

The Danish Medicine Verification Organization

DMVO Information meeting

14-12-2018





56 days to 9th. of February 2019
Equaling 36 work days



What would you like to discuss?



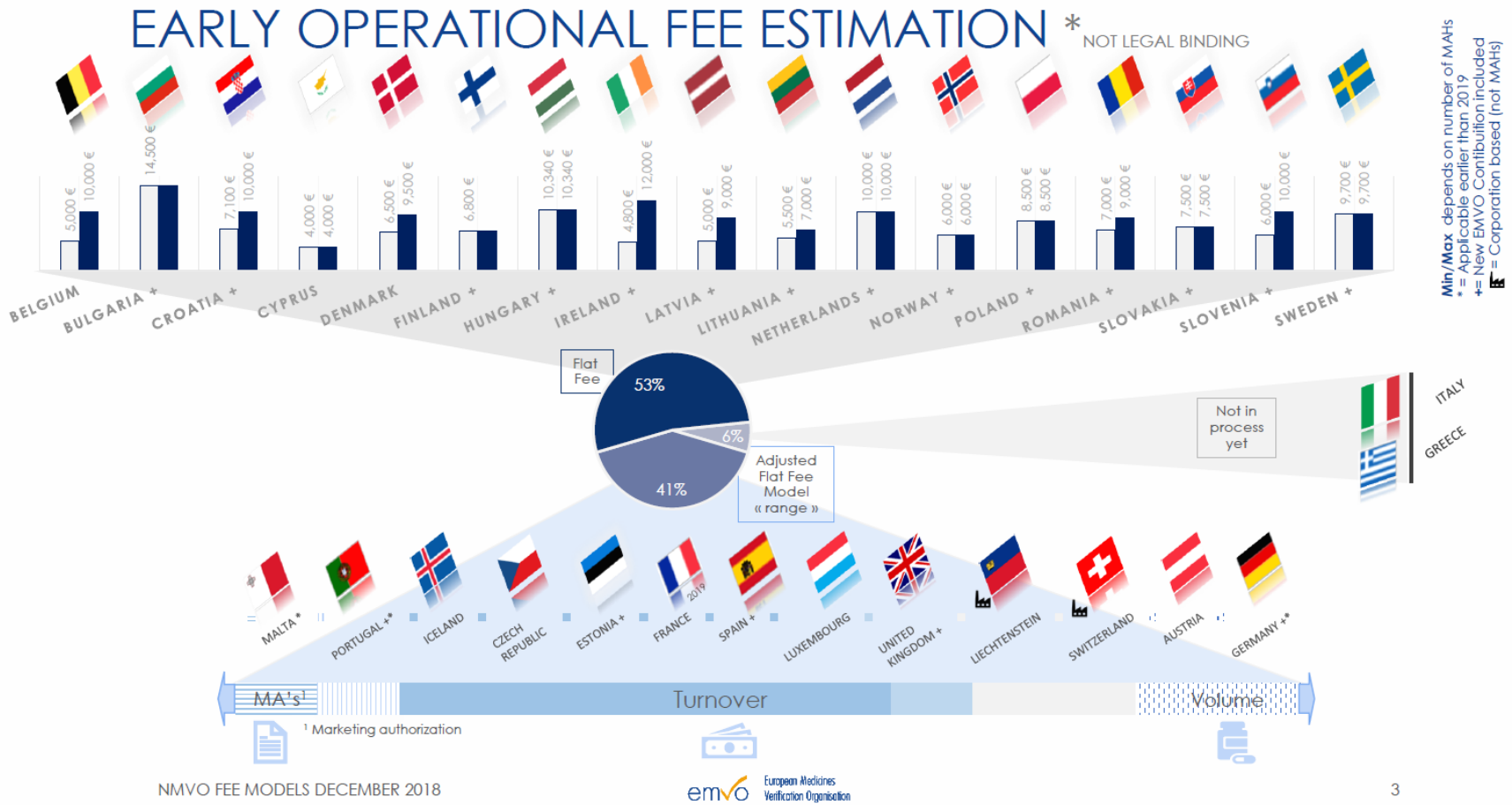
Agenda



- Status in DK
 - News from DMVO
 - News from Lægemiddelstyrelsen/NCA
- What is DMVS
 - The system and a demo of the system
 - Onboarding to DMVS
 - Onboarding of pharmacies
 - The Downtime Information System - DIS
- Status on stakeholders
- Other topics
 - Alert handling
- Questions

- EMVO - NMVO agreement
- Release 4 - Primarily reports
- Code freeze from 15th of January - cancelled
 - New release: 4.1. end January 2019
- Yearly fee
- From implementation to operational phase

