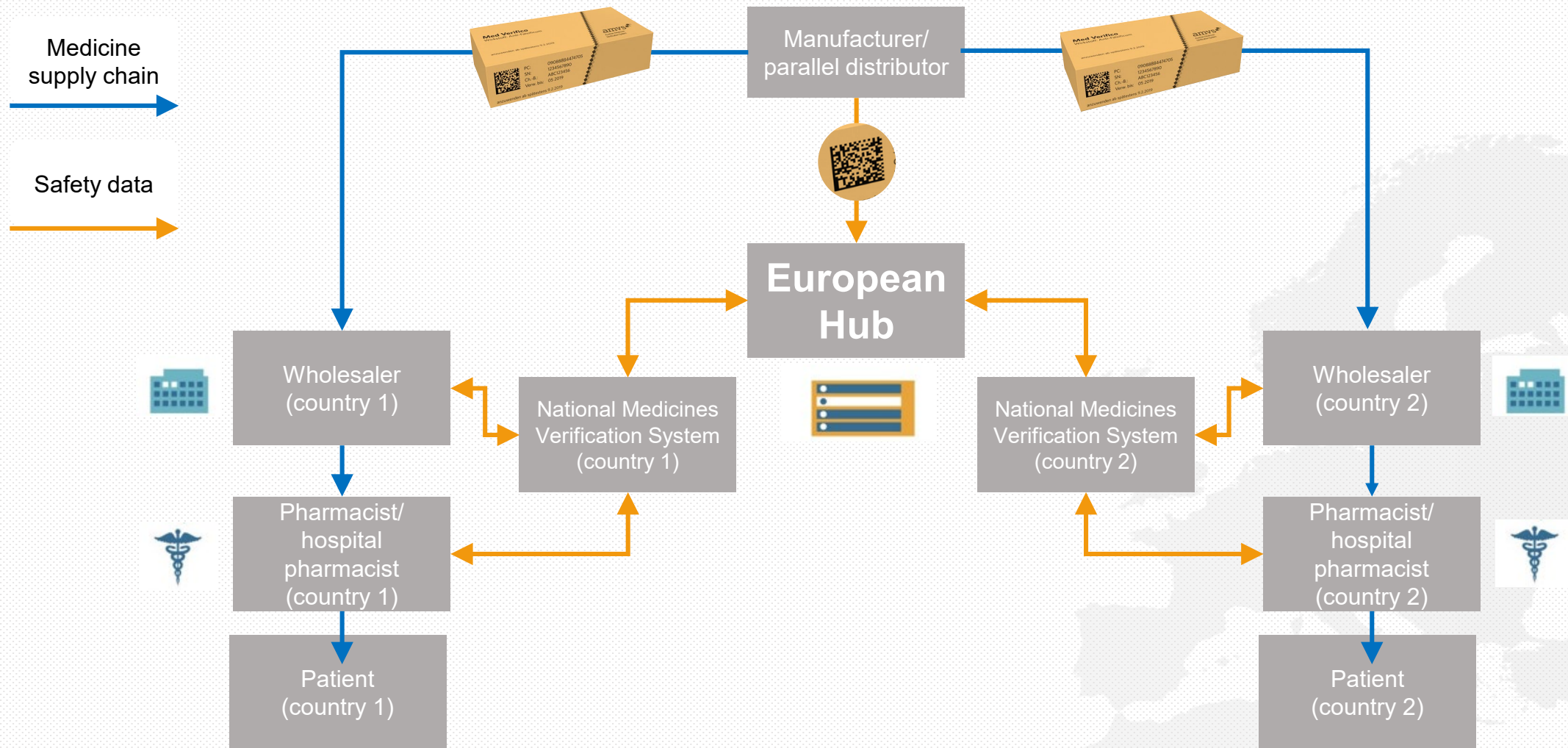
EMVO is responsible for the EU Hub, which stores and transmits product data to the relevant national systems

National Medicines Verification Organisations (NMVOs) run national repositories (covering the EU and EEA)

Together these are the EMVS

- The system carries the baton on from the Falsified Medicines Directive (FMD) and the Delegated Regulation
- The EMVS Operational Phase is the culmination of several years' work
- The main purpose of the European Hub is to serve as the principle place for storage of master data and as a gateway for the transmission of manufacturer data to the national systems

# How the system works





# What EMVO and the NMVOs have achieved



Established a PoD system which enables supply chain actors to comply with the FMD and Delegated Regulation



