

Danish Medicine Verification Organization

DMVO Information meeting

18-01-2019





21 calendar days to 9th. of February 2019
Equaling 16 working days incl. today



What would you like to discuss?



Agenda

- Status in DK in comparison to other EU countries
- The alert handling process by LMST & DMVO
- Audits & inspections by LMST
- Status onboarding by DMVO
 - MAH's
 - End Users
- Quality of uploaded data to the European Hub by DMVO
- DDIS - Downtime & Disruption Information System by DMVO
- Largest challenges by DMVO
- Questions
- Thank you

Current status in DK



- 2 wholesalers ✓
- 2 IT providers of Pharmacy Systems, Cito& NNIT ✓
- 1 hospital Pharmacy System -
 - ApoVision
 - Stand alone solution ✓
- 1 private hospital - Stand alone solution ✓
- “Statens Serum” Institute - Stand alone solution ✓
- Min. 7 3PL’s - third part suppliers / ‘wholesalers’ - stand alone solutions, 4 are operational
- 234 primary pharmacies, 72 are operational

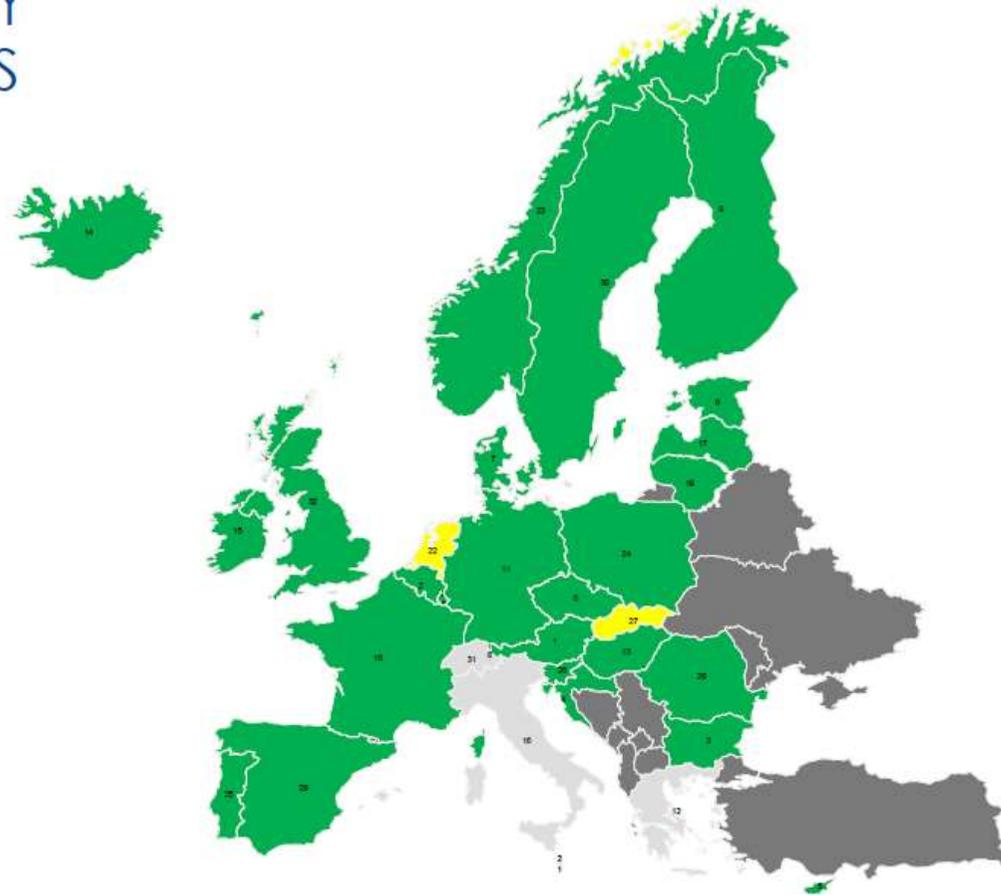
End User Readiness

EXECUTIVE SUMMARY A3: END USER READINESS



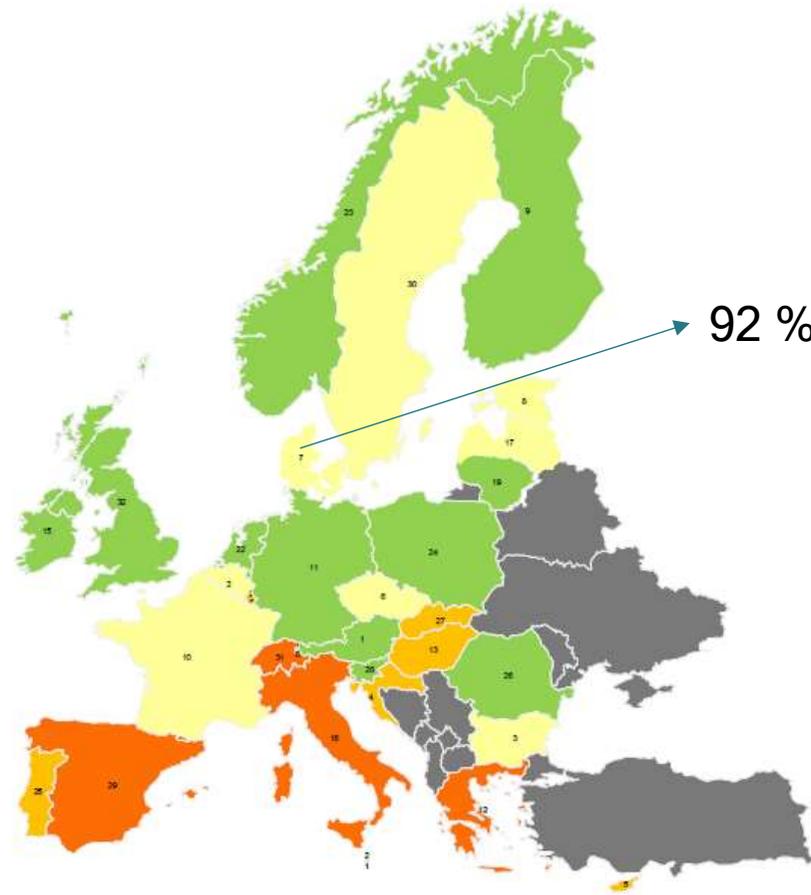
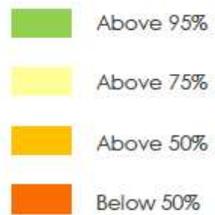
NMVS Readiness

