

# Dansk Medicin Verifikation Organisation

DMVO Informationsmøde

18-01-2019





21 kalenderdage til 9. februar 2019

Heraf 16 arbejdsdage inkl. idag



# Hvad vil I gerne høre om?

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# Agenda

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- Status i DK sammenholdt med øvrige EU lande v. DMVO
- Alert håndteringsprocessen v. LMST og DMVO
- Audits og inspektioner v. LMST
- Status på onboarding v. DMVO
  - MAH'er
  - Slutbrugere
- Datakvalitet ved upload af data til hub'en v. DMVO
- DDIS - Downtime & Distruption Information System v. DMVO
- Største udfordringer v. DMVO
- Spørgerunde
- Tak for i dag

# Hvad er status i DK



- 2 grossister ✓
- 2 Apoteks IT leverandører - Cito og NNIT ✓
- 1 sygehusapotekets system -
  - ApoVision
  - Stand alone løsning ✓
- 1 privathospital - Stand alone løsning ✓
- Statens Serum Institut - Stand alone løsning ✓
- Min. 7 3PL - Tredje parts leverandører / 'grossister' - stand alone løsninger, 4 er operationelle
- 234 Hovedapoteker, 72 er operationelle

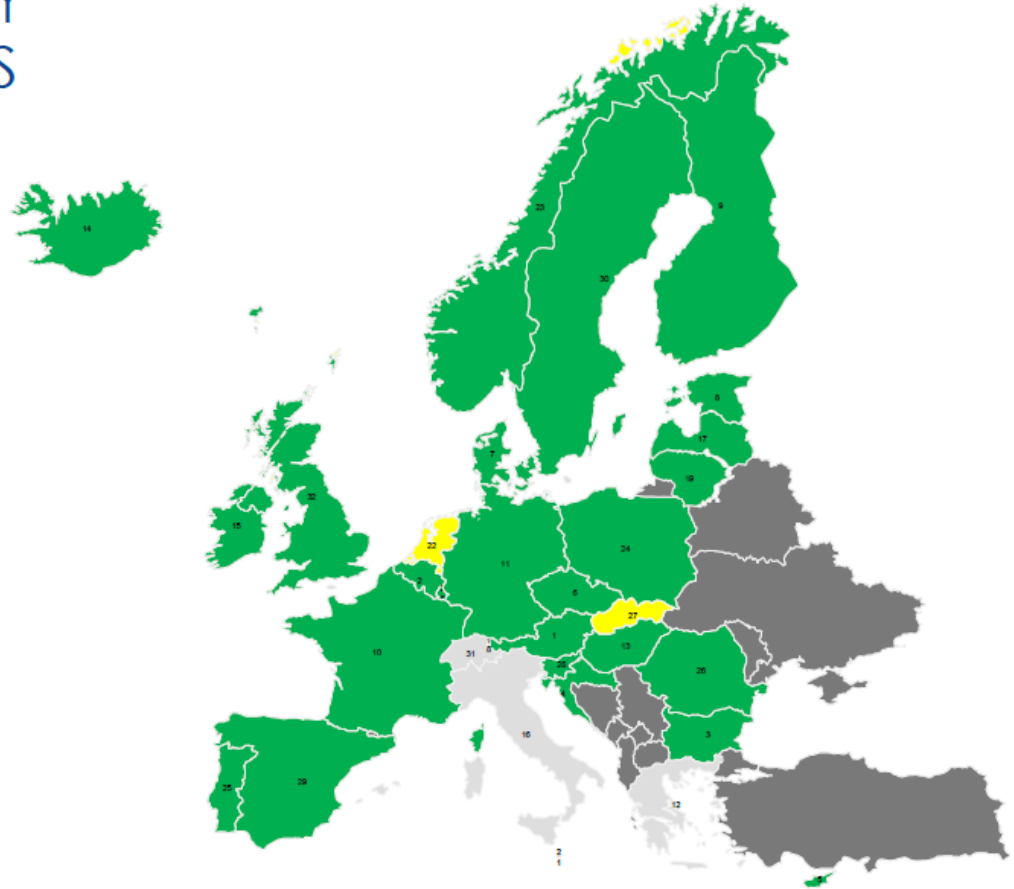
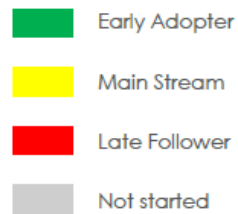
# End User Readiness

