

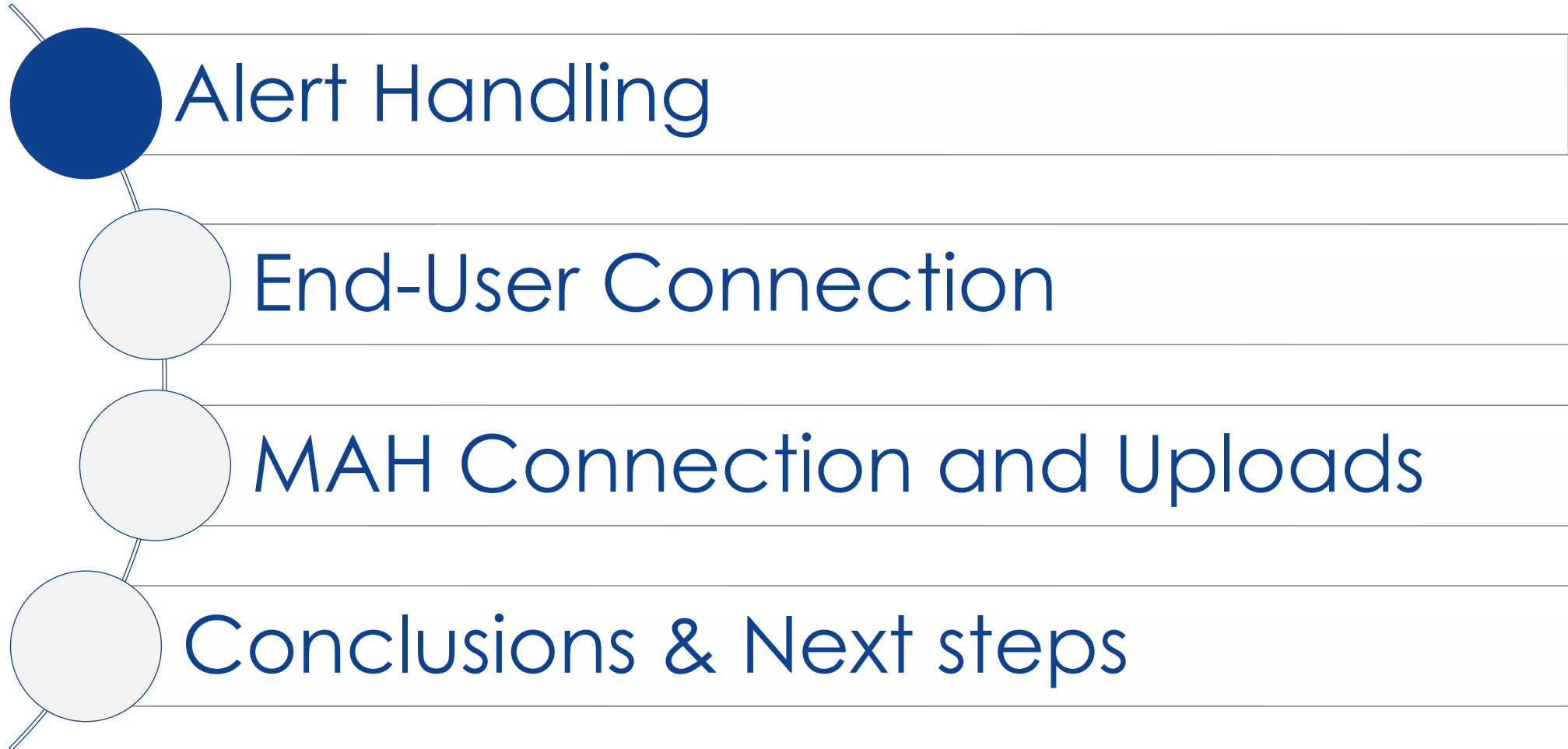


STATUS OF THE IMPLEMENTATION OF THE FMD

Fanny Trenteseaux

Project & Partner Manager
European Medicines Verification
Organisation

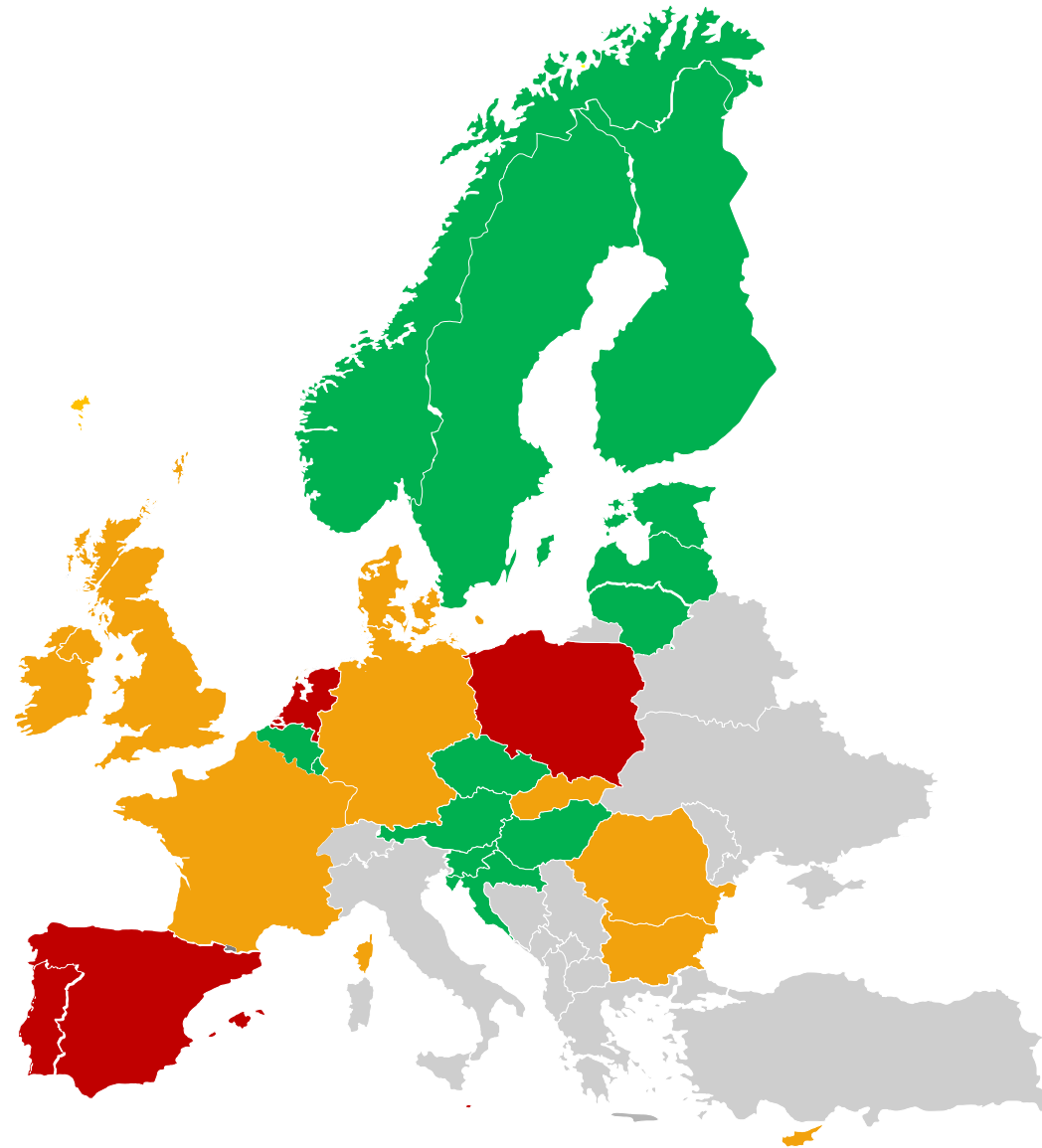
AGENDA