EXECUTIVE SUMMARY A2: NMVS READINESS



MAH Onboarding

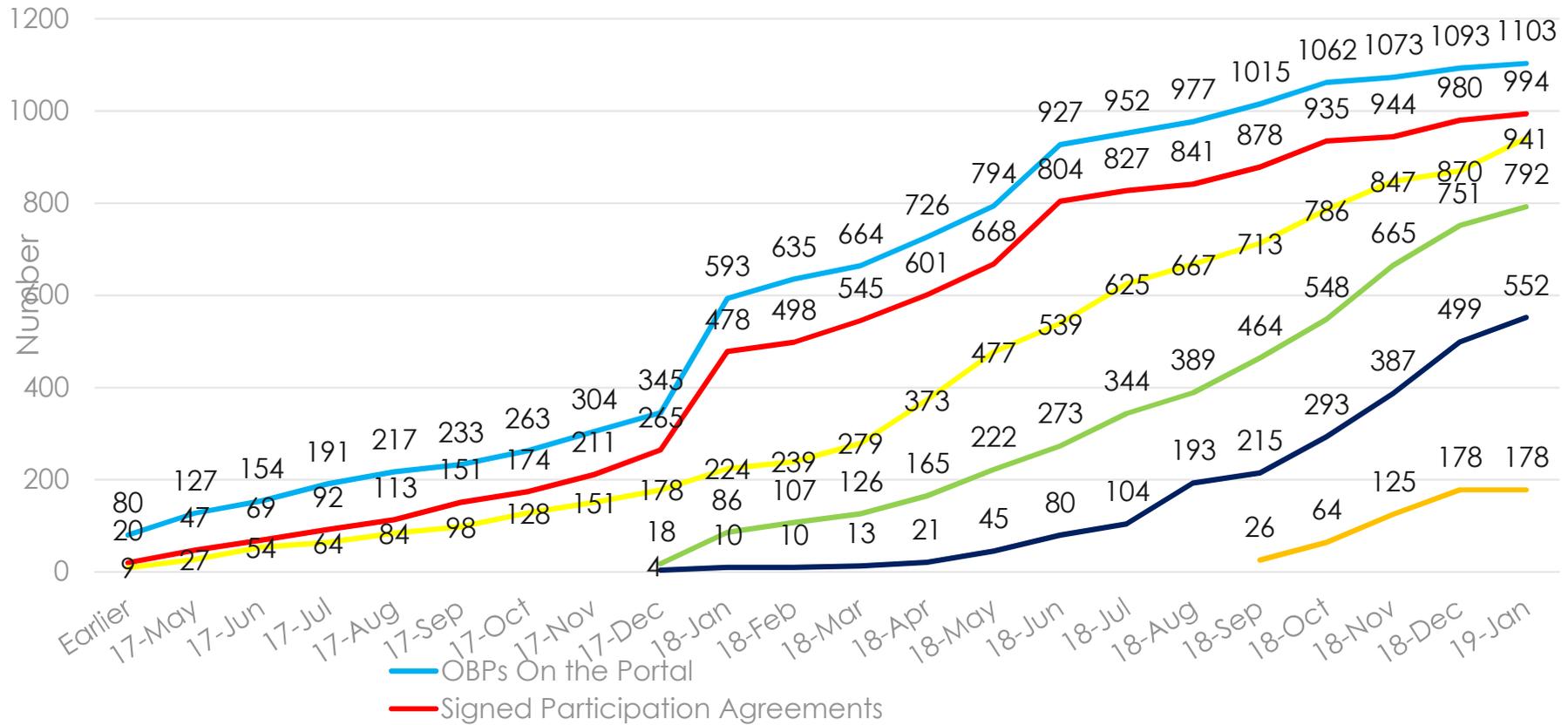
EXECUTIVE SUMMARY A1: MAH ON-BOARDING *



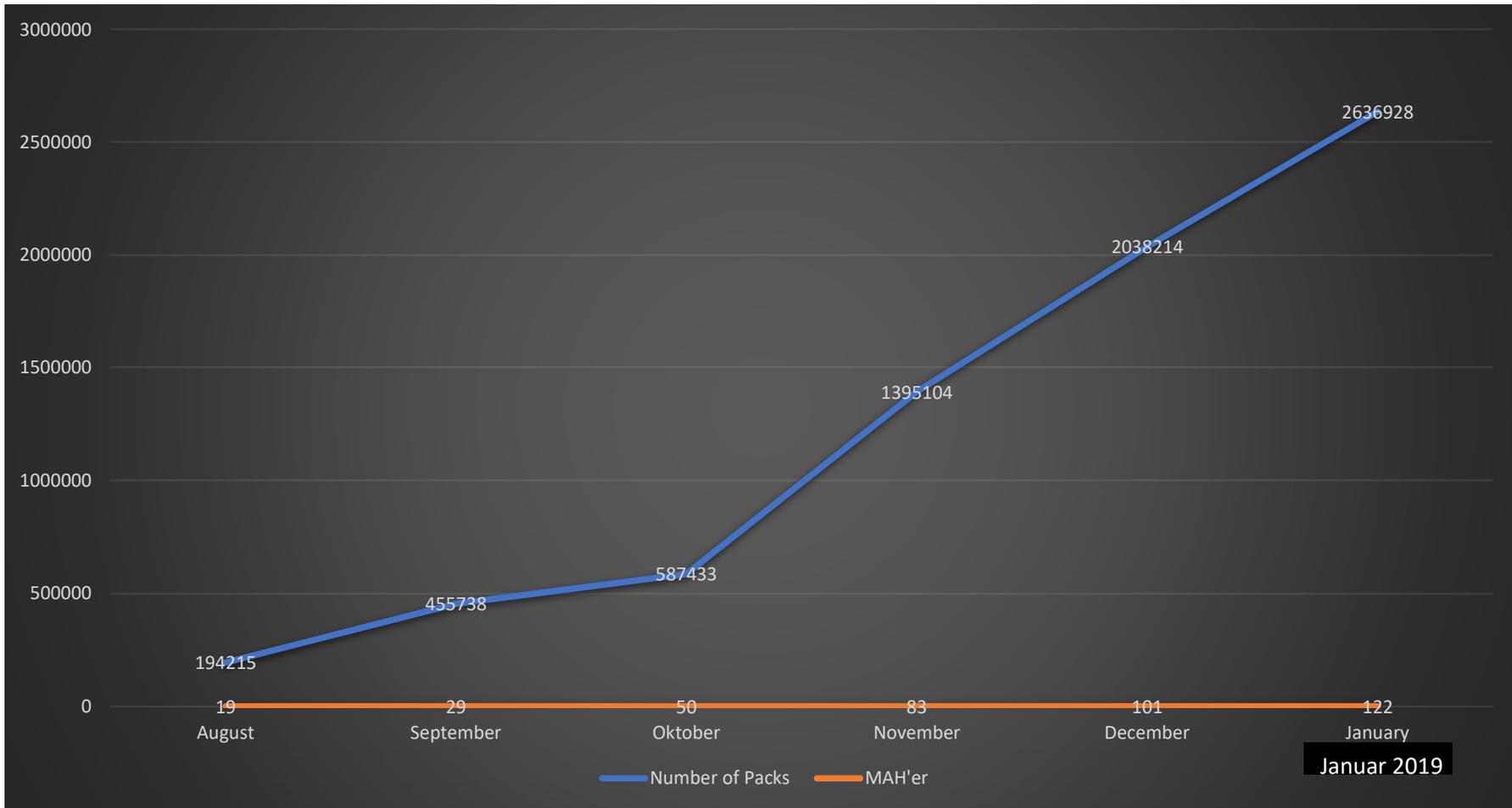
92 %

STATUS ON-BOARDING

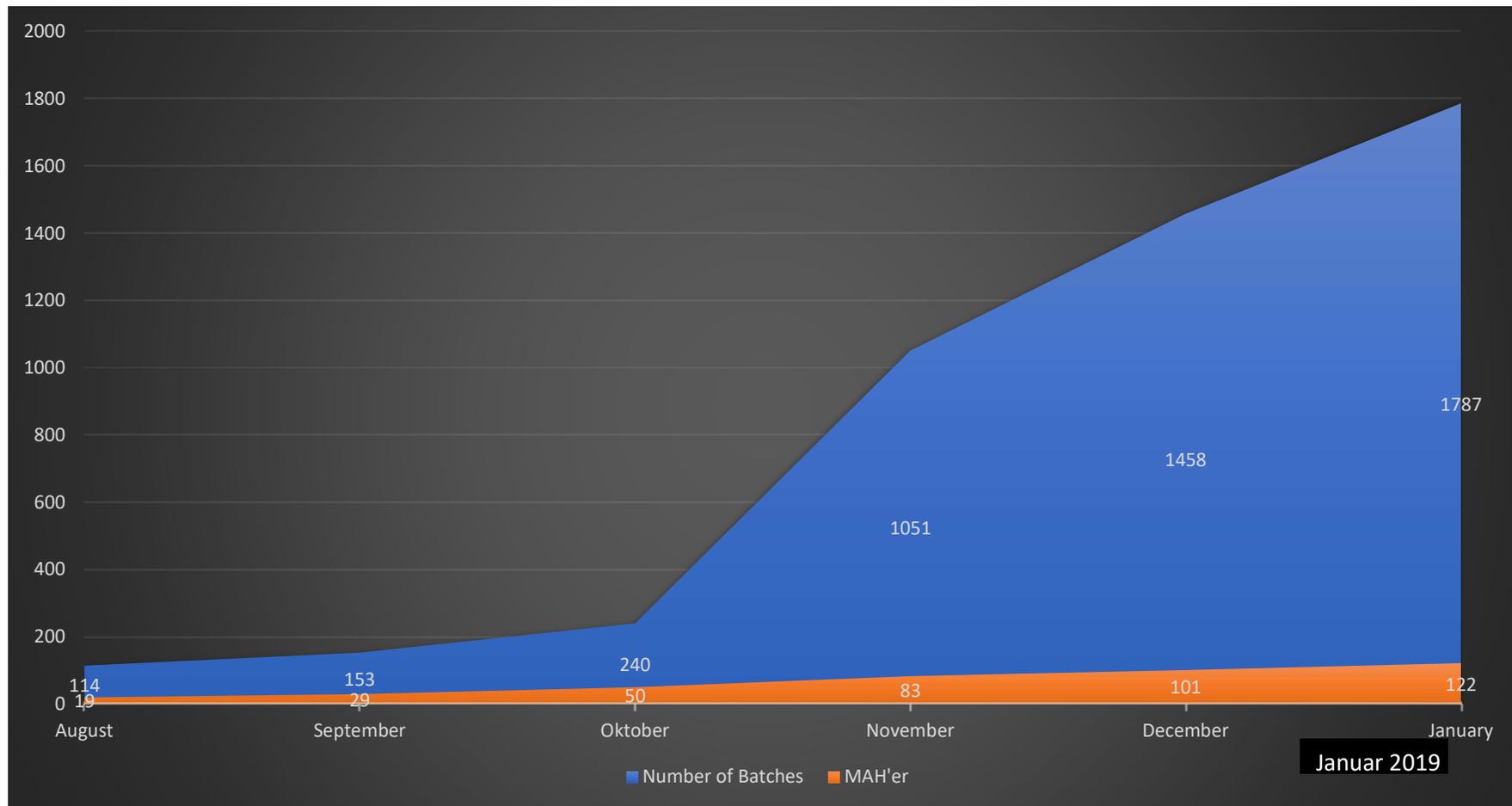
Data collected on January 15th 2019



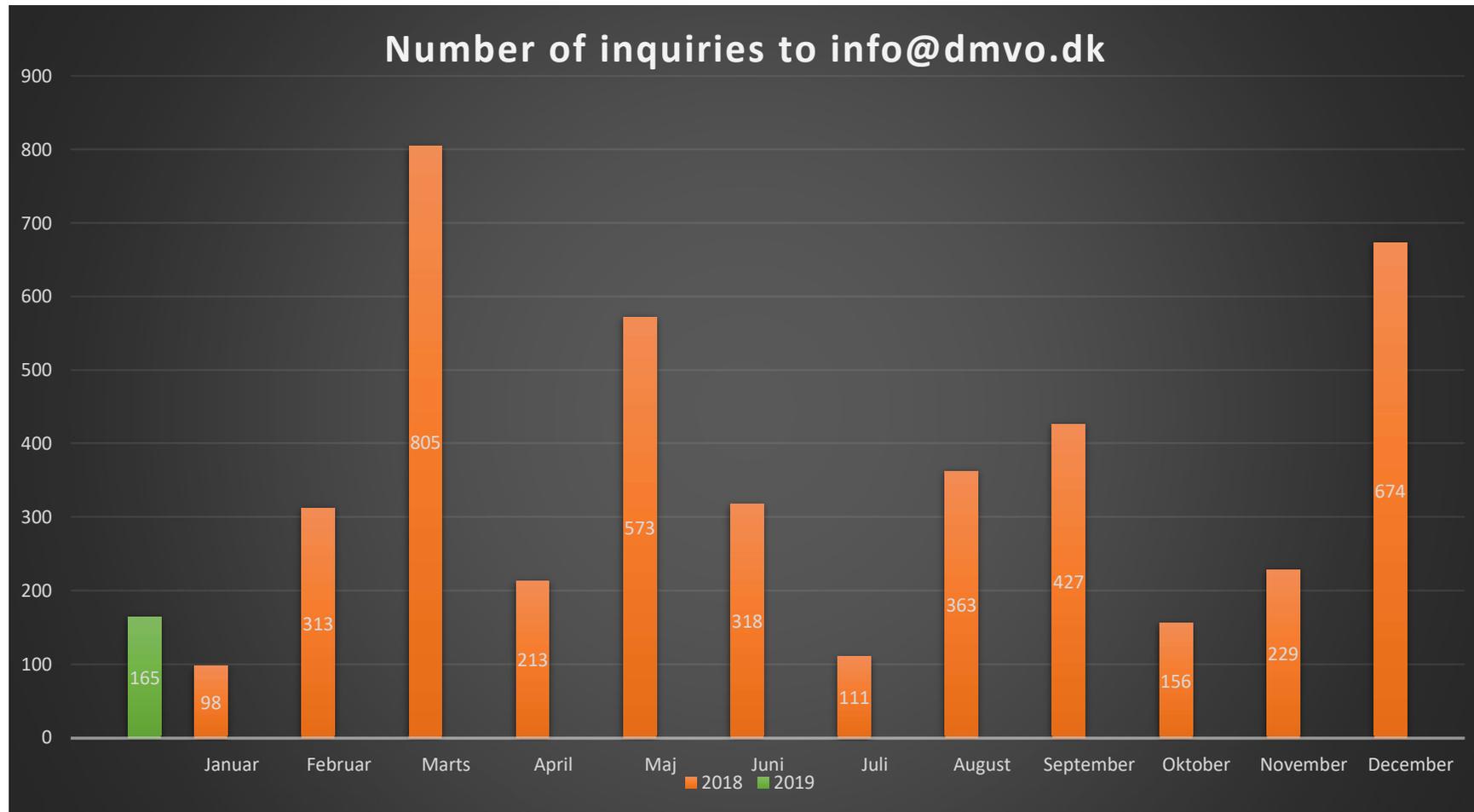
Number of packages in DMVS PRD



Batches and number of MAH's in DMVS PRD



