FiMVO

Suomen Lääkevarmennus

Info meeting for MAHs 20.5.2021

Agenda

- Overview - Maija Gohlke, General Manager
- Contract matters - Maija
- EMVS change management - Teijo Yrjönen, QA Manager
- Alerts in Finland - Mirka Koski, Service Manager
- Tips for MAHs - Mirka
- Final words - Maija

FiMVO Board

Nina Ekholm Wenberg

Pharma Industry Finland

(Janssen Finland)

Juho Hellman

Orion Pharma

Tia Geijer

Finnish Paraller Traders

Kai Kaasalainen

Wholesalers Association

Charlotta Sandler

Pharmacy Association

Heikki Bothas

Finnish Generics Association

FiMVO Team

Maija Gohlke
GM

Teijo Yrjönen
QA

Mirka Koski
Service Manager

Henna Rönkkö
Assistant

Susanna Sunila-Eklund
End User Management

Stanley Eklund
Alert Management

FiMVO
Suomen Lääkevarmennus

100%
Users

0.04%
Alerts

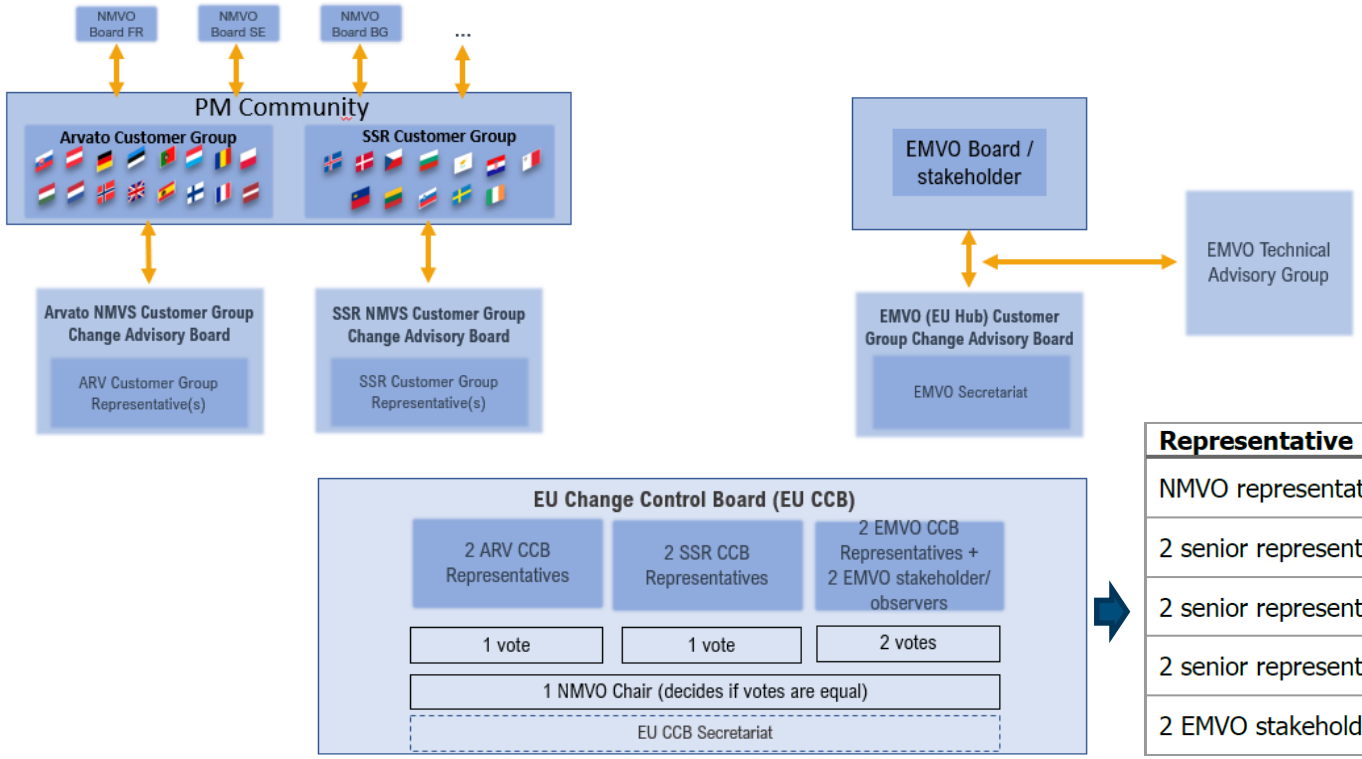

help
Please help us by keeping your contact
and invoicing details up to date!

EMVS Change Management

EU CCB

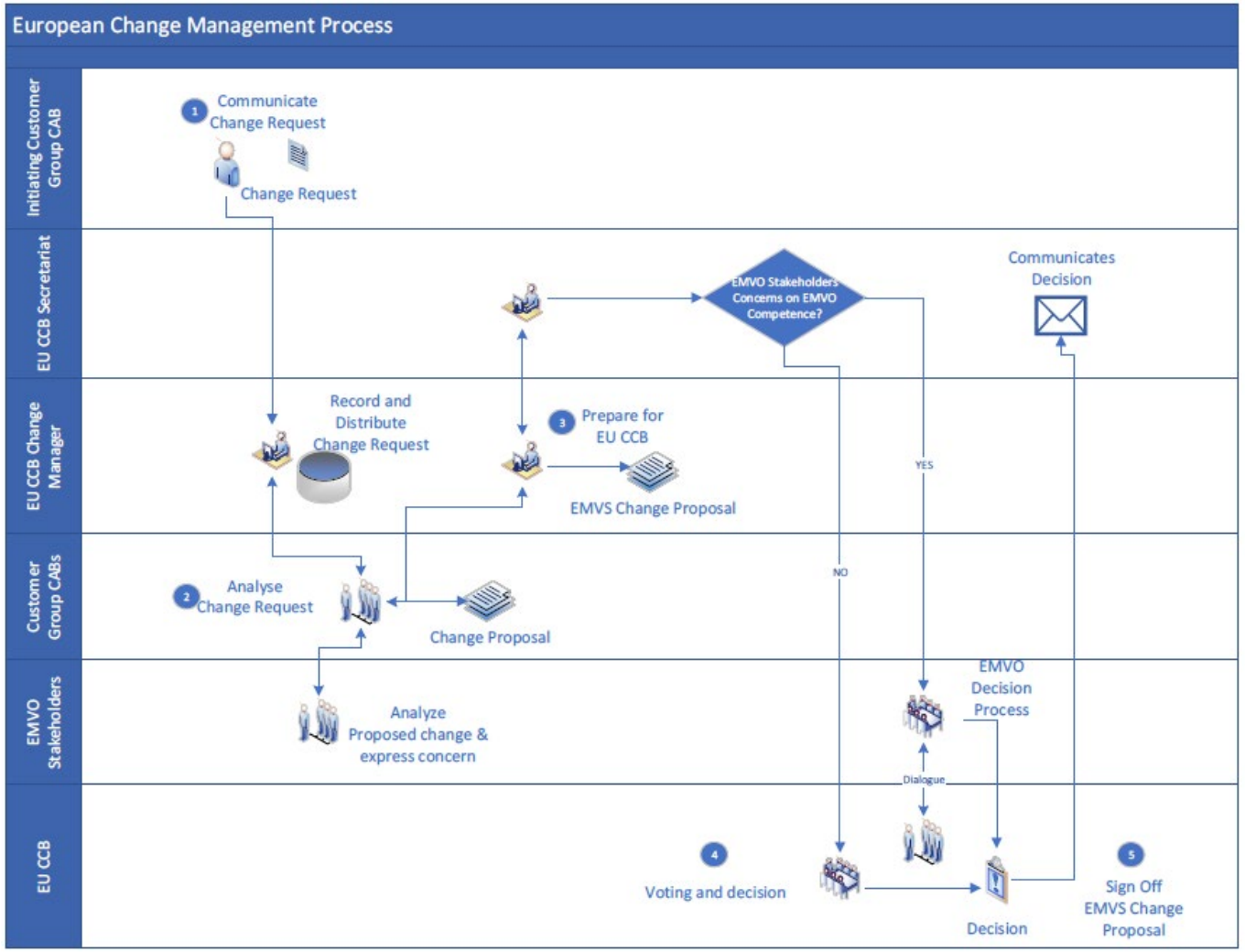
- All changes and fixes planned for any component of the EMVS (EU Hub, ARV NS, SSR NS) are to be assessed and approved/rejected by the EU Change Control Board, EU CCB
- Also, new releases are subjected to EU CCB approval
- All Customer Groups (EMVO, ARV CG, SSR CG) have two representatives in the EU CCB, in addition all CGs have assigned an EU CCB IT SPOC and a EU CCB QA SPOC with deputies
- The EU CCB Chair and Deputy Chair are nominated from NMVOs, independent roles and in the interest of all CGs
- High-level process defined in EMVO_0409 EU CCB Terms of Reference

