



FiMVO

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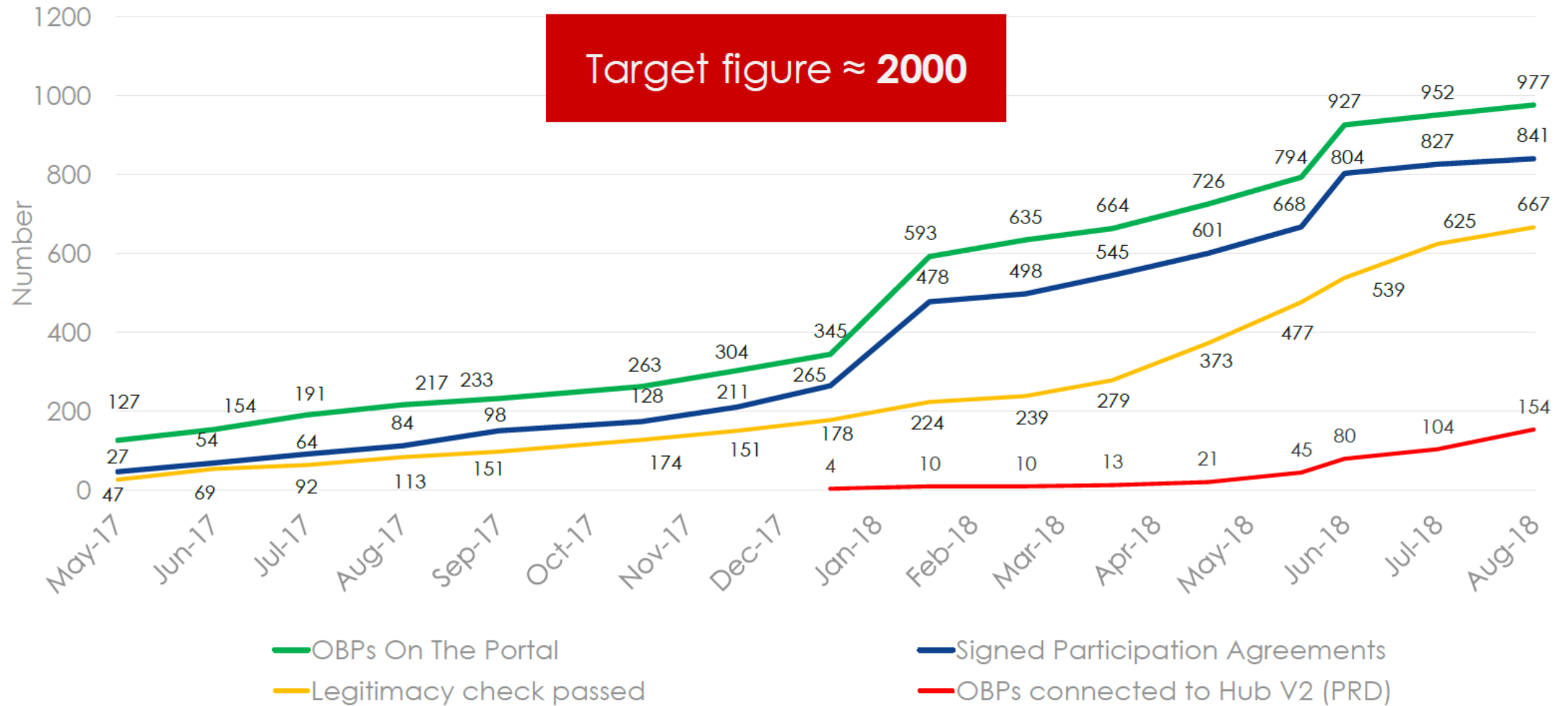
Building a safe medicines supply