## EXECUTIVE SUMMARY A3: END USER READINESS



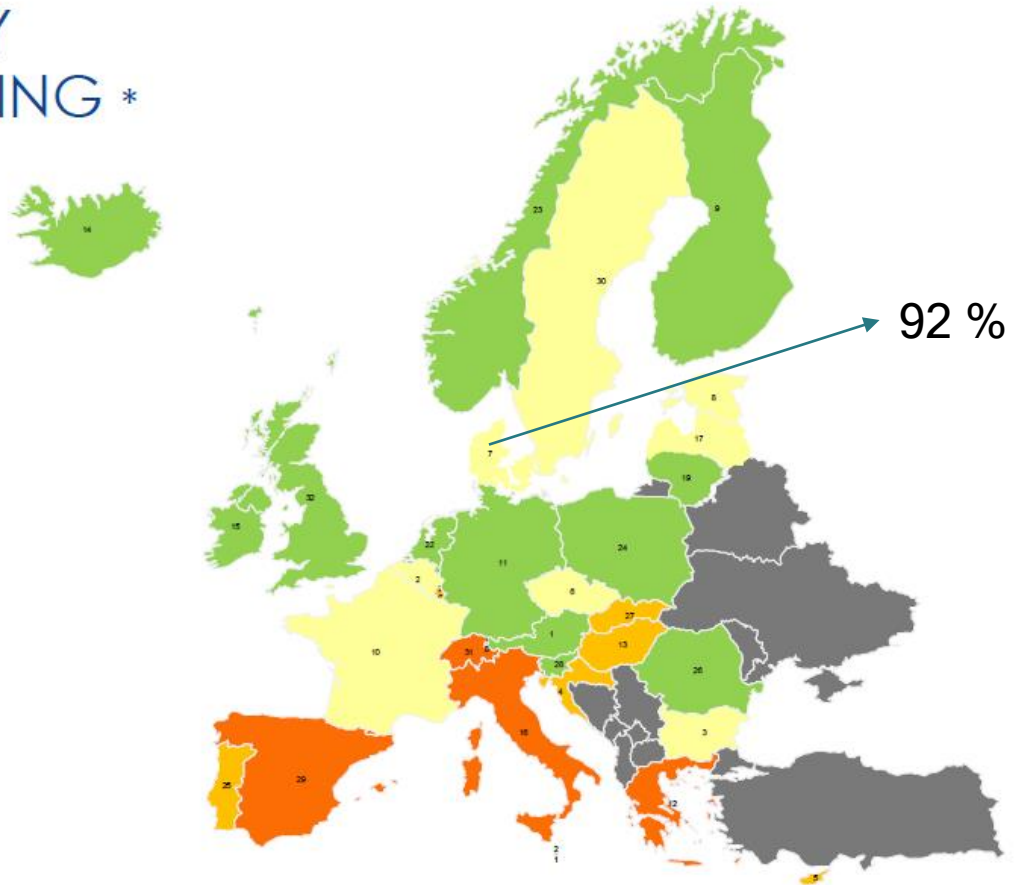
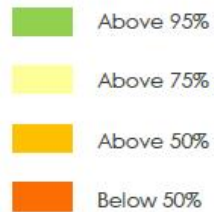
# NMVS Readiness