EU CCB



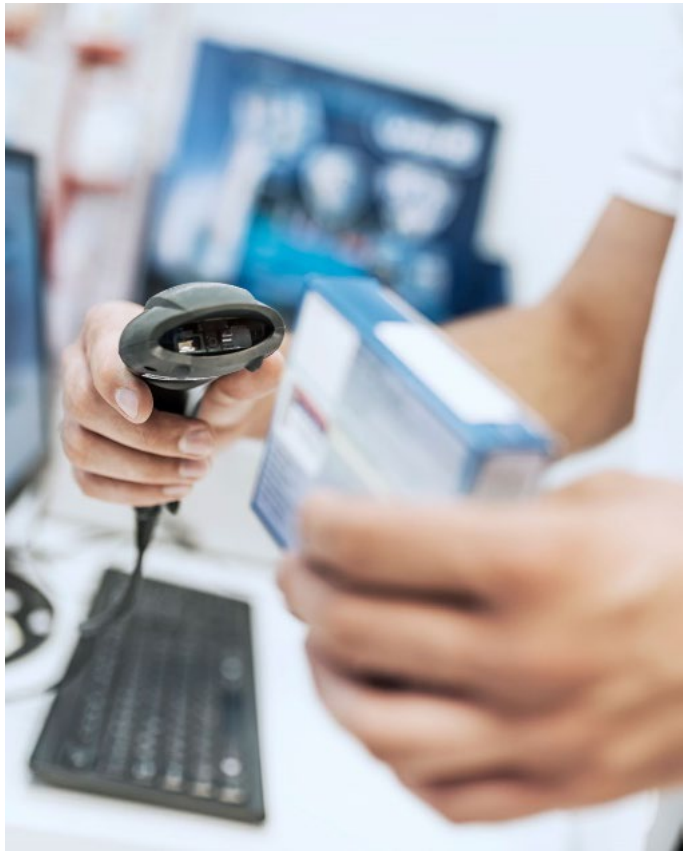
Representative	Role
NMVO representative	Chair
2 senior representatives from the EMVO Customer Group	Member
2 senior representatives from the Arvato Customer Group	Member
2 senior representatives from the SolidSoft Customer Group	Member
2 EMVO stakeholder representatives	Observer

EMVS Change Management Process



EMVS Change Management Process

- Change Requests, Fix Requests and Release Requests are created in Azure DevOps maintained by EMVO
- Are subjected to:
  - A pre-check by all CGs
  - EU IT Analysis (EU CCB IT SPOCs/deputies)
  - EU QA Review (EU CCB QA SPOCs/deputies)
  - EU Business Review (CG Management Groups/EU CCB Members)
  - EU CCB Meeting (EU CCB Members)
- The whole process is managed and monitored in DevOps
- The internal ARV CG and SSR CG Change Advisory Board (CAB) procedures are managed outside EMVO DevOps