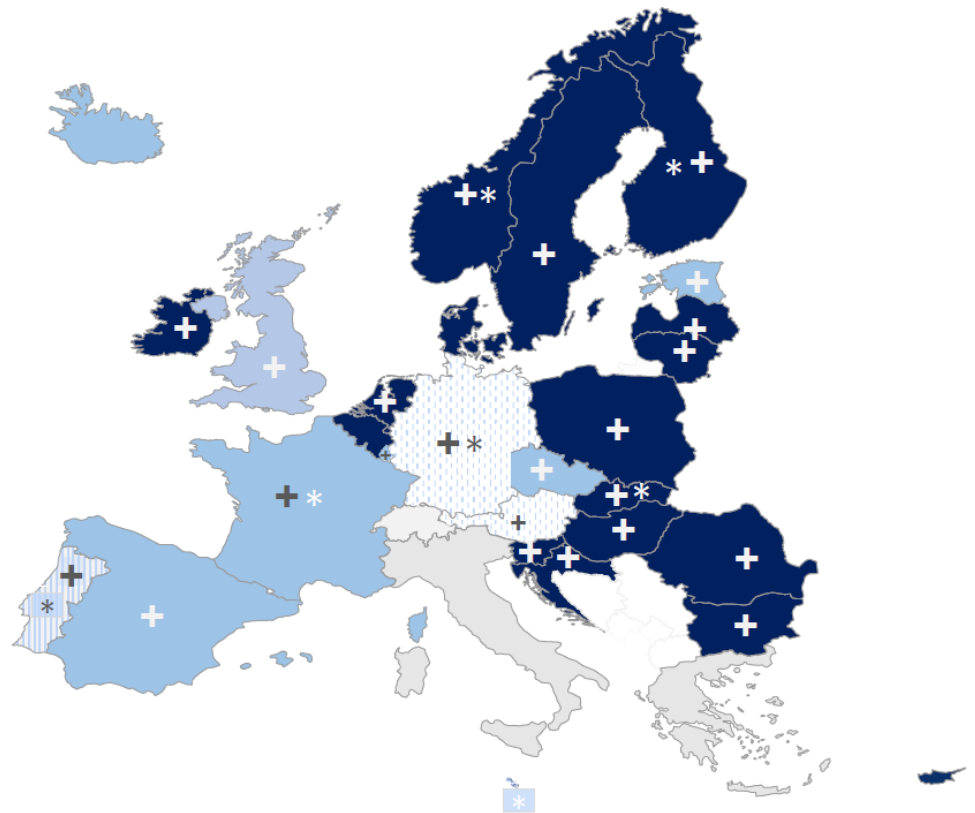
Yearly fee for DK



Fee models in EU

FEE MODEL TYPES * Not legal binding

- Flat Fee Model
- Adjusted Flat Fee Model
- ▨ MA based model
 - ▨ MA & Turnover based model
 - ▨ Turnover based model
 - ▨ « Micro MAH » Model
 - ▨ Mixed model
 - ▨ Volume & Turnover based model
- Not in process yet
- + New EMVO Contribution included
- * Application of annual fees earlier than 2019