## EXECUTIVE SUMMARY A2: NMVS READINESS



# MAH Onboarding

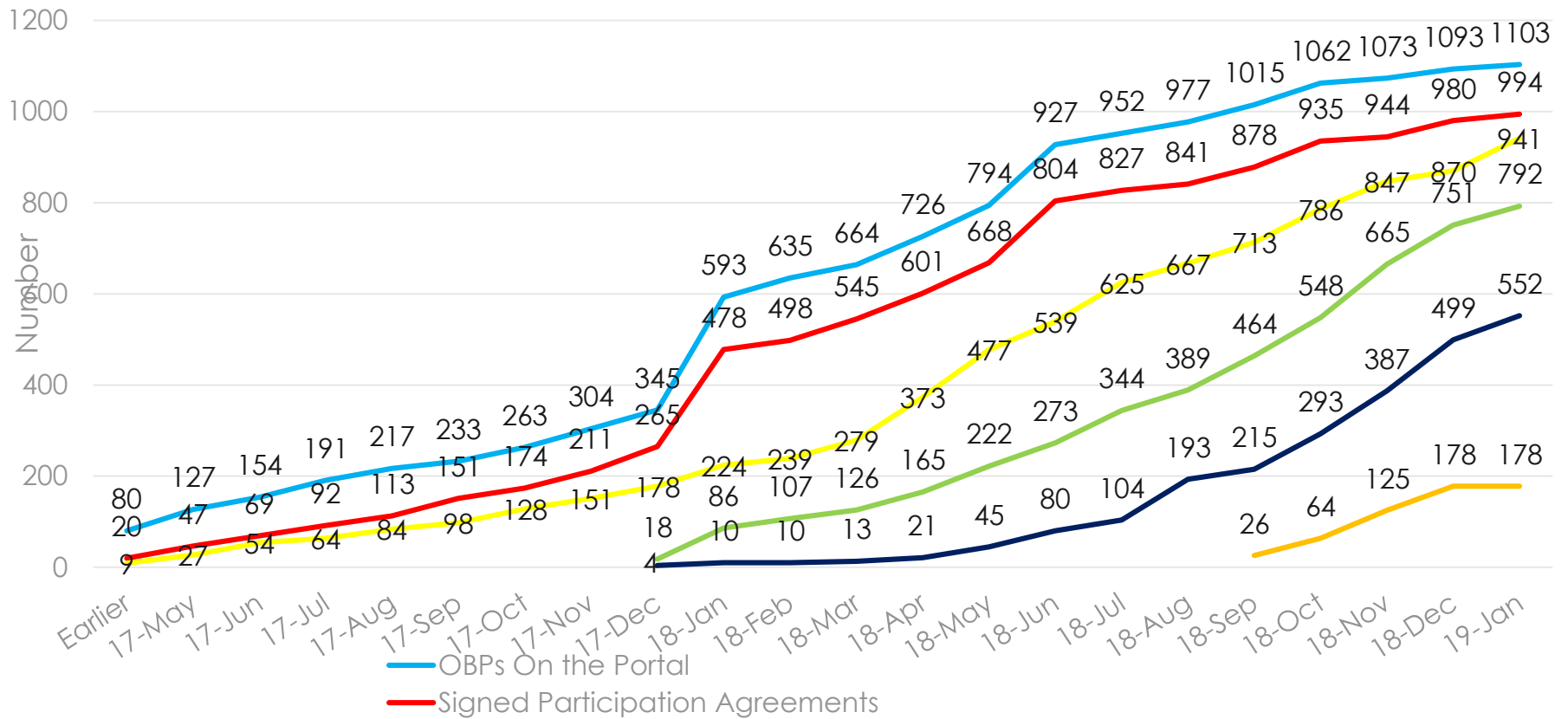
## EXECUTIVE SUMMARY A1: MAH ON-BOARDING \*