The EMVS (Hub + NMVSs) is functioning and detects falsified medicines



30\* EEA countries connected



# AGENDA

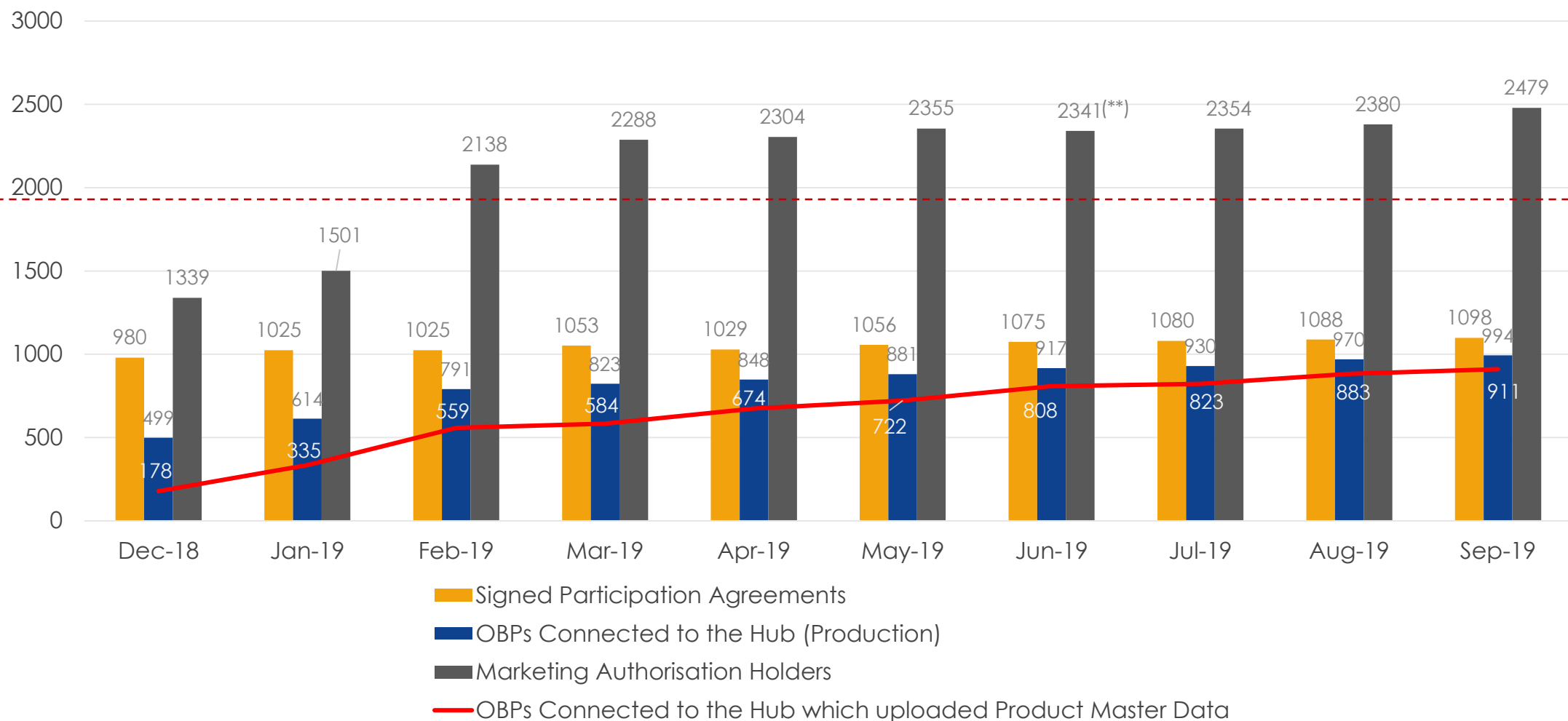


# STATUS OBP/MAH ON-BOARDING(\*)

(\*)The information figuring hereunder was collected in Calendar Week 40 and will be updated on a monthly basis