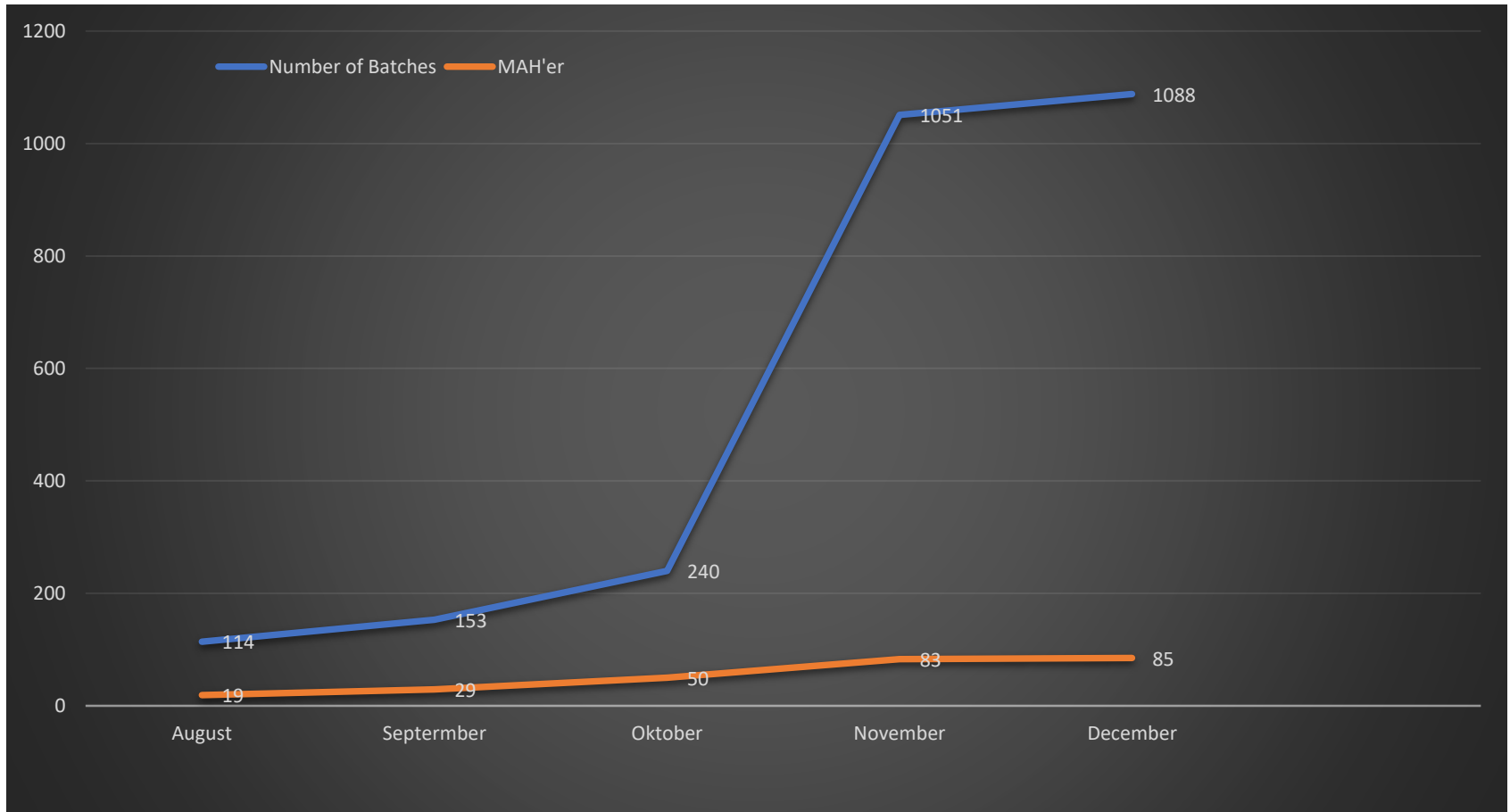


NMVO FEE MODELS DECEMBER 2018