Inquiries to info@



Top priority areas in focus until 9th. of February 2019



To be discussed in workshops

1. Serialization
2. Communication
3. Data Quality - hereunder deficiency of indication of Designated Wholesaler
4. SPOC /Help Desk for stakeholders
5. Lack of goods - stock runs put
6. The cheapest product 'fails'
7. Response times
8. How do we handle products we cannot scan?

Alert handling - Instructions by NCA: The Danish Medicines Agency

Safety features - Alert handling

Christina Palvad



18. JANUAR 2019

Audits and inspections



Onboarding status for MAH`s

- Today 245 MAH`s have signed the contract with DMVO



Invoicing



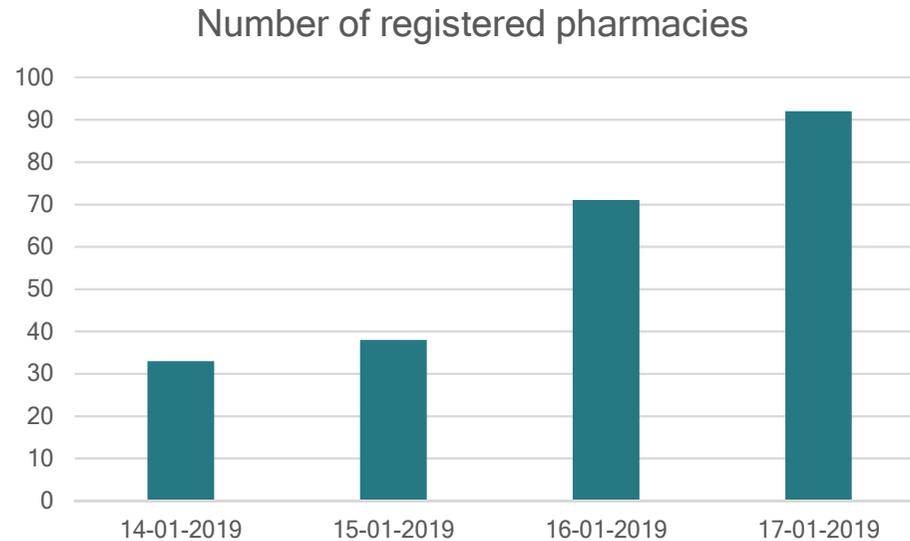
- The invoices for the "One Off Registration Fee" have been sent out
 - Cf. the contract, the deadline is 31st. January 2019
 - "Newcomers" are invoiced as they sign and have a payment deadline of + 30 days

- The yearly fee invoices for MAH's are sent the 30th of Jan. 2019
 - The fee is: EURO 8.500,00 pr. MAH
 - The fee includes the increase the EMVO has foreshadowed for the respective NMVO's.

- Pls. do send PO number for the yearly fee if it is to be applied to the invoice and if different from the one used for the One Off Registrastion Fee.