Challenges and lessons learned

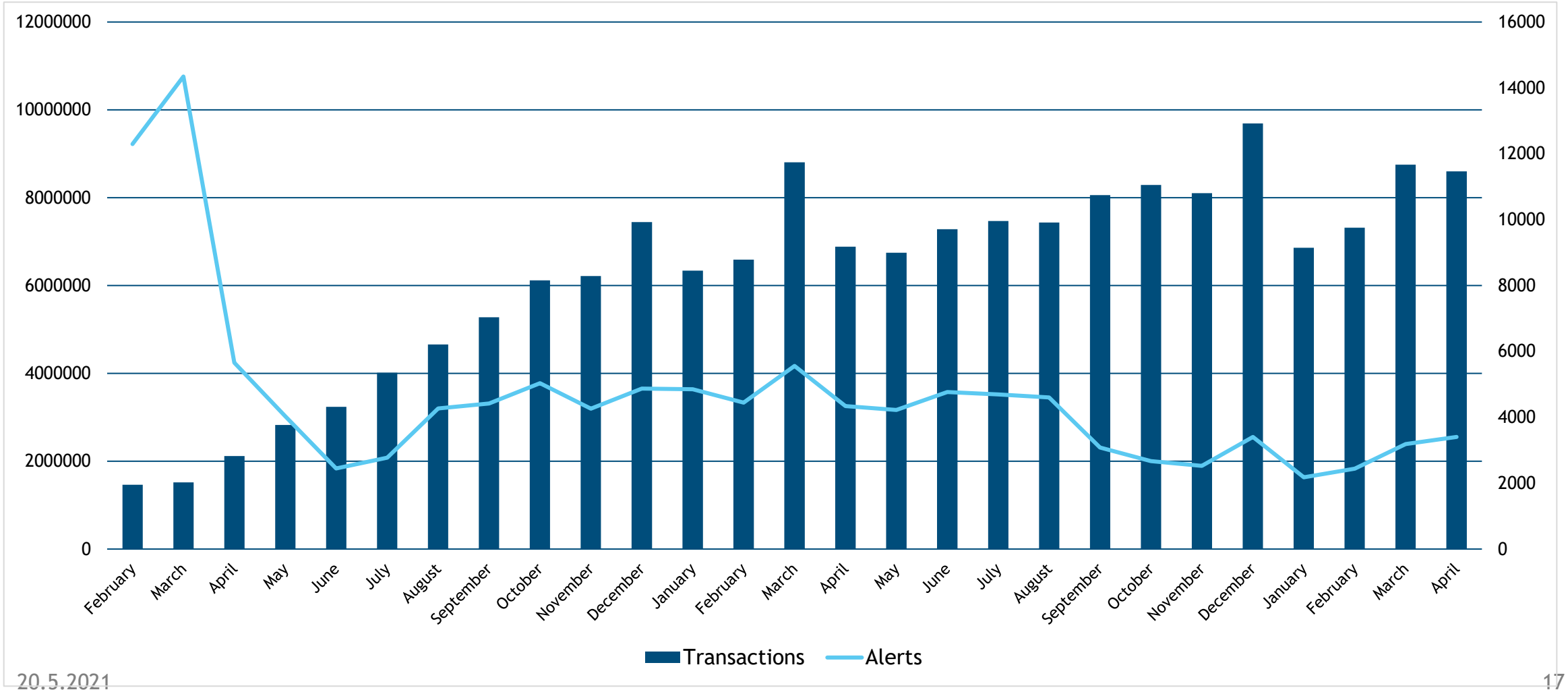
- Change and fix descriptions often very technical in nature, difficult to understand by QA and management
- Time constraints:
  - CRs and FRs have to be created in DevOps and submitted to the EU CCB process approx. 8 weeks before the EU CCB meeting
  - The time available for the EU QA Review sometimes very short
- Late stakeholder responses/comments on some CRs
- Classification of some CRs/FRs
  - CR or FR
  - Emergency fix or other fix
  - Standard change – within or outside the deployment window
  - Maintenance change
- EMVS Roadmap