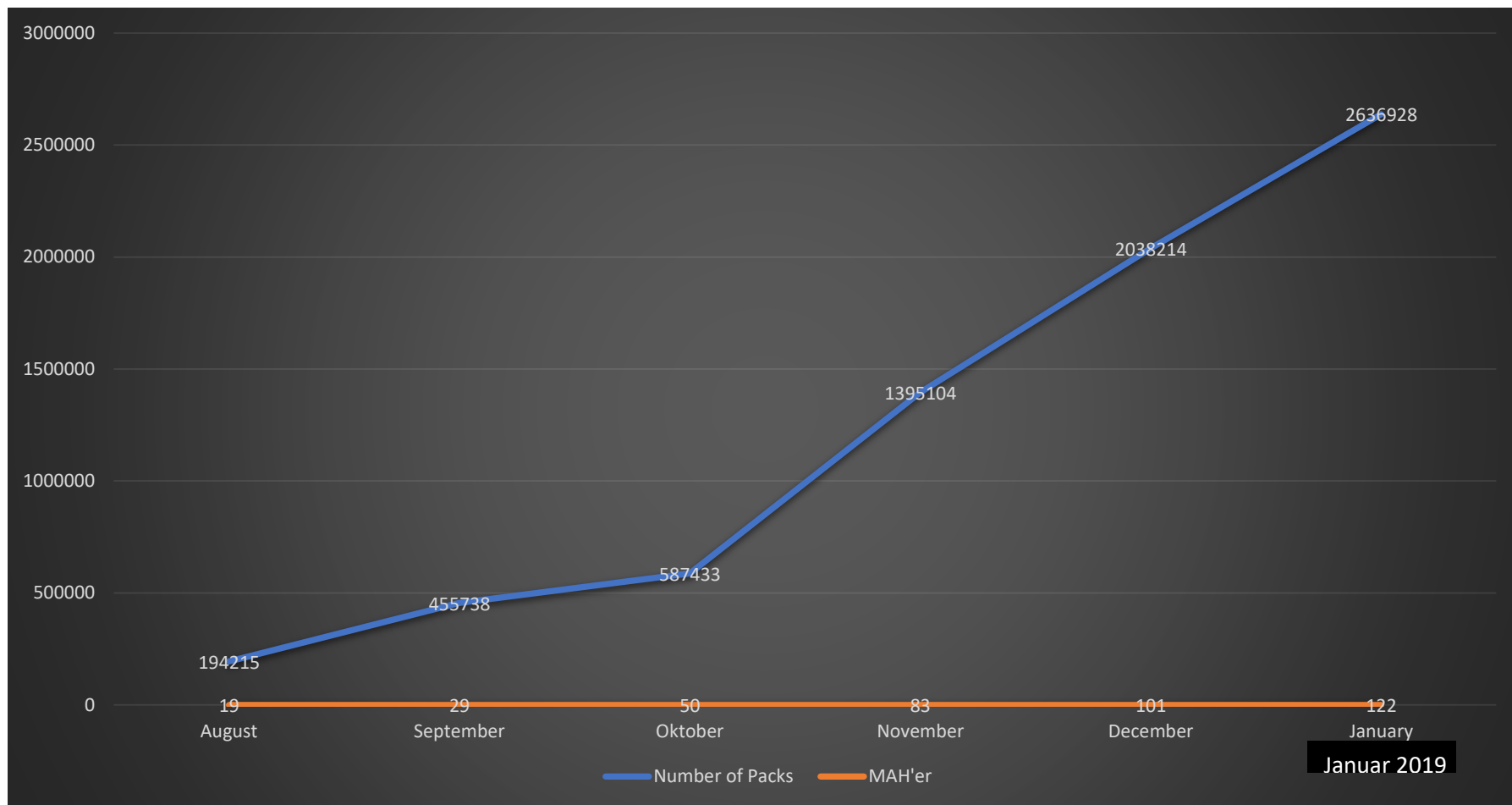


# STATUS ON-BOARDING

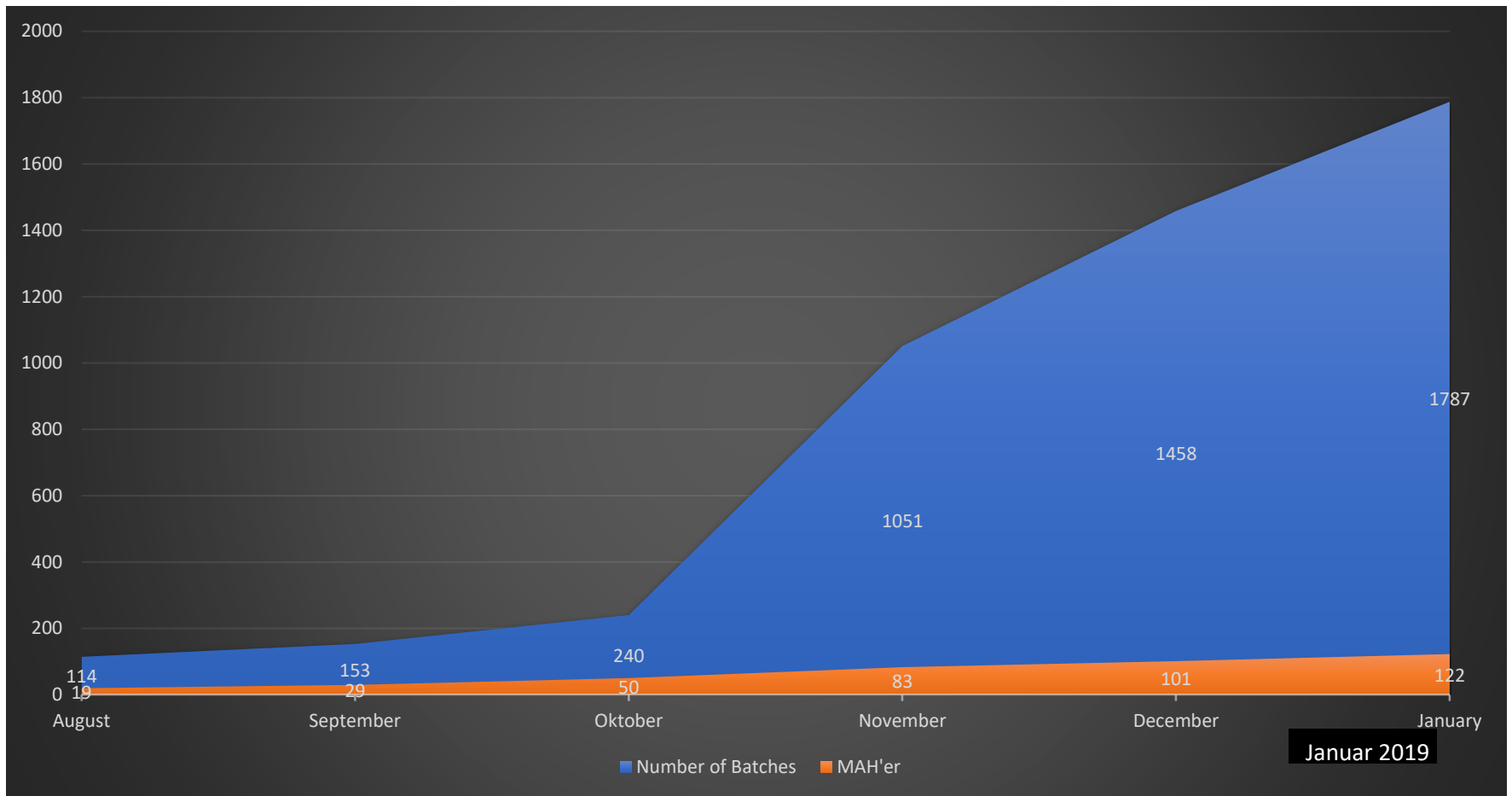
Data collected on January 15th 2019



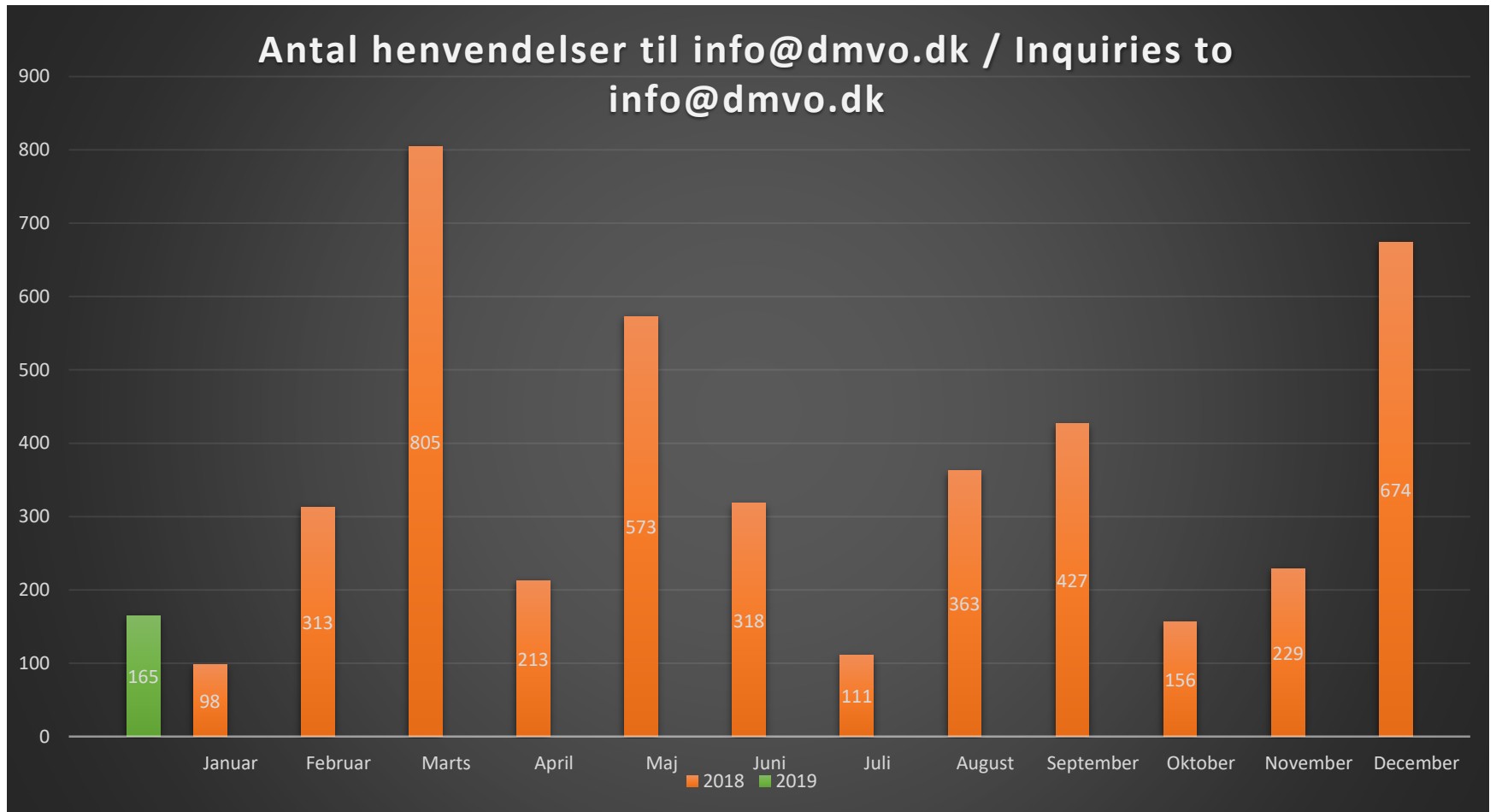
# Antal pakker i DMVS PRD



# Batches og antal MAH'er i DMVS PRD



# Henvendelser til info@



# Fokusområder frem til 9. februar 2019



Håndteres i arbejdsgrupper

1. Serialisering
2. Kommunikation
3. Datakvalitet - herunder mangel på angivelse af Designated Wholesaler
4. SPOC /Help Desk hos stakeholdere