ALERT RATE



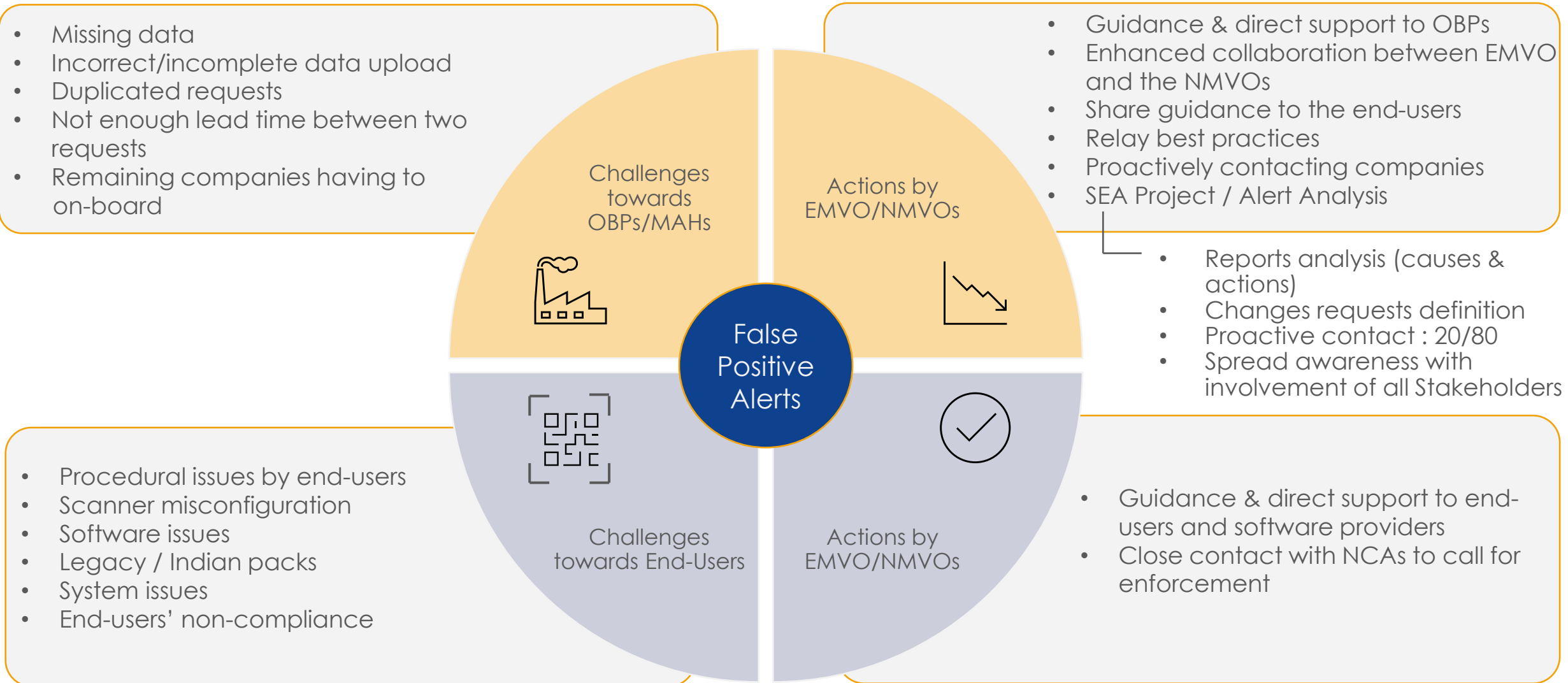
Note: the objective for the EMVS countries is to reach an alert rate of less than 0,05%



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SYMPOSIUM - FMD IMPLEMENTATION STATUS