Alerts in Finland

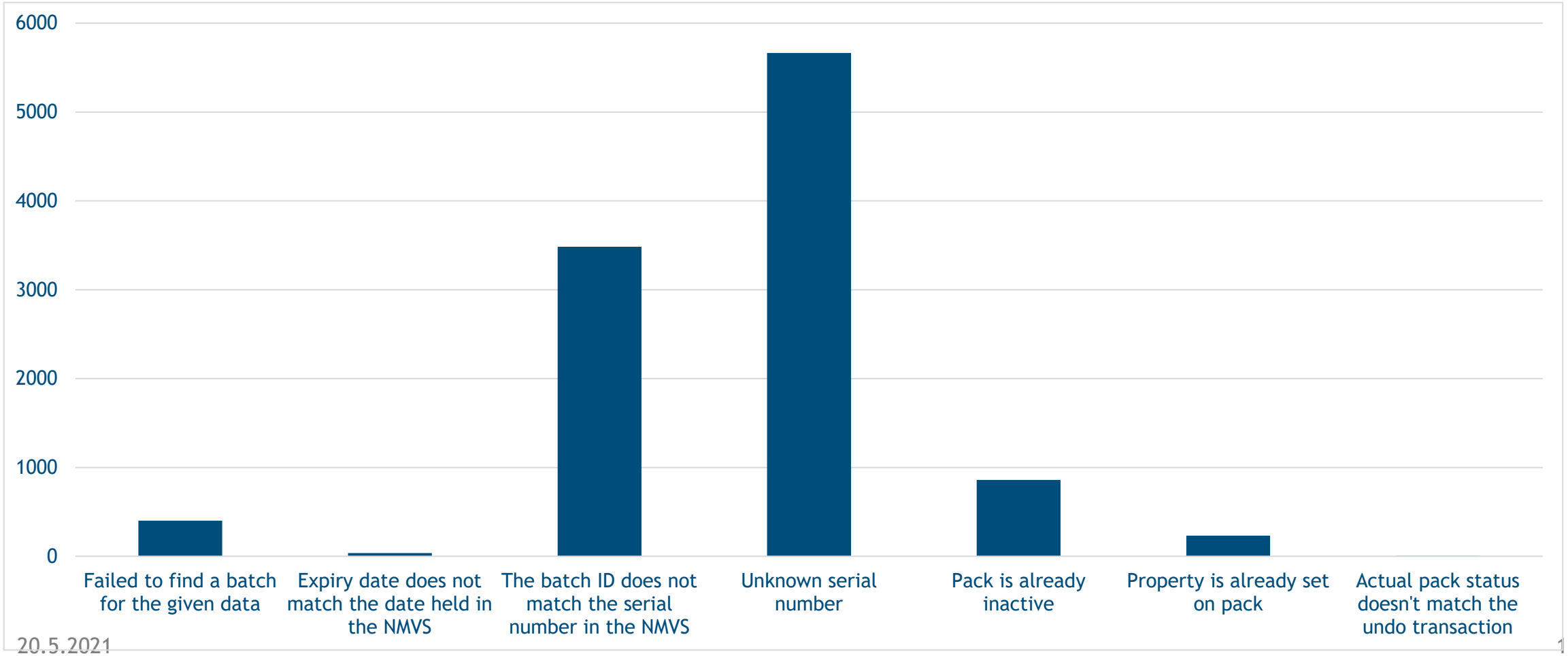
FiMVO's statistics

- Please note that the alert statistics of FiMVO include only the alerts caused by the end users in Finland => the following statistics do not include any alerts created via the EU HUB, e.g. alerts raised by IMTs or OBPs