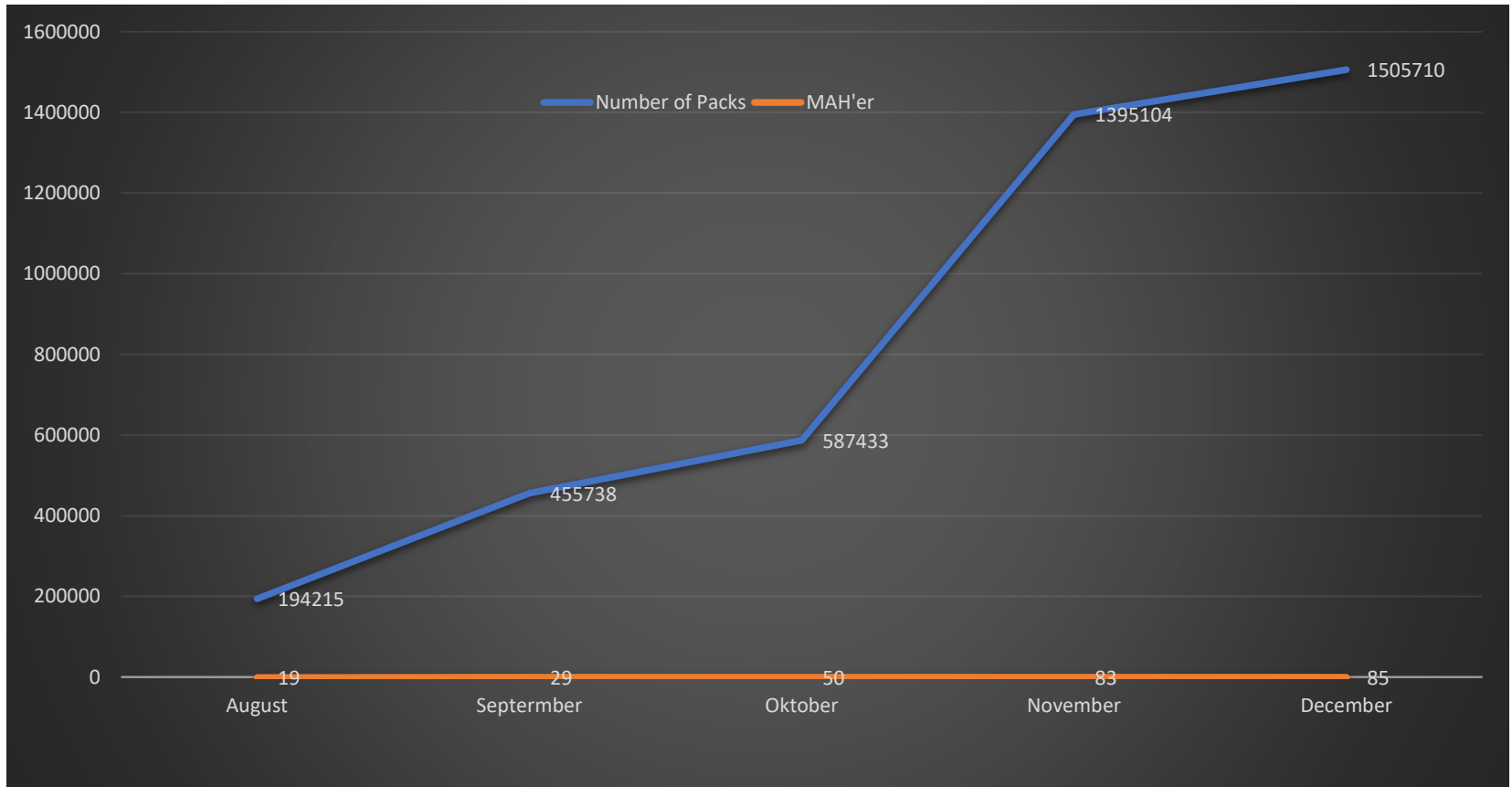
emvo European Medicines Verification Organisation