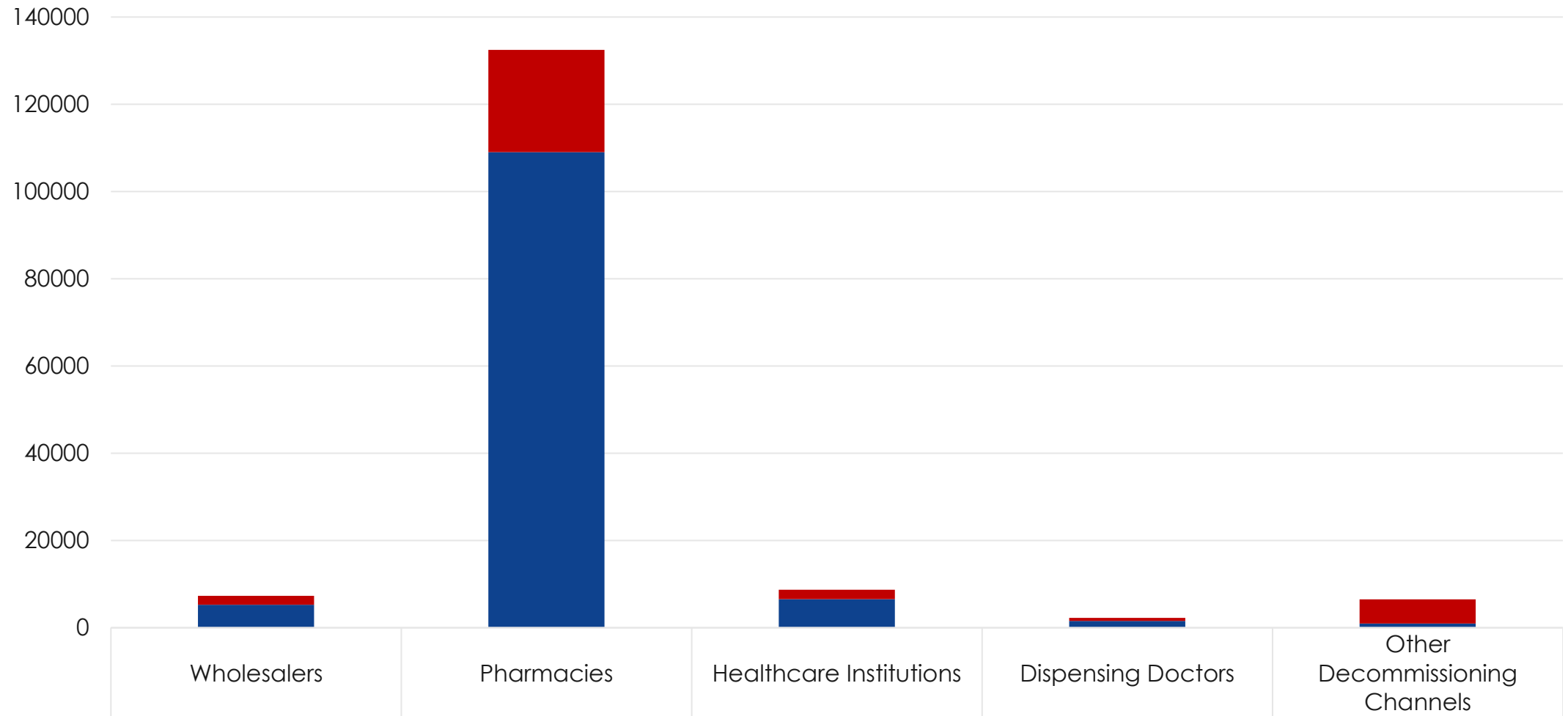
REDUCTION OF ALERTS



AGENDA



END-USERS NOT CONNECTED

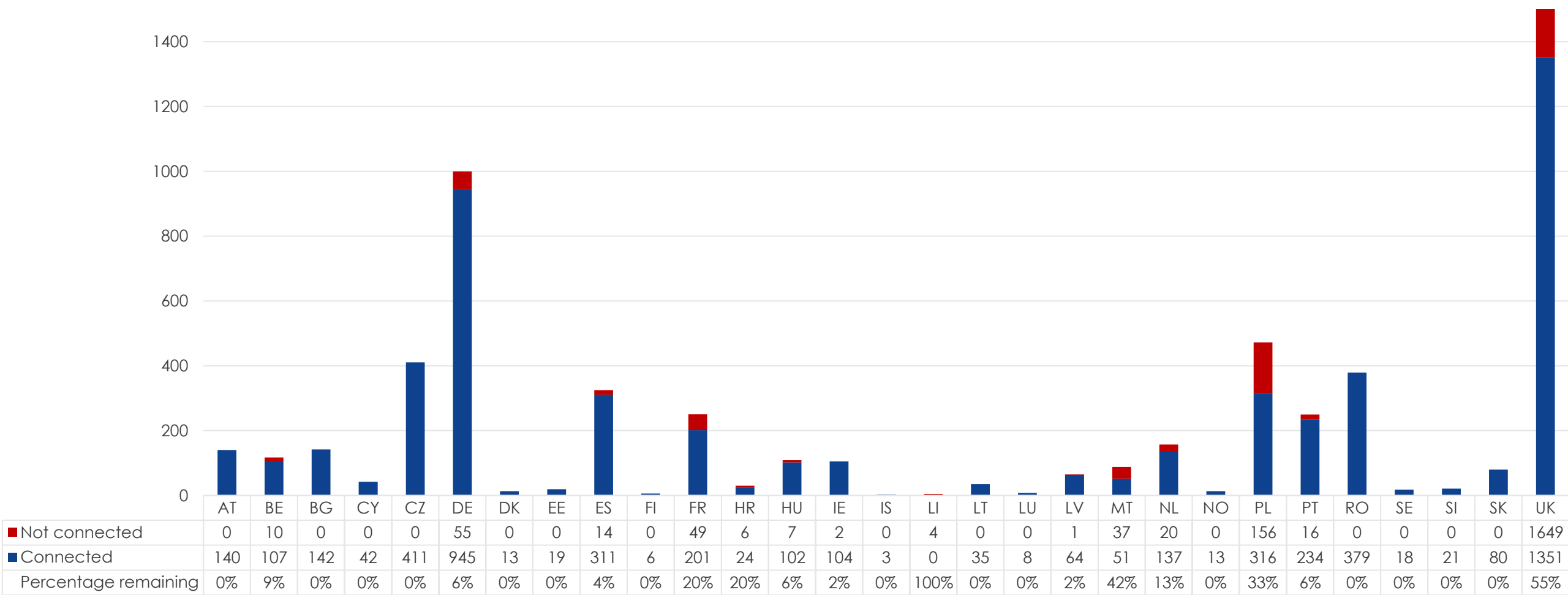


■ Not connected	2026	23430	2172	734	5531
■ Connected	5277	109053	6557	1564	986
Percentage remaining	27,74%	17,69%	24,88%	31,94%	84,87%

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SYMPOSIUM - FMD IMPLEMENTATION STATUS