The number of transactions and alerts per month Feb 2019 - Apr 2021



The number of alerts by type in 2021



Most common alert types and root causes in FiMVS

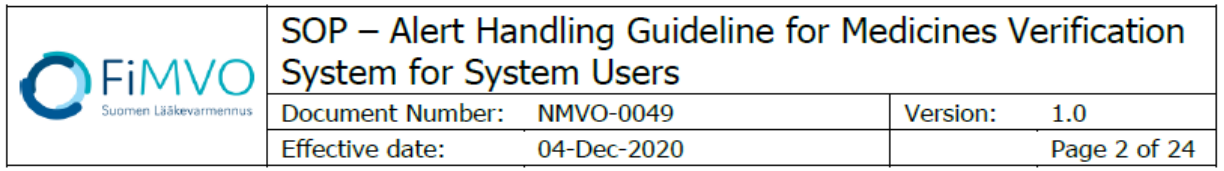
- Unknown serial number
  - Usually end user data entry errors (scanning or manual data entry error)
  - In some cases a part of the batch data has not been uploaded in FiMVS by MAH/OBP
- The batch ID does not match serial number in FiMVS
  - Practically all caused by end user data entry errors (scanning or manual data entry error)
  - An EAN code on the pack often causes an incorrect scan – please remove EAN codes from packs if possible (EAN codes not needed by supply chain)

Alert management process at FiMVO

- FiMVO does not expect the MAH/OBP to report alerts and/or the results of their investigations on a regular basis, unless FiMVO has been a part of the alert investigation
- FiMVO is not allowed to provide the end user contact information to the MAH/OBP (as stated by the NCA)
- FiMVO will contact the end user if there is a reason suggesting a possible falsification
- Regarding many alerts, especially unknown serial numbers, the alerting pack is often successfully verified after an alert due to a data entry error – no need to contact FiMVO
- The end user is also responsible for solving an alert which they receive – they are expected to contact the MAH/OBP if the root cause is unclear (non scanner issue)

Alert Handling Guideline

- FiMVO has published a guideline on handling the alerts from both end user and from the MAH/OBP point of view
- FiMVO has prepared the document in cooperation with our stakeholders in the pharmaceutical distribution chain
- The guideline is available in Finnish, Swedish and English:
  - Lääkevarmennusjärjestelmän hälytysten käsittelyohje järjestelmän käyttäjille
  - Anvisning för hantering av läkemedelsverifikationssystemets larm
  - Alert Handling Guideline for Medicines Verification System for System Users



FiMVO Suomen Lääkevarmennus	SOP – Alert Handling Guideline for Medicines Verification System for System Users		
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Tips for MAHs

Data management by OBPs

- Product Master Data (PMD) and Product Pack Data (PPD) must be uploaded to all the target markets and only the target markets (also the contract with the FiMVO must be in place before uploading PMD)
- Retrospective uploads are possible (please remember to update also the PMD if needed)
- Please keep the Nordic Vnr-numbers and product notifications up-to-date: https://www.laaketietokeskus.fi/en/pharmaceutical-information/vnr-services

A few additional reminders to OBPs

- Packs must not be verified when not at hand (excluding cases of alert investigation)
- Bulk transactions may lead to a large number of false alerts – please, pay attention when performing these operations!
- Please keep also FiMVO informed of:
  - Batch recalls and product withdrawals
  - Products sold under a special license in Finland
  - Any information letters sent to the distribution chain

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Follow the news and contact us!

- Social media: FiMVO.fi I LinkedIn I Twitter
- Subscribe to FiMVO's newsletter: https://uutiskirje.fimvo.fi/
- For alerts, system and data related inquiries and support, please use: nmvs@fimvo.fi
- For contracts and invoicing, please use: info@fimvo.fi

Thank You!

The Finnish Medicines Verification Organisation FiMVO

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