Topics for today

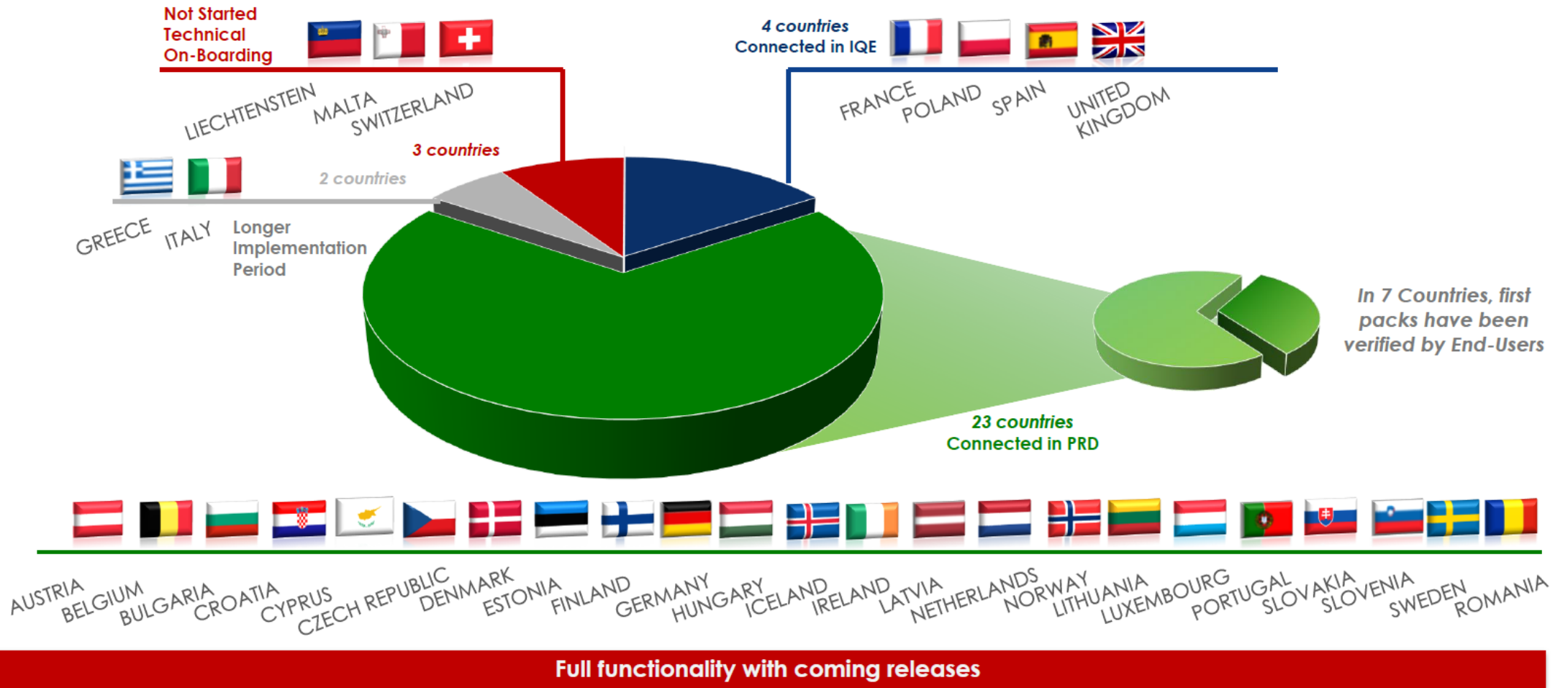
- Contracts and invoicing
- Status in Europe
- What's new with the Hub
- Packs from India (and some other countries)

STATUS ON-BOARDING

Data collected on 31th of August 2018



NMVO ON-BOARDING - PROGRESS OVERVIEW



Contracts and invoicing

- We have just under 300 contracts - thank you everyone!
- First invoices have just been sent out
 - Covering operational fees 11/2018 - 12/2019
- Next invoices will be sent out in January 2019
 - Covering first set of ramp-up phase fees (FiMVO will pay back loans to stakeholders)
 - Second set of ramp-up phase fees will be charged in January 2020
 - Estimated costs 5 000 - 8 000 € in total
- A guidance on how fees will be charged from latecomers will be published on our website shortly

What's new with the Hub

- Release 1.4 successfully deployed in production 19th August
- Business critical features confirmed to be operating
- Changes in the pipeline
 - Recipients of Alerts
 - NCA Reports
 - Control MAHs
 - Master Data Synchronisation
 - Update PMD Report
- Missing call backs from NMVS
 - Some OBPs are reporting not receiving "FAILED" or "DISTRIBUTED" messages when downloading data via the Hub
 - EMVO is investigating the issue with NMVOs

Packs from India (and some other countries)

- Packs manufactured in India must include a 2D matrix and serialisation data - identical to FMD requirements
 - However the data isn't in the EMVS
- Products cause an alert in the EMVS and create confusion in the End Users
- Some packs have one GTIN value in the 2D matrix and completely different value in the linear bar code
 - Even if the data is downloaded into the EMVS, these packs will cause an alert if the wrong GTIN is scanned
 - Note that two different GTINs in different carries are not allowed

Hospital aggregation

- Aggregation (i.e. clustering unique serial numbers into clusters e.g. on a palet) is not supported by the EMVS
- Hospital readiness to implement medicines verification is low on a European level
- Commission is suggesting alternative methods for aggregating serial numbers so that verification would require less resources
- These methods
 - Pose a risk to data security
 - Are slow to implement (will not help with deadline of 9th Feb)
 - Are costly for the pharma industry
- Hospitals will remain responsible for decommissioning
- Checking tamper evidence?
- EMVO: aggregation should be discussed together with all relevant stakeholders taking sufficient time