WHOLESALE CONNECTION BY COUNTRY

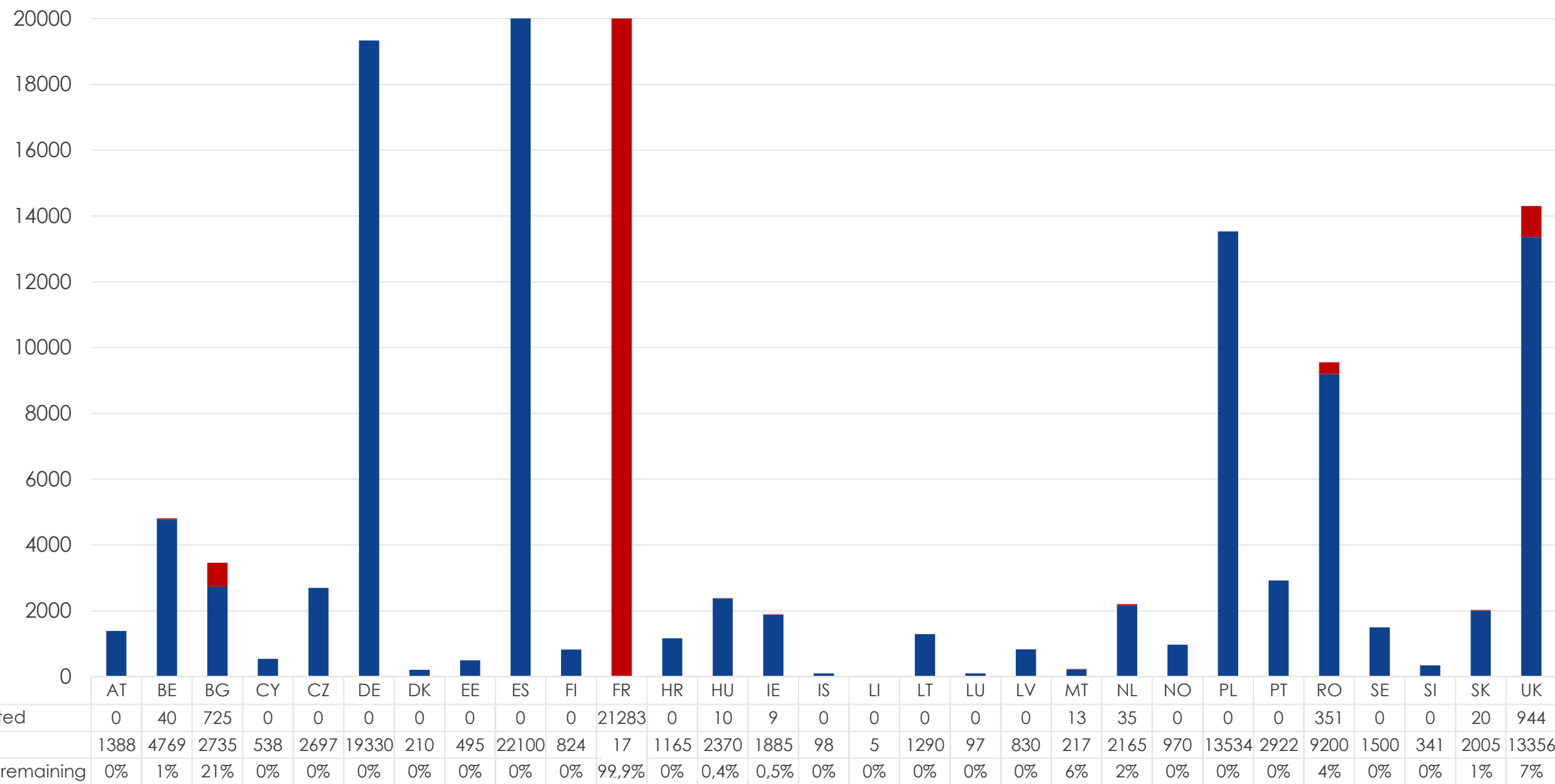


Country	AT	BE/LU	BG	CY	CZ	DE	DK	EE	ES	FI	FR	HR	HU	IE	IS	LI	LT	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK
Number of Wholesale distribution authorisations (EudraGMDP)	416	296	241	100	709	2213	208	53	722	93	722	110	149	422	16	9	121	84	89	416	154	547	399	260	261	86	191	2078

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SYMPOSIUM - FMD IMPLEMENTATION STATUS

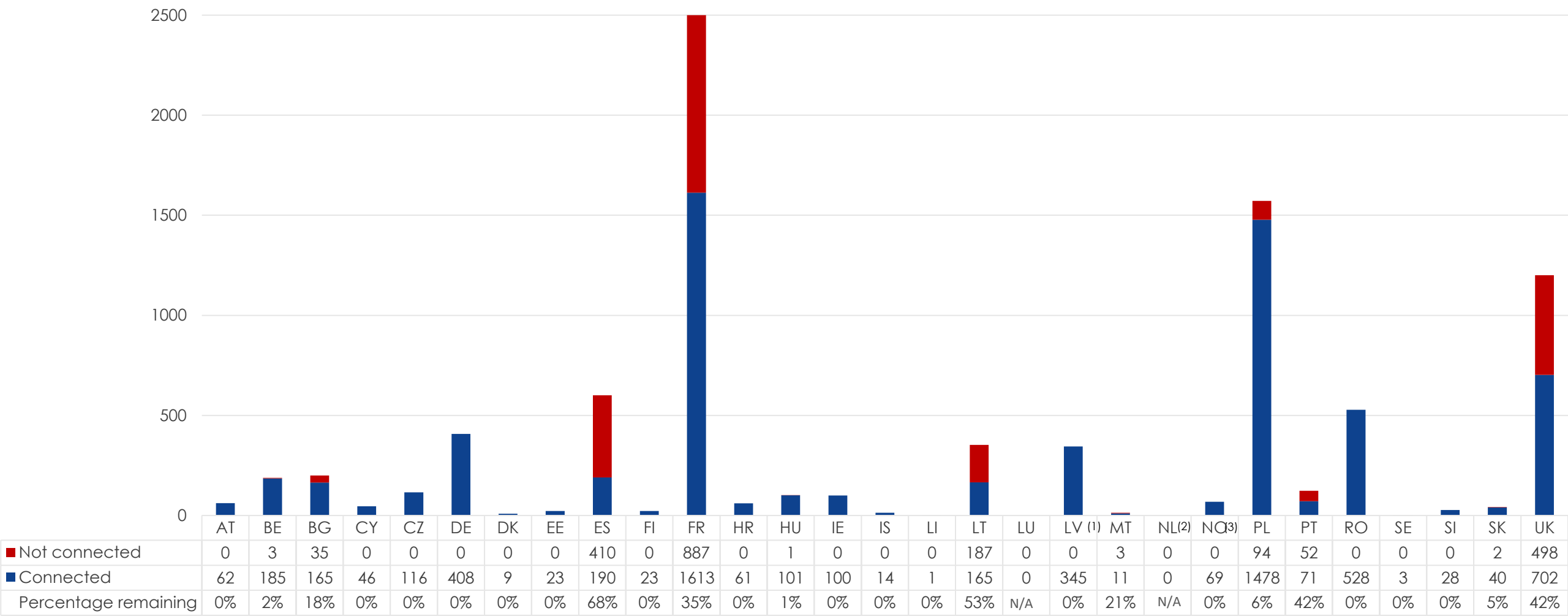
PHARMACIES CONNECTION BY COUNTRY CAP 20.000



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HEALTHCARE INSTITUTIONS CONNECTION BY COUNTRY



(1) As of November, dispensing doctors in Latvia have been added to the healthcare institutions report as legally they all are healthcare institutions.