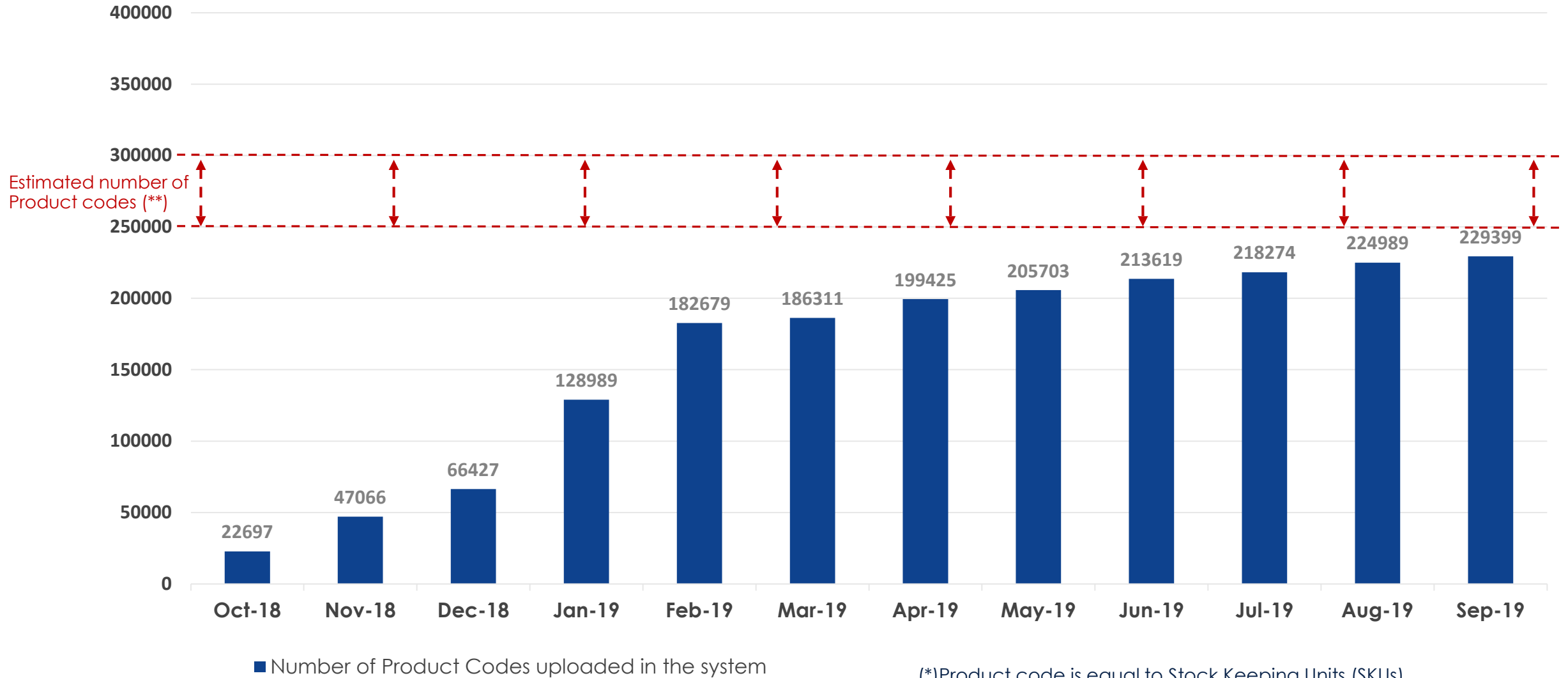
1.600

Estimated number of OBPs



(\*\*) The figure reflecting the number of MAHs listed in the OBP Portal has decreased between May and June as a quality check analysis has been performed on the reporting tools and the duplicate MAHs have been deleted.