4

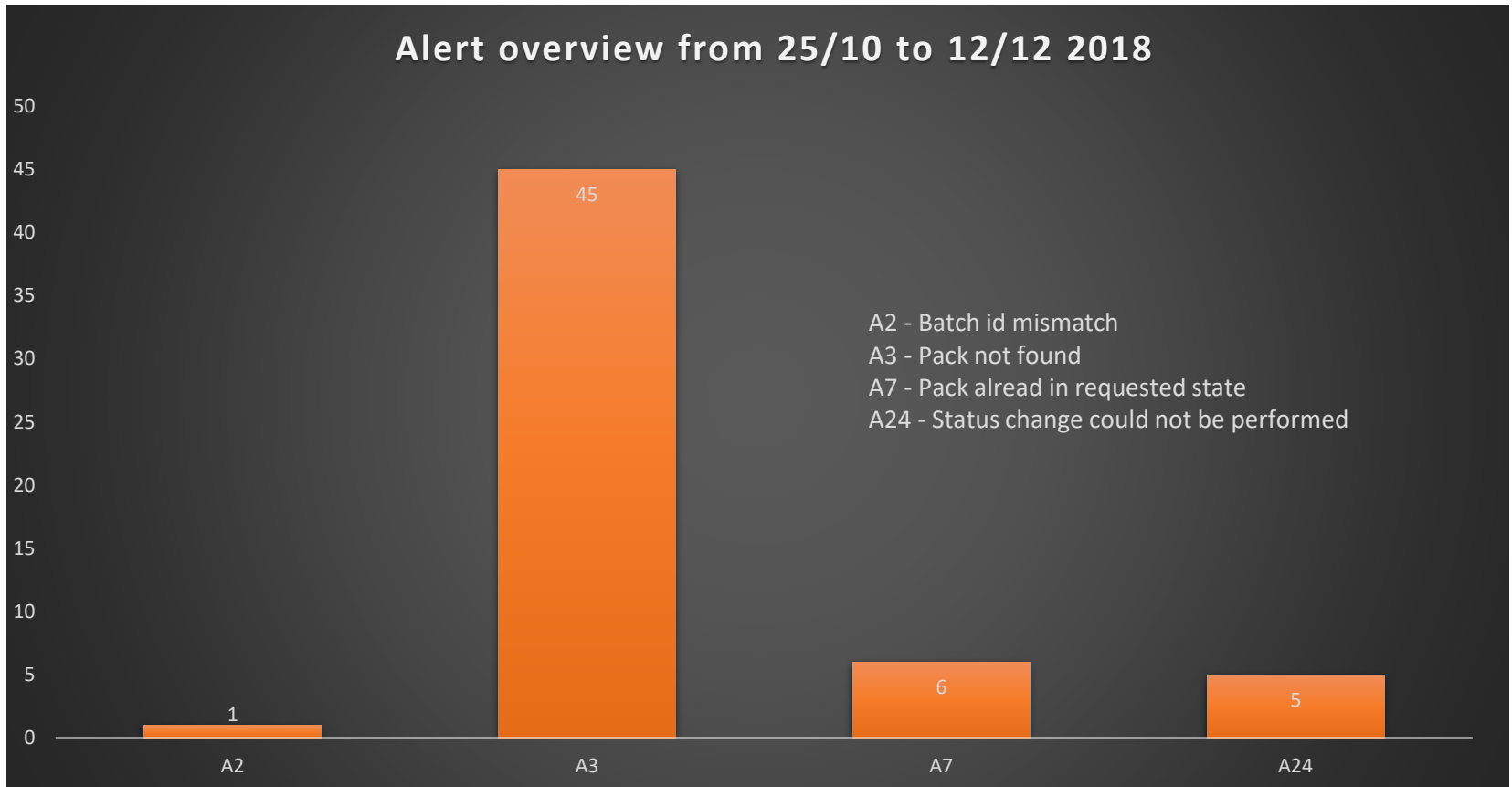
DMVS - PRD



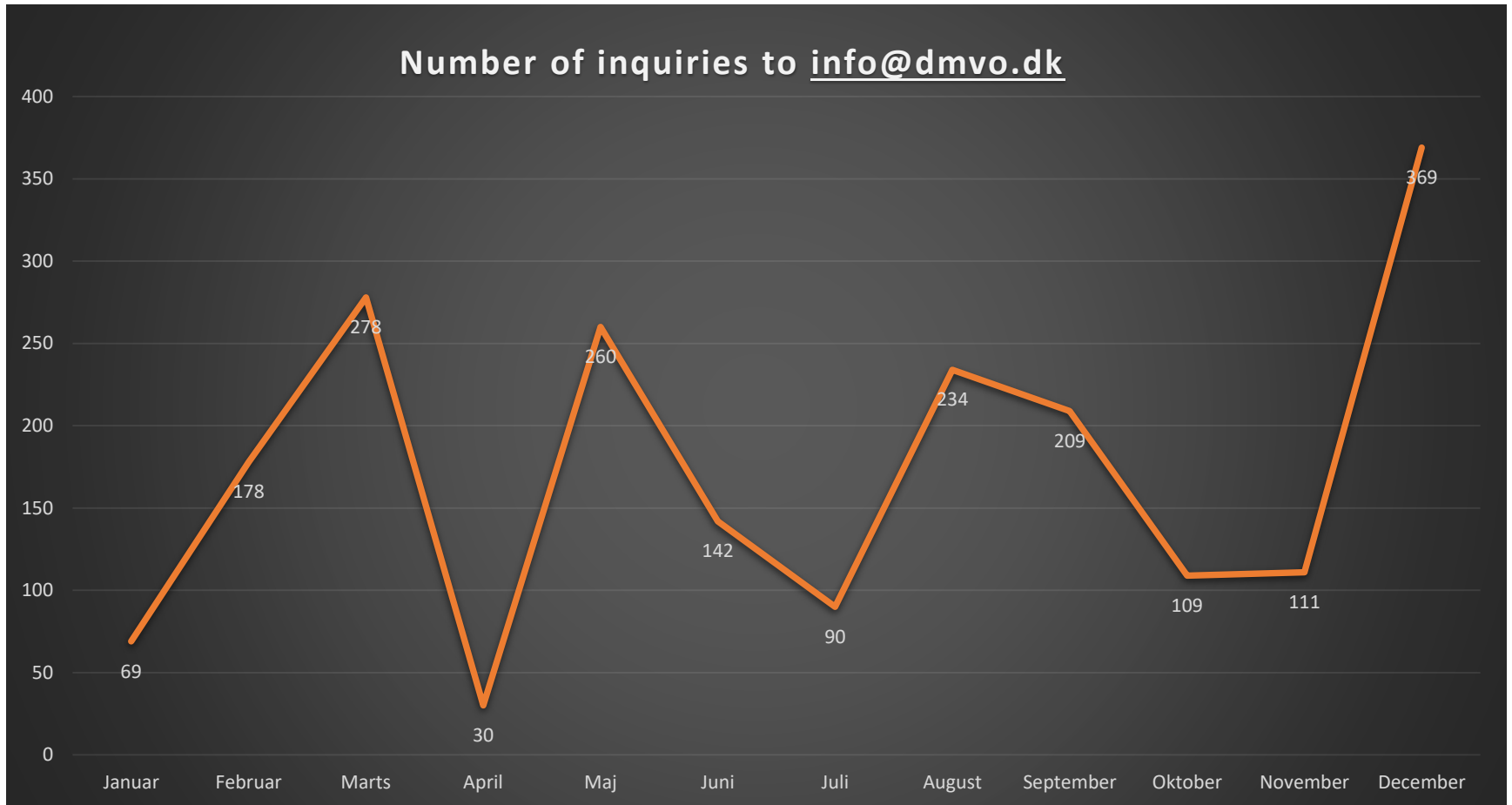
DMVS - PRD



Alerts in PRD



Number of inquiries to DMVO



News from Lægemiddelstyrelsen/NCA

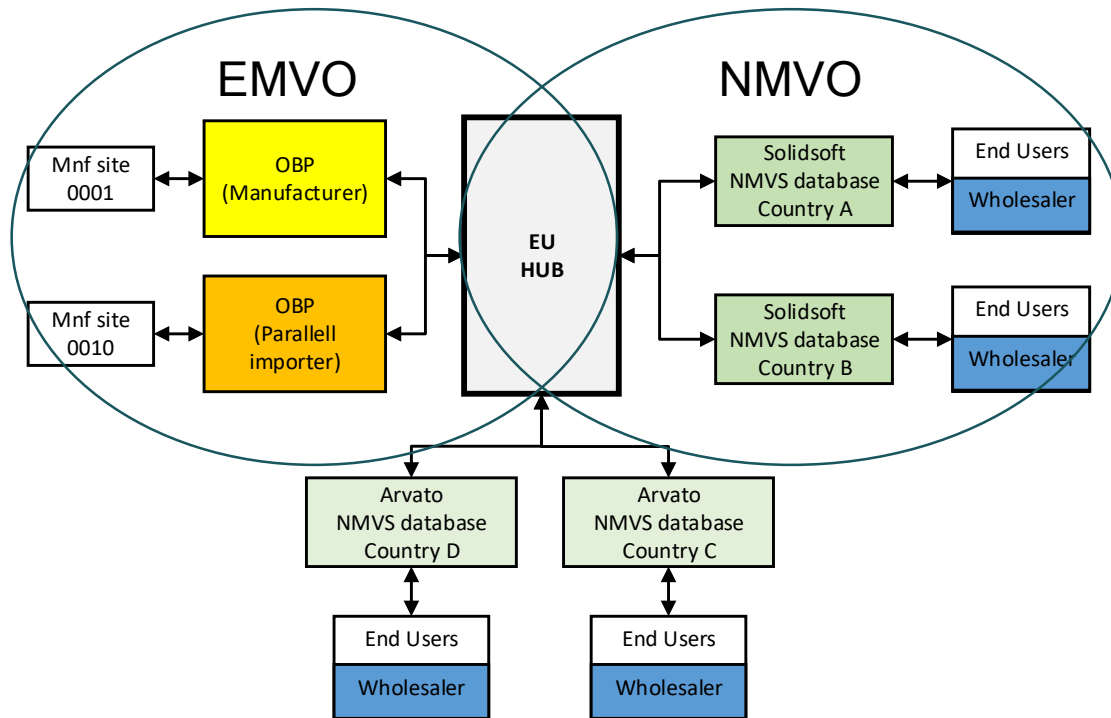
(((BREAKING NEWS)))

- Update of Q&A
 - Update of point 28 is soon to come

- Process description and alert handling from the lægemiddeldatabasen/ the drug database per stakeholder

- Taksten will shortly be updated

EMVS System Diagram



EU HUB: A «router» to/between National Systems & OBP

Use Case	Initiator			
	Manufacturer	Par. Distributor	Pharmacist	Wholesaler
Upload product master data	X	X		
Upload product pack data	X	X		
Recall batch	X	X		
Verify pack	X	X	X	X
Dispense pack	X	X	X	X
Decommission pack		X		
Export pack from EU	X	X		X
Withdraw Product	X	X		
Mark pack as Stolen	X	X		X
Mark pack as Destroyed	X	X	X	X
Mark pack as Free Sample	X	X		X
Mark pack as Sample	X	X	X	X
Mark pack as Locked	X	X		X

The portal

Portalen

DMVO Velkommen [admin@dmvo.dk](#) 
Ikke [admin@dmvo.dk](#)? Venligst [log af](#)