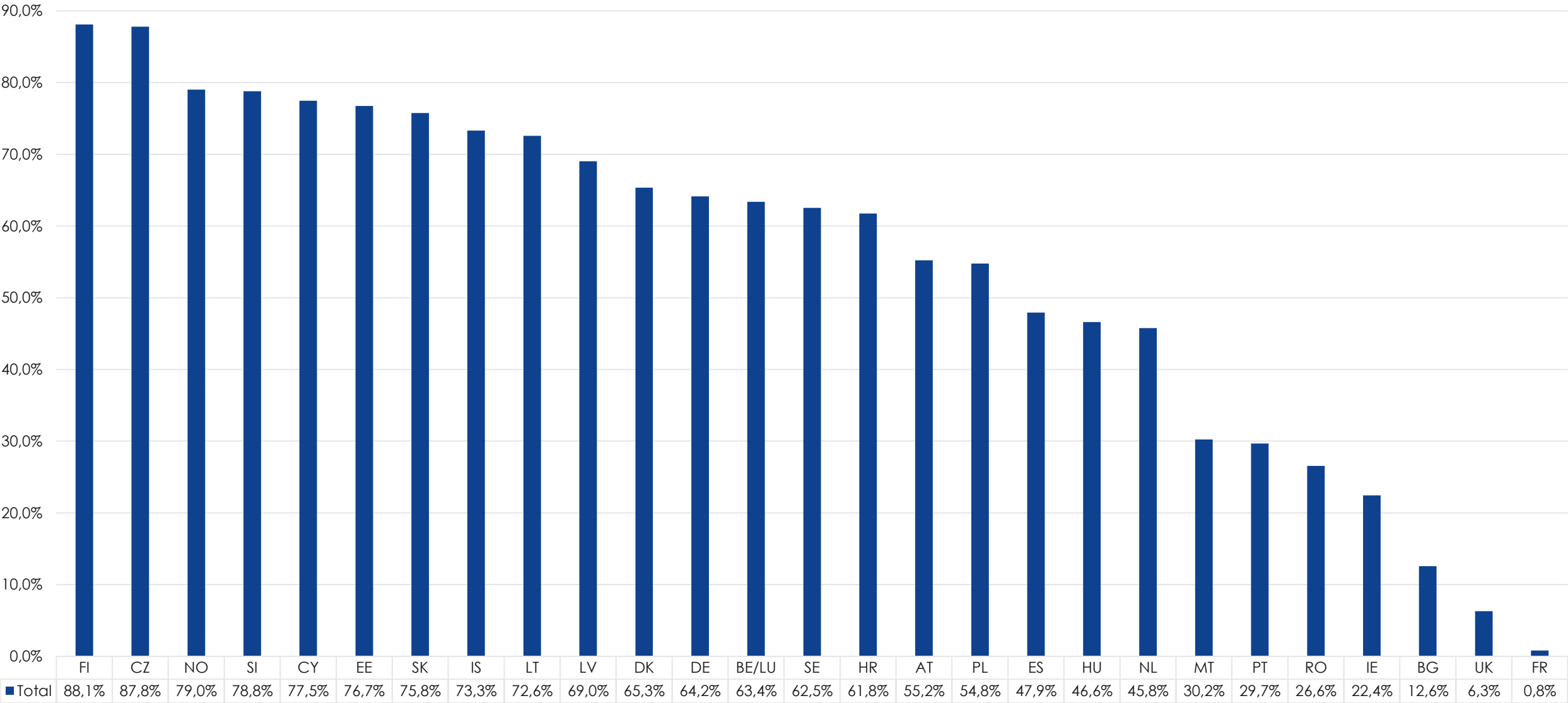
(2) In The Netherlands (NL) healthcare institutions are connected as pharmacies. Therefore, the On-boarding of healthcare institutions in NL is reflected in the overview on pharmacies connection.

(3) In Norway (NO), hospital pharmacies are connected as pharmacies. The overview on healthcare institutions reflect only the number of hospitals that are connected.

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SYMPOSIUM - FMD IMPLEMENTATION STATUS

DECOMMISSION FOR DISPENSE IN RELATION TO THE MARKET SIZE – IN DECLINING ORDER



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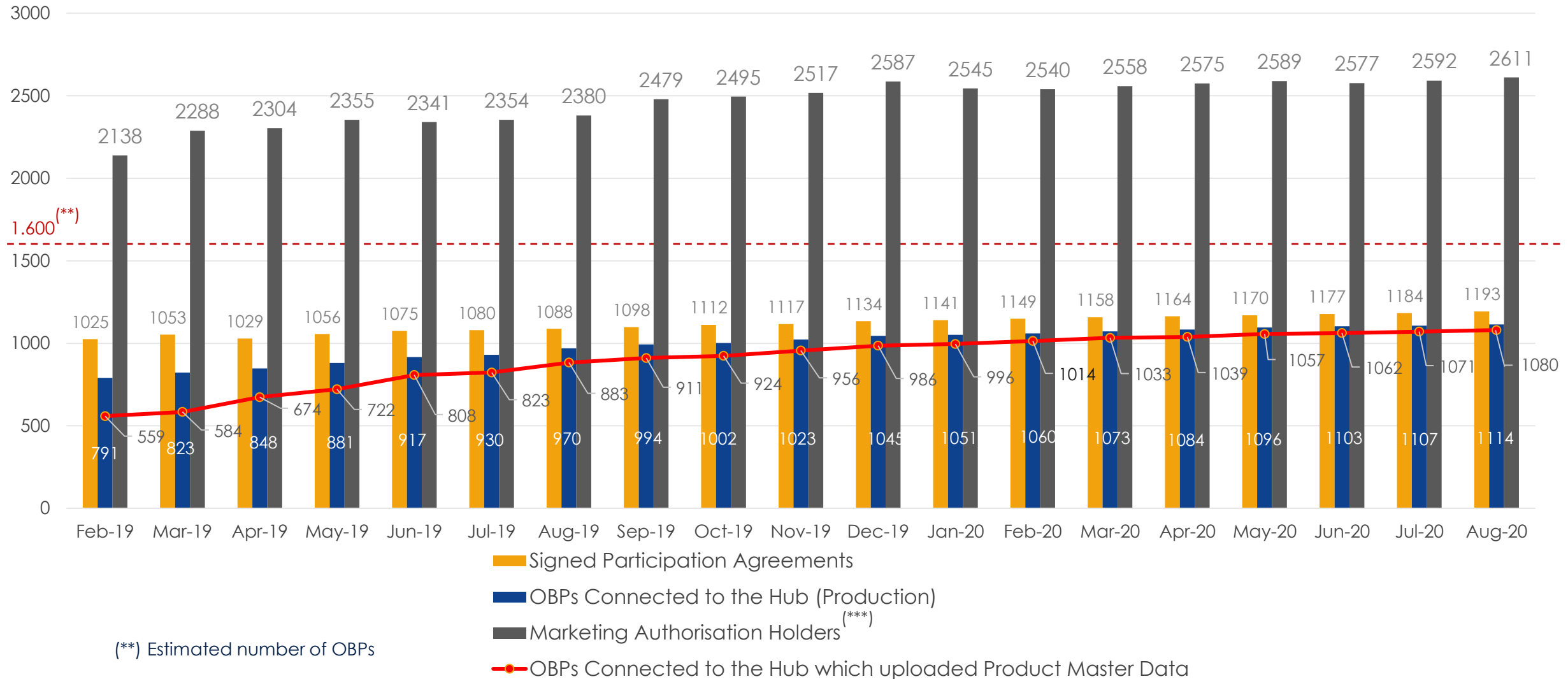
SYMPOSIUM - FMD IMPLEMENTATION STATUS

This overview reflects the number of successful transactions of decommission for dispense per country, in comparison to the average market size per country, for the Q2 2020.