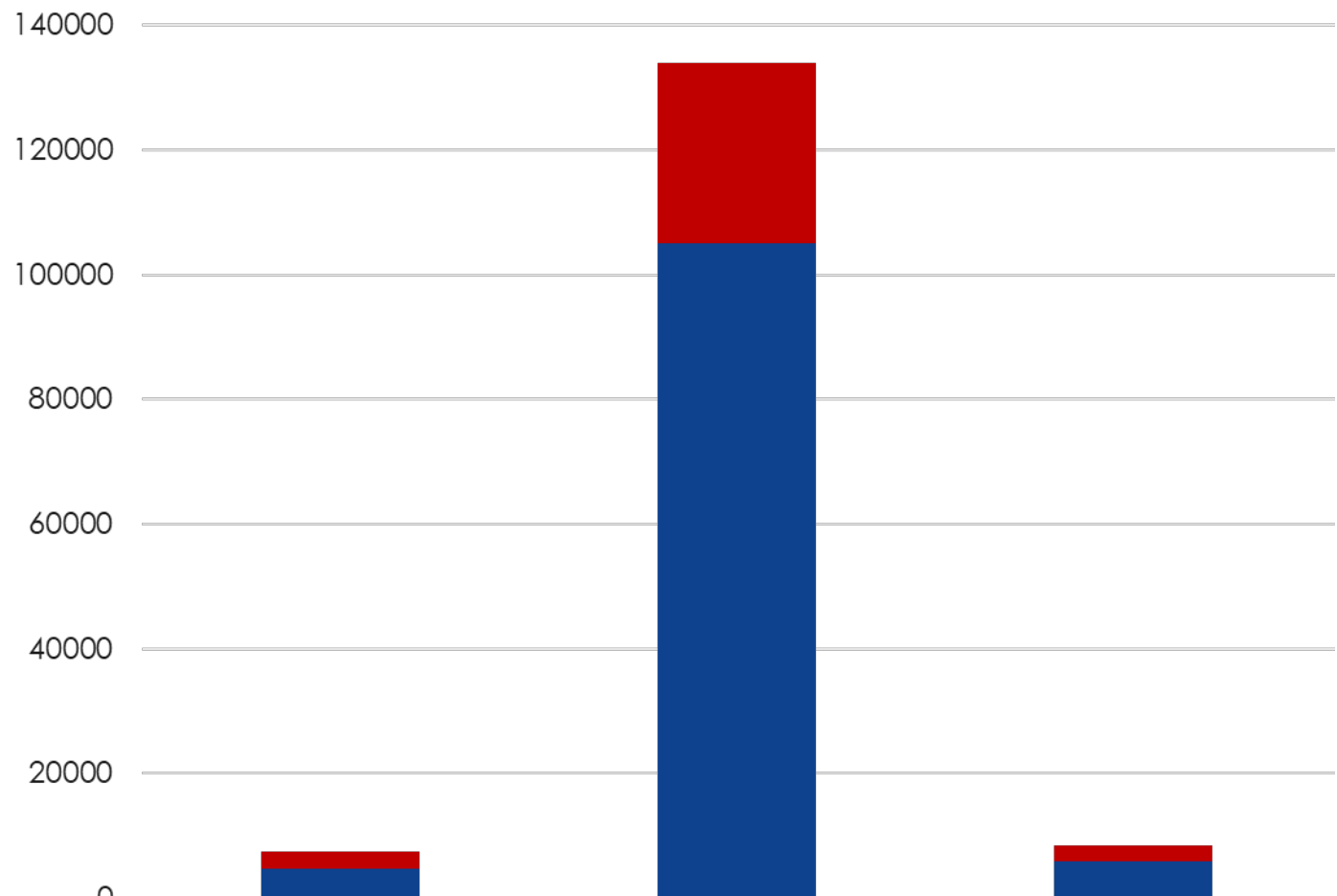
# UPLOADED PRODUCT CODES(\*)



(\*) Product code is equal to Stock Keeping Units (SKUs)

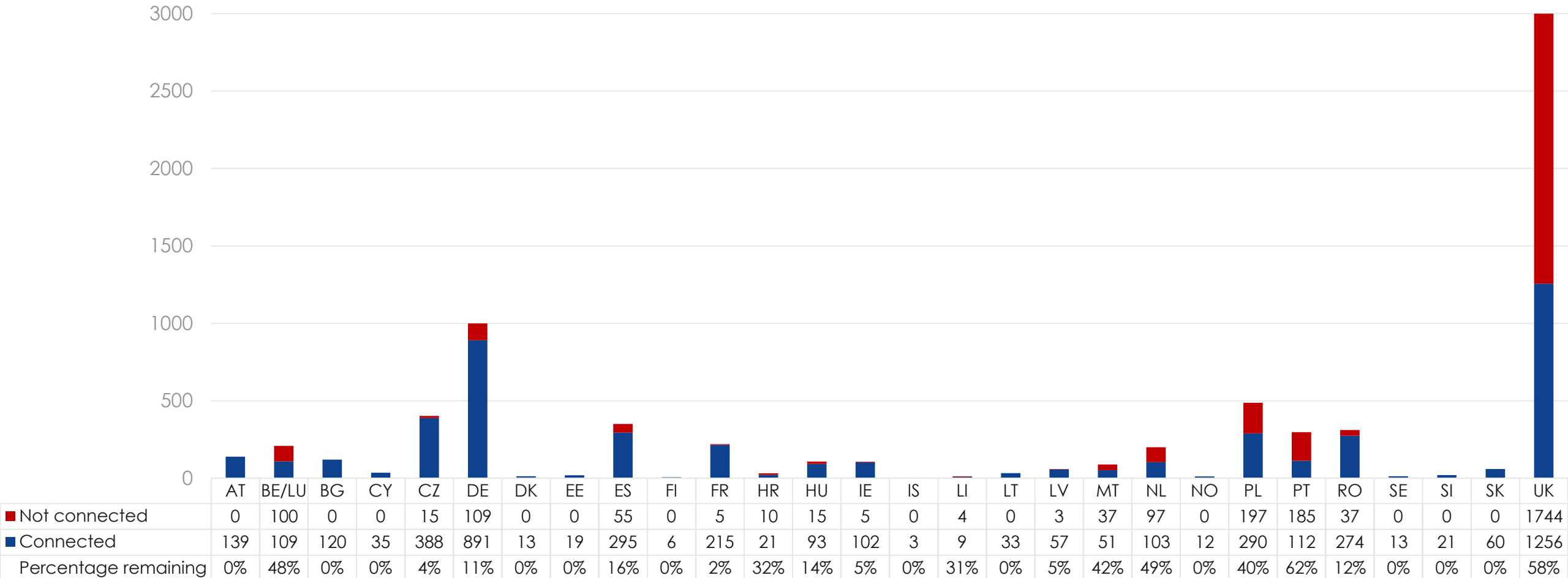
(\*\*) Please note that the reported base value is only a rough estimation and is subject to continuous change. EMVO does not warrant that this information is error-free, accurate, complete and up-to-date.