Forside

Brugere

Rapporter

Organisationsindstillinger

Organisationer

Meddelelse

Skift adgangskode

Råd og vejledning

Log af

Forside > Organisationer

Medicin Verifikation Administrationsportal

Organisationer

Opret

Upload

Registrér

Alle

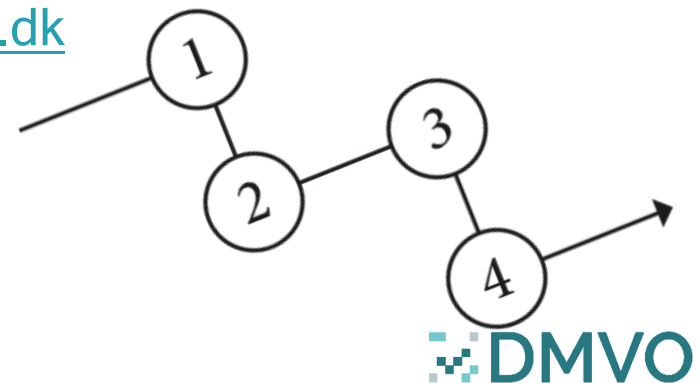
Organisationsnavn	Organisationstype	Status	Registreringsdato	Sidste dato for invitation	Udløbsdato for registrering	Navn på kontaktperson	E-mail på primær kontaktperson	Udvidede produkt datasæt	Aktiviteter
3D Logistik	Grossist	Aktiv	21-11-2018	21-11-2018	05-01-2019	Jakob Stenderup-Jensen	jsj@3dlogistik.dk		 
Albertslund Apotek	Apotek	Afventer				Vinnie Rye Krogh	apoteket@albertslundapotek.dk		 
Amgros	Grossist	Afventer		30-11-2018	14-01-2019	Ulla Bonderup	uob@amgros.dk		  
Apopro Online Apotek	Apotek	Afventer				Tine Vestergaard	vestergaard@apoteket.dk		 
Apotek 1	Grossist	Suspenderet	10-04-2018	10-04-2018	17-04-2018	Apotek1fornavn Apotek1efternavn	z_amanii@yahoo.com		 
Apotek1	Grossist	Suspenderet	17-04-2018	17-04-2018	24-04-2018	SuperBrugerFornavn SuperBrugerEfternavn	Apotek1SuperBruger@gmail.com		 
Apotekeren	Grossist	Suspenderet	19-04-2018	19-04-2018	26-04-2018	Lars Martinussen	dmvogrossisttest@gmail.com		 
Cito IT	Grossist	Aktiv	22-03-2018	22-03-2018	29-03-2018	Mikkel Andersen	mikkel@cito.dk		 

Process for onboarding to DMVS

- DMVO (admin@dmvo.dk) sends an email containing the registration info and a "verifying answer" to be applied in a mail from:
 - Solidsoft **EMVS Authorization** (emvsauthorization@emvs.eu)
 - The email address given to "Danmarks Apotekerforening/The Danish Pharmacy Association" should be stated
 - A temporary username and a passcode is sent from DMVS
 - Using the instructions in the first email, the user is completing the registration

Onboarding of pharmacies

- Instructions sent by email
- DMVO has made a step-by-step guidance for technical registration of pharmacies, which can be found on the homepage of DMVO: www.dmvo.dk
- A tutorial video will be available ultimo December on www.dmvo.dk
- Questions can be directed to: info@dmvo.dk



The portal

Rapporter

DMVO Velkommen [admin@dmvo.dk](#) 
Ikke [admin@dmvo.dk](#)? [Venligst log af](#)



Forside

Brugere

Rapporter

Organisationsindstillinger

Organisationer

Meddelelse

Skift adgangskode




Råd og vejledning

Log af

Forside > Rapporter

Medicin Verifikation Administrationsportal

Rapporter

Dato for forespørgsel	Navn	Rapporttype	Efterspurgt af	Status	Aktiviteter
11/12/2018 09:59	Audit sporringsrapport for produkt tilbagekaldelse (Withdraw Product Audit Trail Report)	Audit sporringsrapport for produkt tilbagekaldelse (Withdraw Product Audit Trail Report)	admin@dmvo.dk	Afsluttet	  

Rapporttyper	Beskrivelse	Aktiviteter
Antal af produkter metriks rapport (Number of Products Metric Report)	Oplisting af total antal produkter i det nationale system pr. produktejende organisation.	
Audit sporringsrapport for produkt tilbagekaldelse (Withdraw Product Audit Trail Report)	Viser samtlige revisionspunkter relateret til et specifikt produkt tilbagekald igennem produktets levetid.	
Batch tilbagekald revisionsspor rapport (Batch Recall Audit Trail Report)	Oplisting af alle batchdetaljer og revisionspunkter i forbindelse med tilbagekaldelsen af et produktbatch fra et bestemt marked.	
Interessentrapport for tilbagekaldelse af produkt (Product Withdrawal Stakeholder Report)	Viser alle revisionspunkter relateret til et specifikt produkttilbagekald igennem produktets levetid samt batch og pakke oplysninger om vellykket tilbagekald.	
Interessentrapport over pakkestatus pr. batch (Pack Status by Batch Stakeholder Report)	Viser antallet af pakker i en given status pr. batch	
Kontraherede grossisters interessent rapport (Contracted Wholesalers Stakeholder Report)	Oplisting af alle kontraherede grossister for et givent produkt	
Metriks rapport for antallet af transaktioner pr. transaktionstype (Transactions by Transaction Type)	Returnerer med antallet af transaktioner pr. transaktionstypen indenfor en bestemt tidsperiode.	