AGENDA



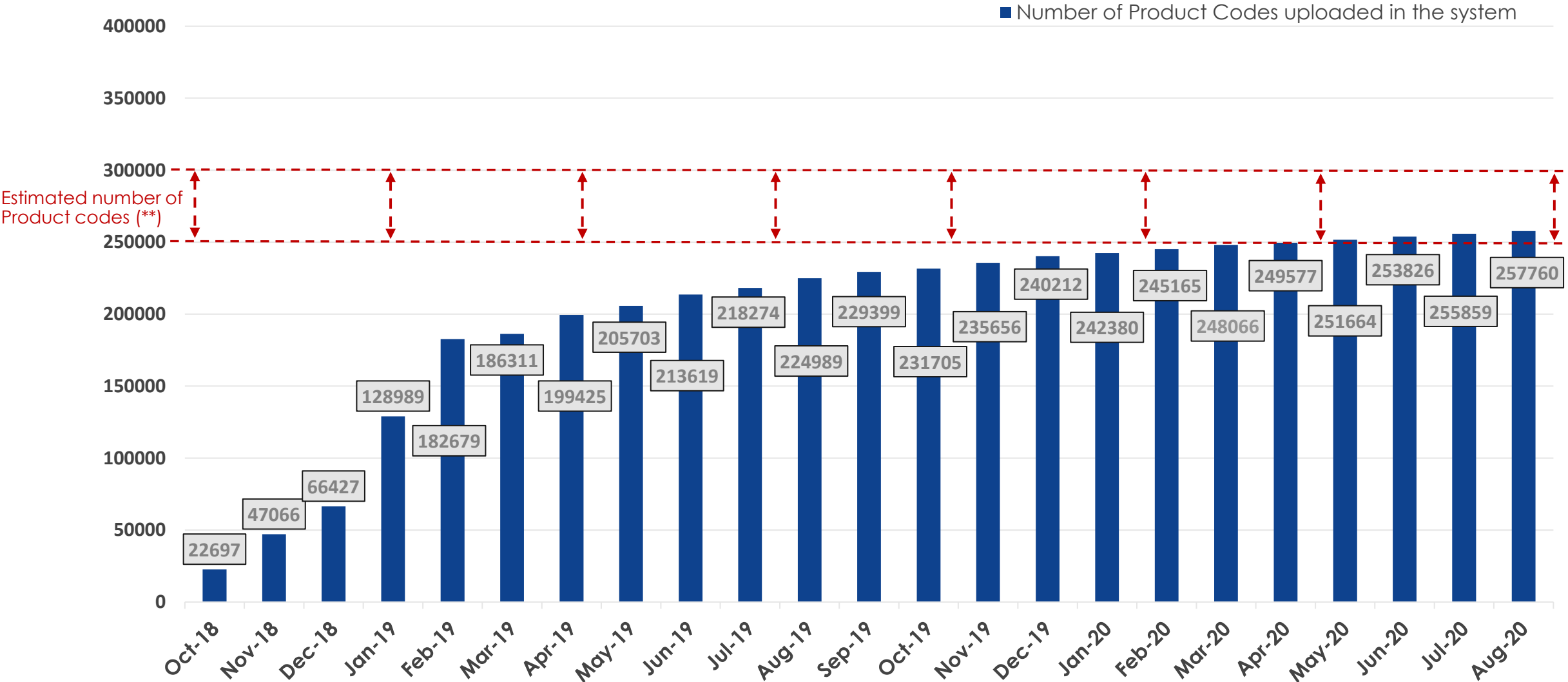
OBP_s NOT CONNECTED



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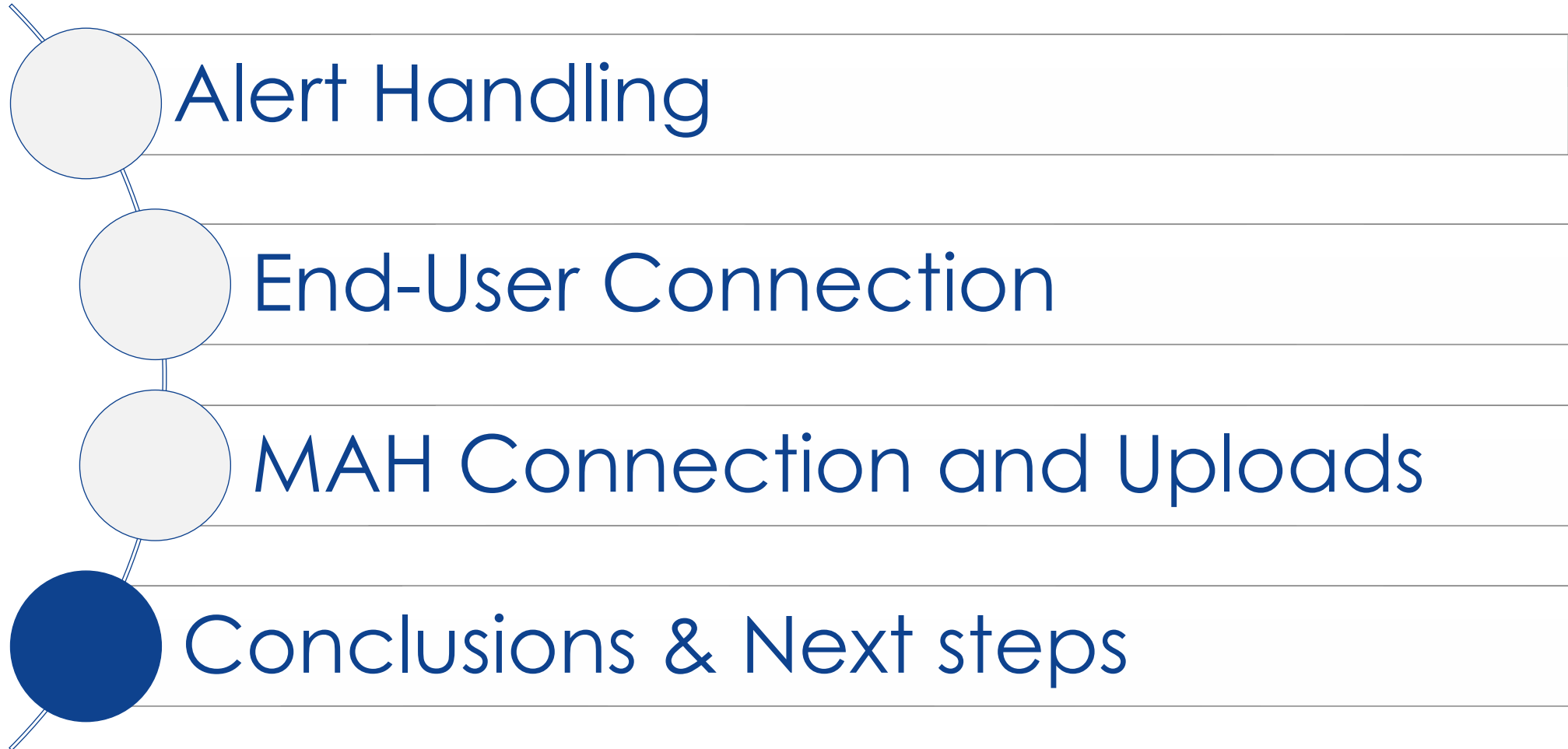
UPLOADED PRODUCT CODES(*)