# END-USERS CONNECTION OVERVIEW(\*)



	Wholesalers	Pharmacies	Healthcare Institutions
■ Not connected	2618	28938	2469
■ Connected	4740	105023	5877
Percentage remaining	35,58%	21,60%	29,58%

# WHOLESALERS CONNECTION BY COUNTRY(\*)



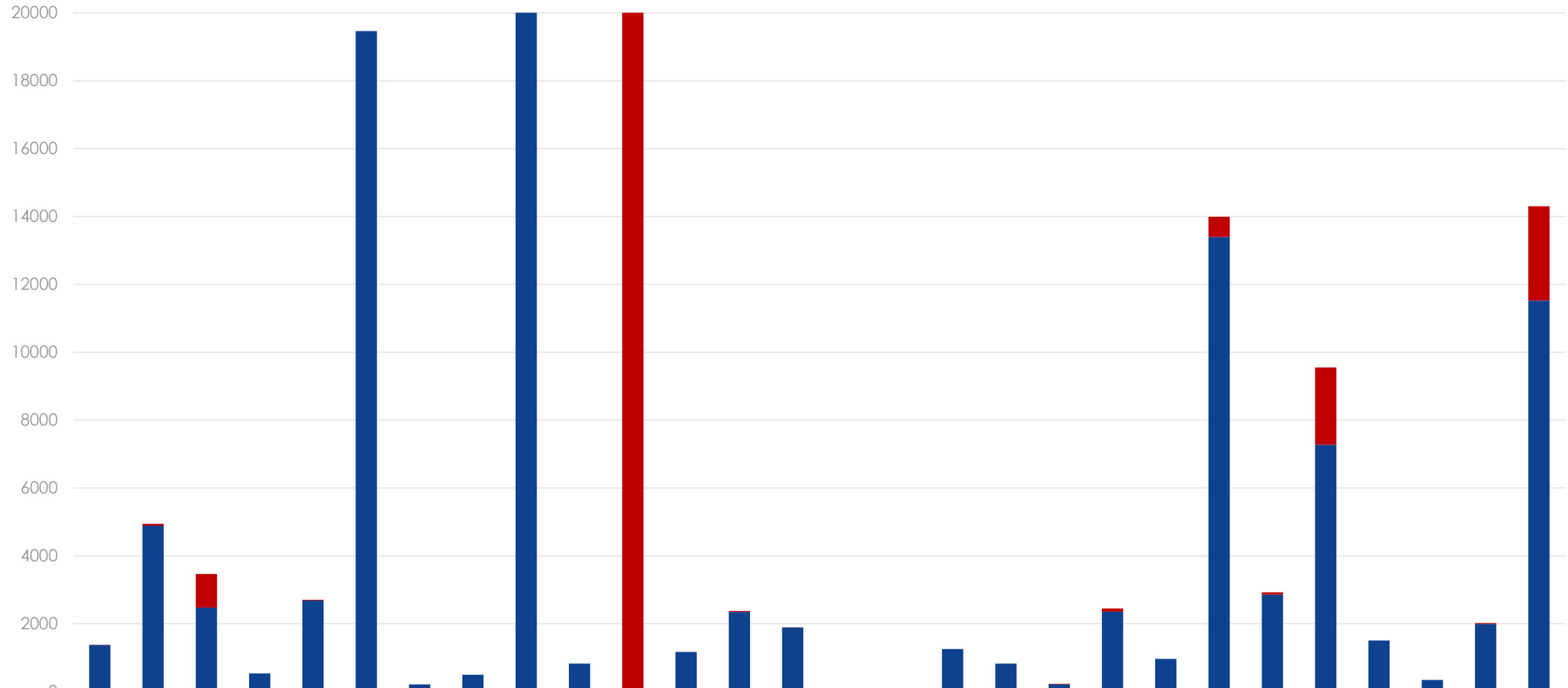
Country	AT	BE/LU	BG	CY	CZ	DE	DK	EE	ES	FI	FR	HR	HU	IE	IS		LT	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK
(1)	392	312	230	105	736	1944	206	62	705	95	708	102	150	405	16		113	84	108	410	180	534	411	222	259	85	160	2126
(2)						3672																		432				