Pharmacies status

Number of primary private pharmacies to be onboarded in total app. 235



Upload of data from OBP's

Data quality

- Upload of data
 - Retrospective upload, products released prior to the 8th of February at: 23:59:59
 - Master data PMD vs. Product PPD
 - Designated Wholesaler / contracted wholesalers

EMVO Downtime & Disruption Information System

- 2 types of downtime:
 - Planned - EMVO has to be informed a month in advance
 - Not planned - has no impact on End Users due to back-lock.

- EMVO DIS example:

Display outages

All status All sectors

All types All causes All selected entities

[Show more criteria](#)

16 653 Result(s)

10 Results displayed per page Sorted by:

Generation unit/Production unit	Type	Power (MW)	Maximum power (MW)	Start date	End date	Publication date	Status
GRAND MAISON 6	Planned	0.00	152	02/08/2018 14:00:00	02/08/2018 16:30:00	25/07/2018 16:51:12	Active

Announcement example for downtime

published: 19 04 2019
Announcement – EU Hub Down for Maintenance

Home announcement - eu hub down for maintenance

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Announcement – EU Hub Down for Maintenance

EMVO would like to inform you that the European Hub is going to be down for maintenance from tomorrow, **Friday 20th of April at 8:00 pm CET, till Monday the 23rd of April at 8:00 am CET.**

This implies that no connection will be allowed during that time period to the EU Hub. A message will inform you accordingly in case you attempt to connect. All three environments are affected, which implies that your OBP Company will not be able to upload data in PRD, neither to perform any test in ITE or QE. Therefore, the OBP should suspend all actions in the Technical On-boarding on the OBP Portal during that time period.

From Monday the 23rd of April at 8:00 am CET, the EU Hub is planned to be available and operating normally.

More Details:

Find more detailed information from the Letter of Announcement

[2019/04/19 | EU HUB DOWN FOR MAINTENANCE](#)

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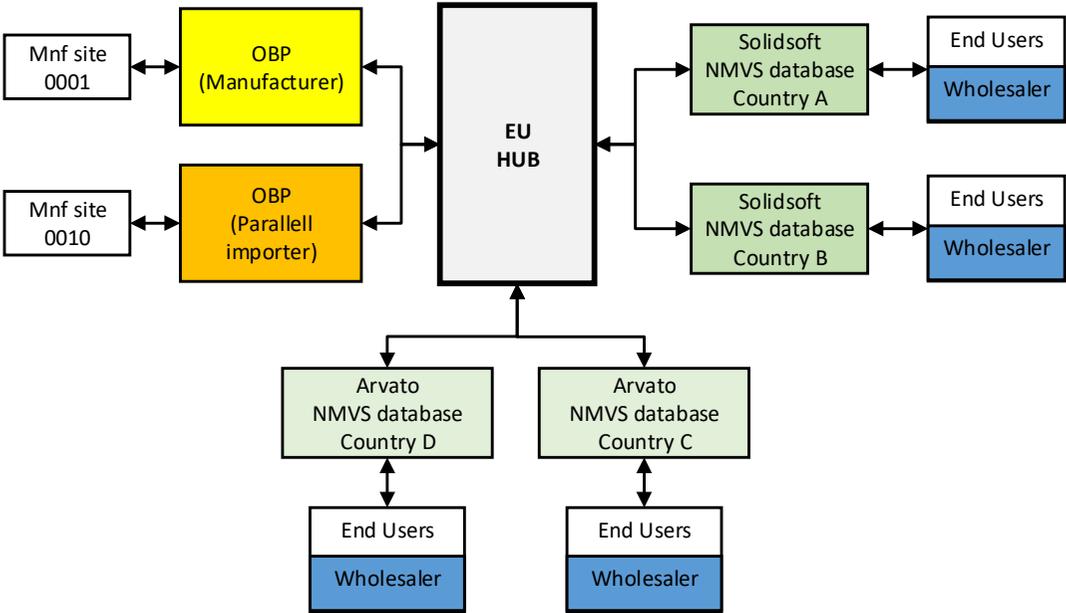
European Medicines Verification Organisation

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System diagram



Largest challenges

- Quality of uploaded data to the hub
- Lack of data - MAH readiness
- End user readiness
- Training and information to End Users
- Late roll out / limited experience with new processes & procedures - Changes takes time



Time for questions



Last meeting before the 9th. of February 2019