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

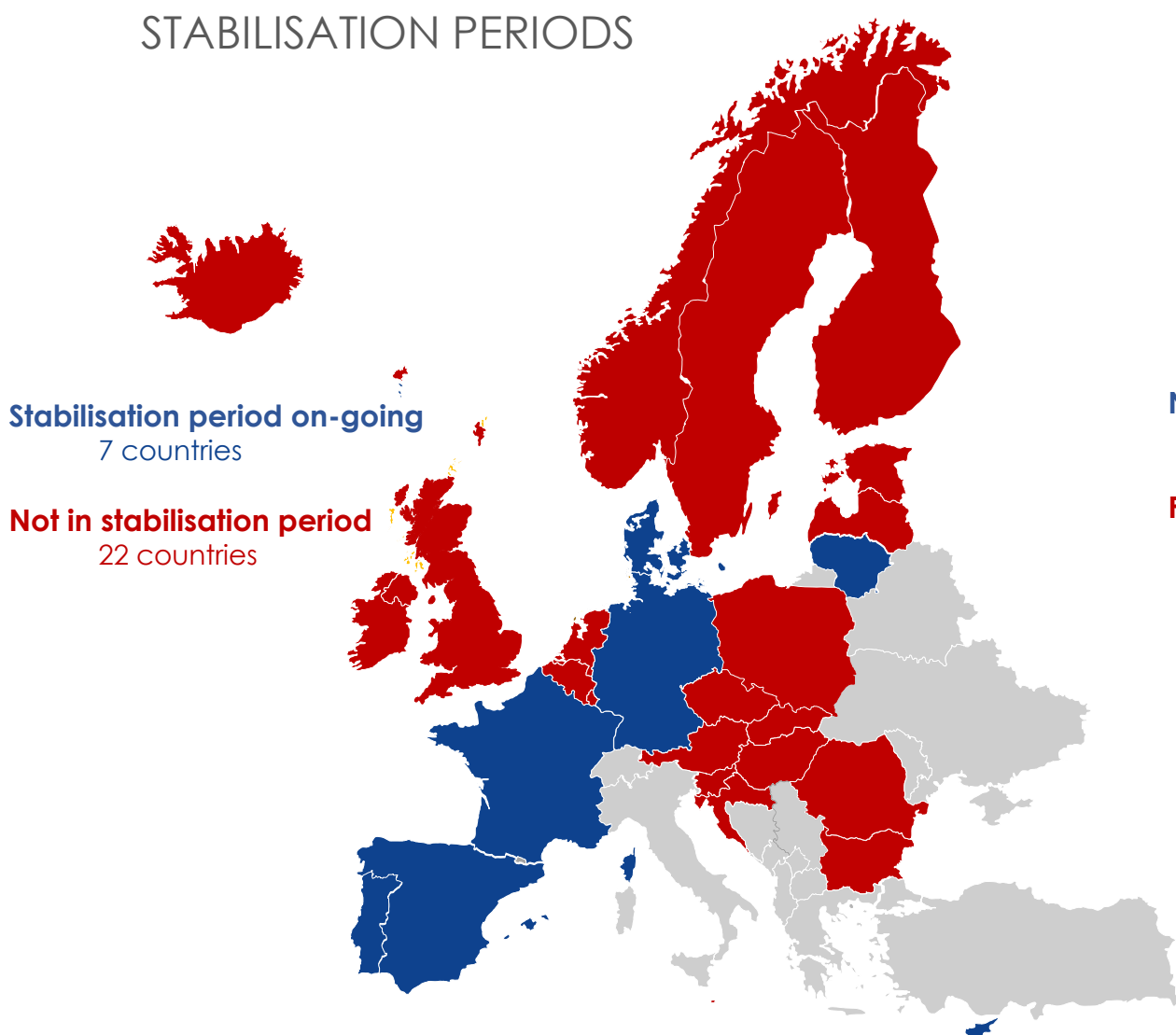
(**) Please note that the reported base value is only a rough estimation and is subject to continuous change. EMVO does not warrant that this information is error-free, accurate, complete and up-to-date.