(1) Number of Wholesale distribution authorisations (EudraGMDP)

(2) GIRP estimate

(\*)The information figuring hereunder was collected in Calendar Week 40 and will be updated on a monthly basis

# PHARMACIES CONNECTION BY COUNTRY CAP 20000(\*)



■ Not connected	1	50	986	0	19	0	0	0	0	22000	0	25	6	0	0	0	0	13	98	0	594	65	2281	0	0	23	2777	
■ Connected	1374	4892	2474	533	2687	19463	210	495	22091	821	0	1165	2350	1883	98	5	1250	822	217	2352	960	13396	2857	7270	1500	341	1994	11523
Percentage remaining	0.07%	1.01%	28.50%	0.00%	0.70%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00	0.00%	1.05%	0.32%	0.00%	0.00%	0.00%	5.65%	4.00%	0.00%	4.25%	2.22%	23.88%	0.00%	0.00%	1.14%	19.42%	

04-06/11/2019

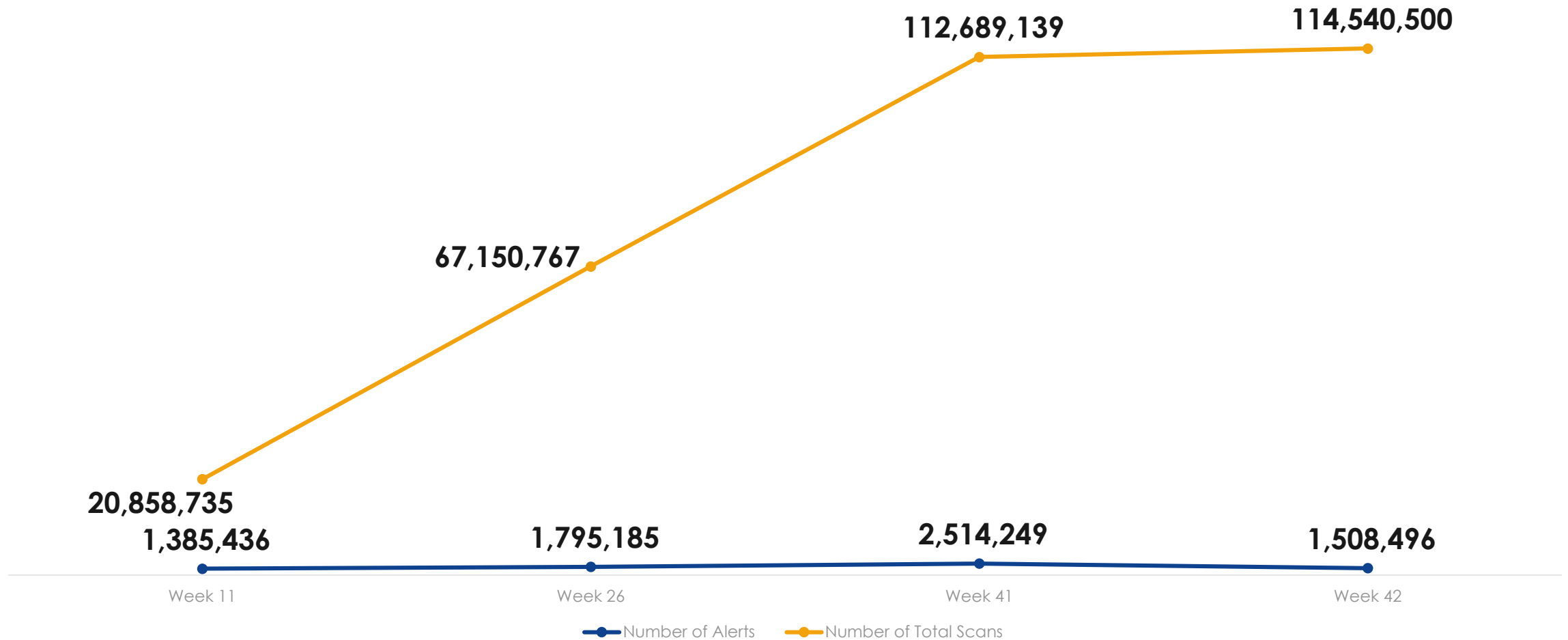
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# AGENDA