5. Mangel på varer - lagerbeholdning slipper op
6. Billigste produkt 'fejler'
7. Svartider
8. Varer vi ikke kan skanne - hvordan skal de håndteres

# Alert håndtering - Lægemiddelstyrelsens vejledning

## Sikkerhedselementer – Håndtering af alarm

Christina Palvad



18. JANUAR 2019

# Audits og Inspektioner



# Onboarding status for MAH`er

- 245 MAH`er har indgået kontrakt med DMVO d.d.





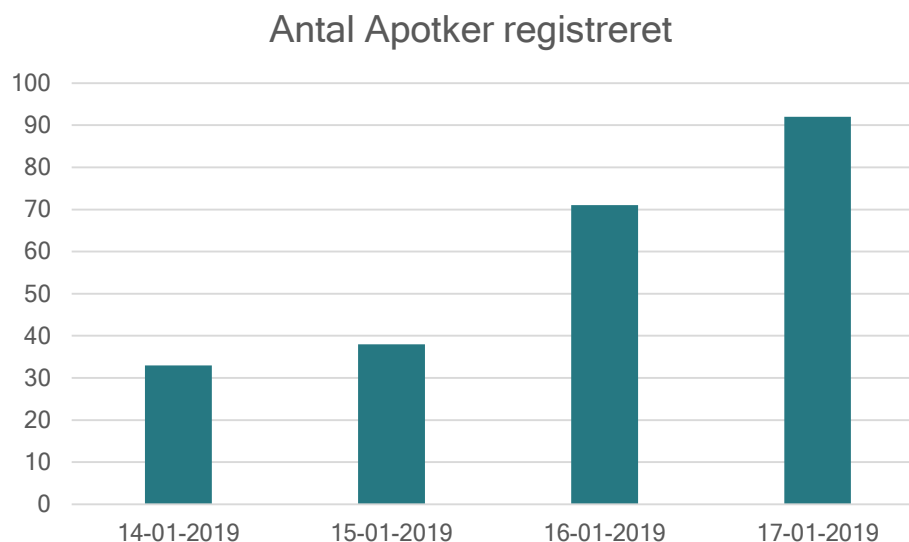
# Fakturering



- Faktura på registreringsgebyr/ "one off registration fee" sendt ud
  - Jf. kontrakten, fristen er: d. 31.01.2019.
  - "Nytilkomne" faktureres d.d. + 30 dages betalingsfrist
  
- Faktura på det årlige gebyr/"yearly fee" for MAH'er sendes d. 30.01.2019
  - Gebyret er fastsat til EURO 8.500,00 pr. MAH/affiliate
  - Gebyret er inklusiv de prisstigninger, EMVO har varslet for de enkelte NMVO'er.
  
- Send gerne PO numre til det årlige gebyr, hvis det skal bruges til fakturering, og afviger fra det tidligere fremsendte.

# Apoteker status

Antal hovedapoteker der skal opboardes ca. 235



# Upload af data fra OBP'er

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## Datakvalitet

### ■ Upload af data

- Retrospektivt upload, produkter frigivet før d. 8 Februar kl. 23:59:59
- Masterdata PMD vs. Produkt PPD
- Designated Wholesaler / Kontraherede grossister

# EMVO Downtime & Disruption Information System

- 2 typer downtime/ "nede-tid":
  - Planlagt - EMVO skal orienteres en måned forud til godkendelse
  - Ikke planlagt - har ingen indflydelse på End Users pga. back-lock.