Verification

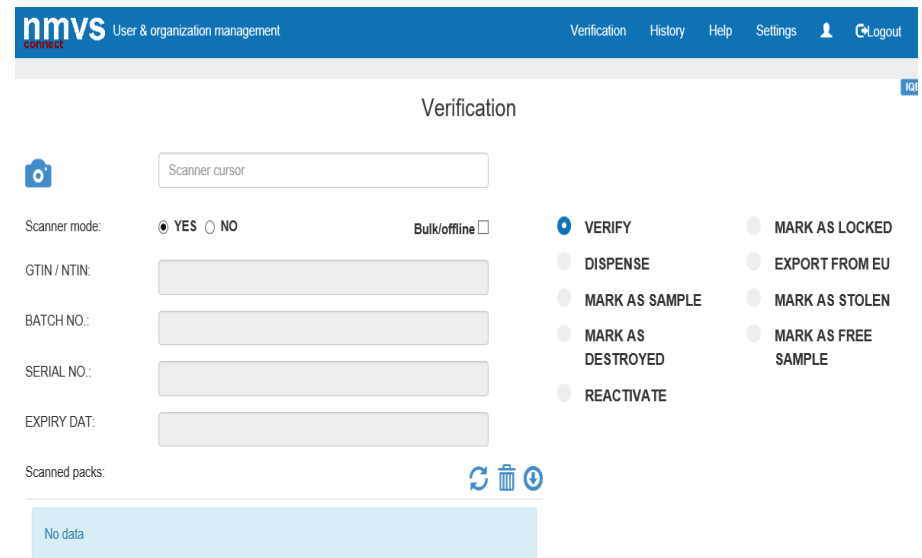
Product Code: 10040108991555 Serial Number: 12077LITJHKTV49HBDJ4 Batch Id: 000003 Expiry Date: 231107	
--	---

GTIN: 11DSARUHH10PU8E00TS4
Serie nr.: 12077LITJHKTV49HBDJ4

■ 3 PL'er:

- Freja
- DHL
- 3D Logistiek
- Statens Serum Institut
- And more.....

NMVS-Connect



nmvs connect User & organization management

Verification History Help Settings Logout

Verification

Scanner cursor

Scanner mode: YES NO Bulk/offline

GTIN / NTIN:

BATCH NO.:

SERIAL NO.:

EXPIRY DAT.:

Scanned packs:

No data

- VERIFY
- DISPENSE
- MARK AS SAMPLE
- MARK AS DESTROYED
- REACTIVATE
- MARK AS LOCKED
- EXPORT FROM EU
- MARK AS STOLEN
- MARK AS FREE SAMPLE

Downtime Information System: DIS

- 2 types of downtime:
 - “Planned” - EMVO has to be oriented a month in advance
 - “Not planned” - 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

Filter

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

Example of planned downtime announcement



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 OSP Company will not be able to upload data in PRD, neither to perform any test in ITE or IQE. Therefore, the OSP 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

HOME MISSION NEWS & EVENTS PHARMACEUTICAL COMPANIES IT CONNECTION PROVIDERS KNOWLEDGE DB CAREERS CONTACT TERMS OF USE PRIVACY POLICY COOKIE POLICY Search

 **European Medicines Verification Organisation**

 **CONTACT:**
+372 611 90 44
helpdesk@emvo-medicines.eu

 **SOCIAL:**
#EMVO #EMV3
#EMO #light@emvo






©2018 - All Rights Reserved to EMVO addr.: Rue de la Loi 20, box 21 - 1049 Brussels, Belgium - VAT no. BE 0838 801 022 - website design: MCOO-D

Stakeholders in DK



Status on stakeholders in DK

- Wholesalers - Nomeco & TMJ are ready
- Hospital pharmacies - Successful UAT, system-wise ready for PRD - supplement with stand alone solution
- Pharmacies - 13 pharmacies (7 new within the last week)
- IT suppliers of pharmacy systems, Cito It is ready, NNIT expects implementation primo February 2019.
- ApoPro (online pharmacy) - integrated solution
- 3PL'er (DHL, DSV, [3D logistik](#), Movianto, Movilitas, Freja, Nomeco HCL) - have chosen stand alone solutions
- SSI - Verilite
- Lægemiddelstyrelsen/NCA - Taksten has been updated and the process of establishing new investigation procedures has begun and will shortly be published

Other topics

- Alert handling



Time for questions



Next meeting



Next information meeting will take place the 18th of January 2019 - same place and time



Feedback is welcome - send an email to info@dmvo.dk