AGENDA

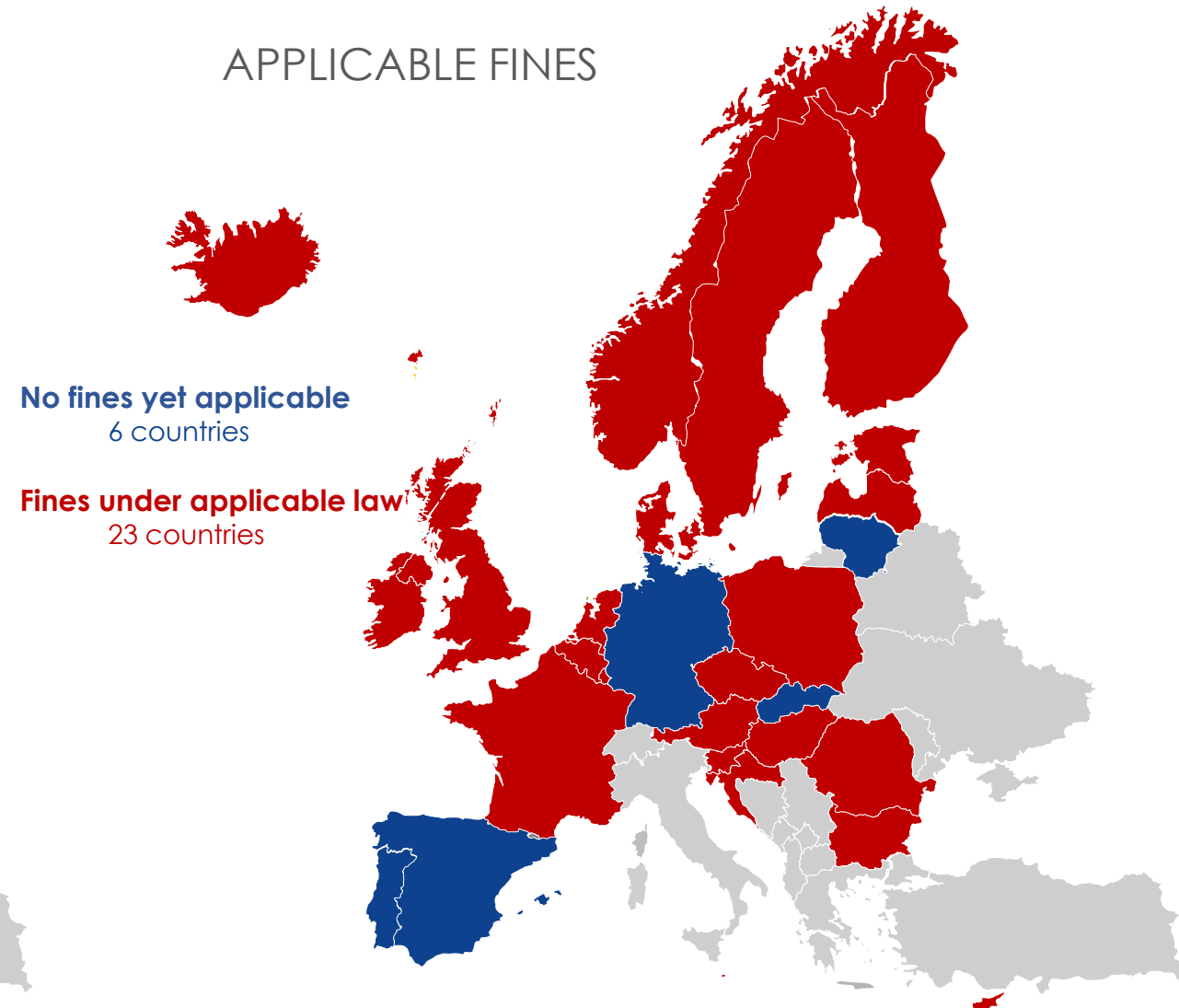


STABILISATION PERIODS & FINES OVERVIEW

STABILISATION PERIODS



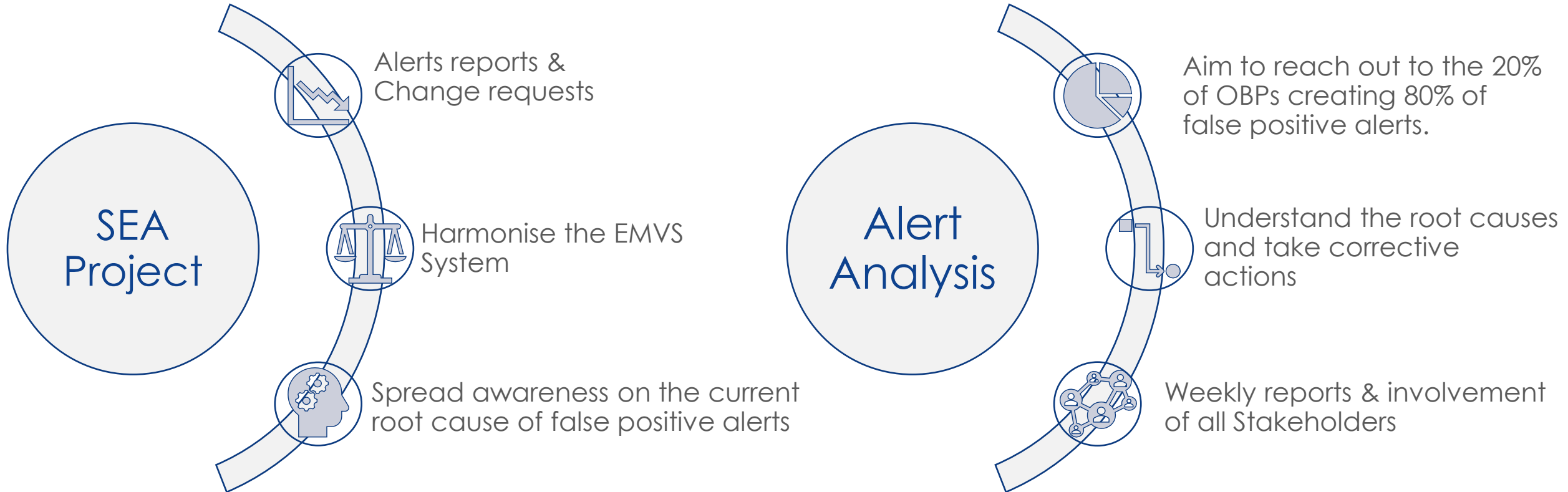
APPLICABLE FINES



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SYMPOSIUM - FMD IMPLEMENTATION STATUS

EXAMPLE OF ALERT REDUCTION PROJECTS



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SYMPOSIUM - FMD IMPLEMENTATION STATUS

ALERT MANAGEMENT WORKING GROUP MEMBERS



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PGEU GPUE

Antonio Grasso

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SYMPOSIUM - FMD IMPLEMENTATION STATUS

AMWG HIGH-LEVEL AGREED PRINCIPLES

AMS URS

The AMS needs to comply with the final and approved AMS URS.

SSOT

The AMS needs to provide consistent information independently of how the user connects to the system.

CHANGE MANAGEMENT

All changes to the AMS need to follow the current EMVS change management process.

USERS ACCESS

The AMS allows users to interface the alert data and participate in the alerts investigations via their current local systems or a new system.

SYSTEM COMPOSITION

The AMS is composed of a European AMS Hub and various local standalone AMSs.

DATA ACCESS & OWNERSHIP

The EMVS data access rights, as laid down in the Delegated Regulation, shall not be altered.

GOVERNING AND DESIGN PRINCIPLES RELATED TO DATA PROTECTION

Whoever creates the data, owns the data

Data generated by an end-user's own IT system is **exclusively owned** and may be freely used **by the concerned end user**



Verification systems are for **preventing falsifications**, not for accessing individual stakeholder data

Access to and/or use of any data from the EMVS for purposes outside of the scope of the FMD and its DR **needs to be agreed by all the stakeholders owning that data**

Data must be stored in such a way that **data confidentiality, per stakeholder, is ensured**

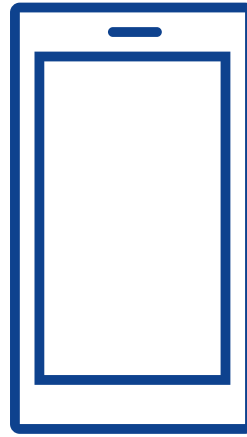
Data storage requirements will be reviewed in the light of **applicable legislation and regulatory requirements**

HOW CAN USERS INTERACT WITH THE AMS?



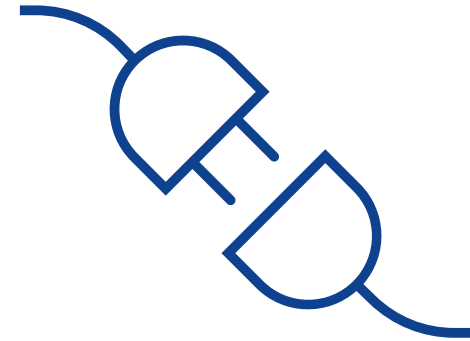
AMS web app

Via a new user interface which will allow users to connect and interact with the AMS;



AMS mobile app

A mobile application will also be available for users to interact with the AMS;



AMS interface

The AMS can be interfaced by any system that respects the AMS interface;

AMWG NEXT STEPS

- Finalize and consolidate the AMS URS according to the Q&A sessions outputs and share it with stakeholders
- Alignment with the NMVO Customer Groups
- PoC enhancement
- High-Level architecture & project plan definition

**Thank you for your
attention.
Any question?**