- EMVO DIS eksempel:

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: Publication date (reverse chronological)

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

# Eksempel på annoncering af planlagt downtime



## 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 5:00 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 IQE. 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.

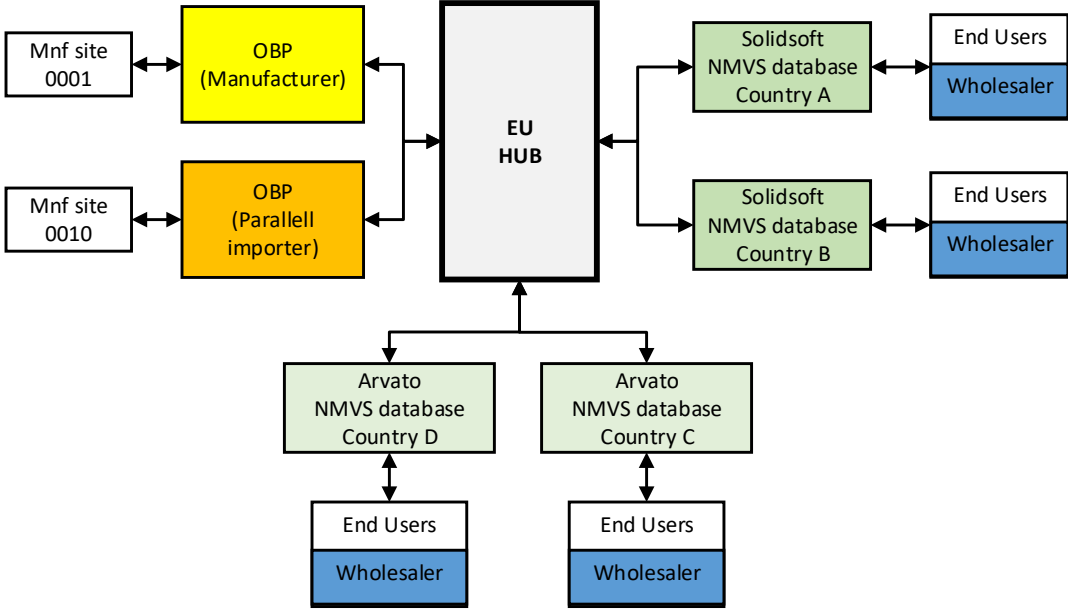
## More Details:

Find more detailed information from the Letter of Announcement.

2018/04/19 | EU HUB DOWN FOR MAINTENANCE

The footer of the EMVO website. It features a dark blue background. On the left is the EMVO logo and the text 'European Medicines Verification Organization'. In the center, there is a 'CONTACT:' section with a checkmark icon, the phone number '+372 611 90 44', and the email address 'helpdesk@emvo-medicines.eu'. On the right, there is a 'SOCIAL:' section with icons for YouTube, LinkedIn, and Twitter, and the text '#EMVO #EMV'S #FMO #lightakes'. At the top of the footer, there is a navigation menu with links: HOME, MISSION, NEWS &amp; EVENTS, PHARMACEUTICAL COMPANIES, IT CONNECTION PROVIDERS, KNOWLEDGE DB, CAREERS, CONTACT, TERMS OF USE, PRIVACY POLICY, COOKE POLICY. A search bar is located on the right side of the navigation menu. At the bottom center, there is a small copyright notice: '©2018 - All Rights Reserved to EMVO srl - Rue de la Loi 20, box 21 - 1049 Brussels, Belgium - VAT nr. BE 0658.001.022 - website design: MCOO-B'.

# Systemdiagram



# Største udfordringer



- Datakvaliteten af data uploaded til hub'en
- Mangel på data - MAH readiness
- End user readiness
- Træning og information til end users
- Sen udrulning / begrænset erfaring med nye processer og procedure - forandringer tager tid



# Tid til spørgsmål





# Sidste møde inden 9. februar 2019