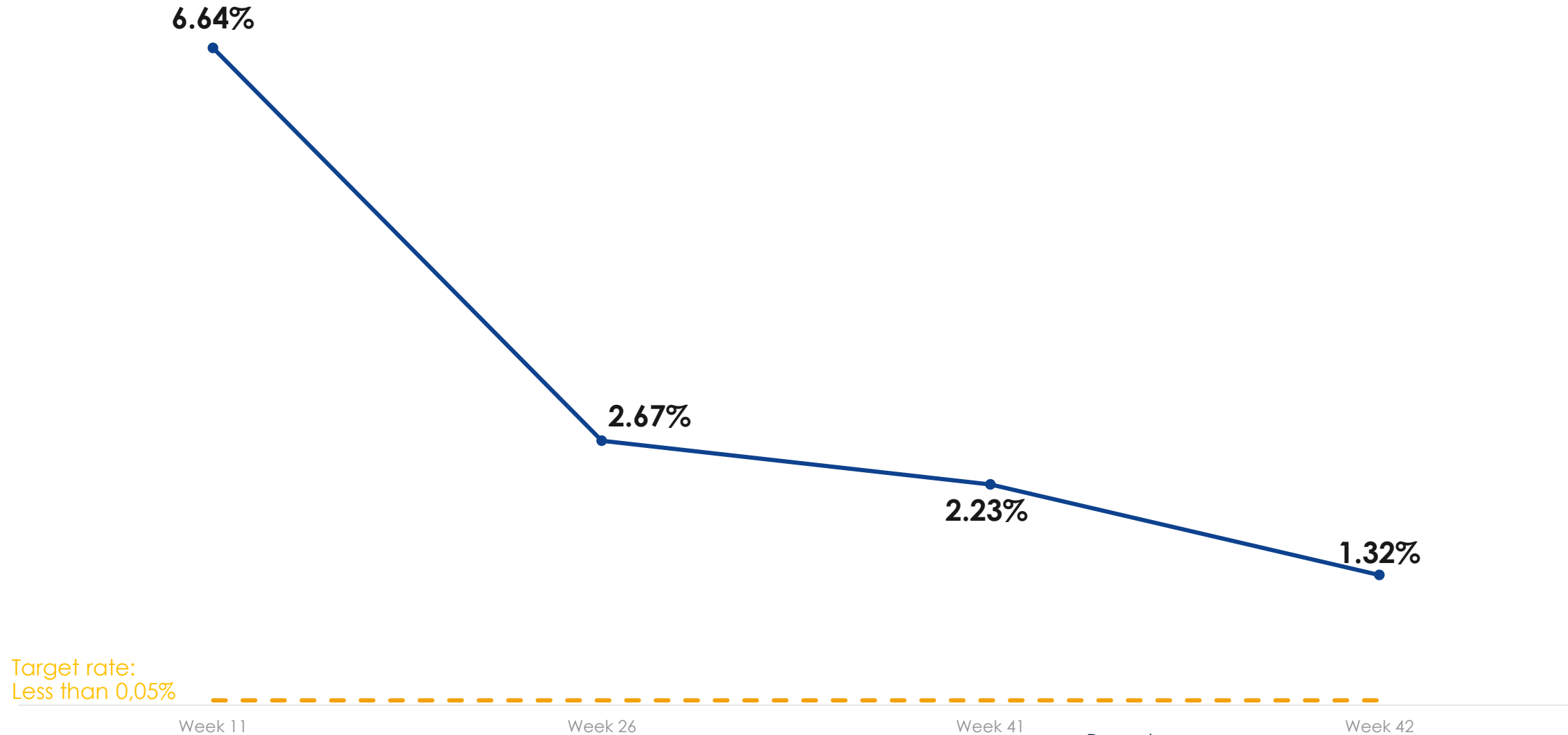
# OVERVIEW OF ALERTS AND SCANS IN ALL COUNTRIES



## Remarks:

- This graph does not reflect the data for the Netherlands in week 26 as no data were communicated at the time.

# TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS IN ALL COUNTRIES



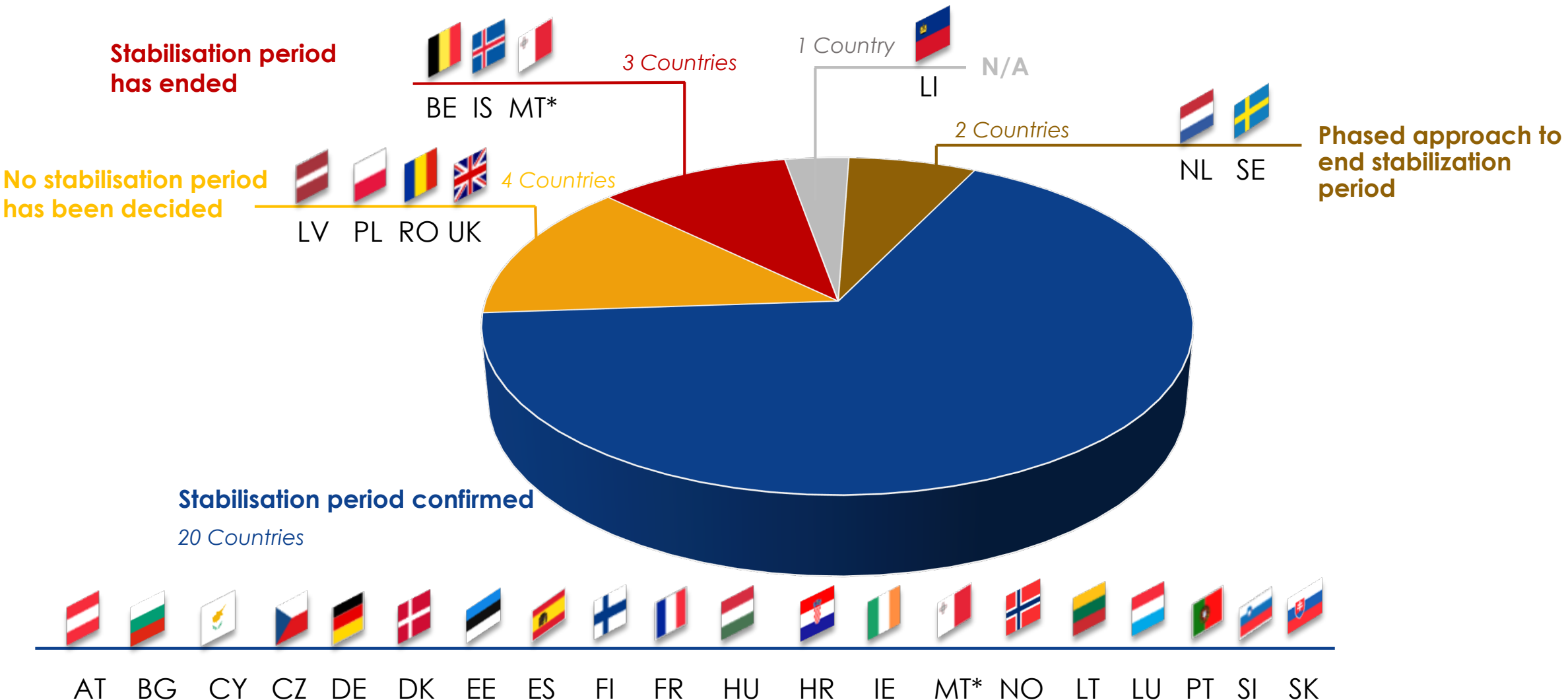
Remarks:

- This graph does not reflect the data for the Netherlands in week 26 as no data were communicated at the time.

# AGENDA



# STABILISATION PERIODS OVERVIEW



\* In Malta the stabilisation period has ended for wholesalers (9<sup>th</sup> August 2019) but has been extended for pharmacies (until the 8<sup>th</sup> February 2020)

Note : stabilisation period only applies to packs released before 9<sup>th</sup> February 2019 for DK, FI, DE, and PL

# (NO DEAL) BREXIT PLANNING



- EMVO has discussed with SecurMed the scenario of EMVO taking a copy of the necessary data from the UK NMVS when SecurMed can no longer finance it in order to use them in a new “proxy” system.
- There is a working understanding about the data that would need to be transferred & about how this might be achieved without any contractual contravention.
- EMVO are working with Arvato to set up this proxy system.
- Regardless of the “progress” in UK parliament, unless Brexit is revoked and/or the UK continues to be subject to the FMD, the issues at hand need to be addressed either now or at the end of 2020.

# AGENDA



Readiness of the EU supply chain stakeholders

Development of alerts and root causes

Stabilisation periods in the EU

Call for a stepwise/phased approach to enforcement

# CONCLUSION (1/2)

- The Hub and the National Systems need to be stabilised
- The system can only work if all actors are connected to it
- Some manufacturers are connected but not uploading the corresponding data
- End-User issues are still present- improper scanning use, not scanning serialised packs, uncompliant End-User software etc.

# CONCLUSION (2/2)

- Until the end of 'stabilisation periods', products triggering 'false' alerts should still be dispensed.
- Without a connection of all supply chain actors using the system, there is a significant risk that alert levels remain high.
- EMVO/NMVOs can provide data to establish a risk map of the supply chain and focus enforcement efforts. EMVO stakeholders continue to believe in the power of 'traditional' on-site inspections to enforce compliance on supply chain actors.
- **In consequence, EMVO would like to encourage NCAs to start enforcing the primary requirements of the FMD and DR.**



# Q&A



04-06/11/2019

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