FiMVO

Suomen Lääkevarmennus

Alert management in Finland and FiMVO's experiences

FMD and Regulatory Affair Symposium,

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FiMVO
Suomen Lääkevarmennus

Topics

- FiMVS by numbers
- Statistics on alerts in FiMVS
- The main principles of alert management process at FiMVO
- FiMVO’s experiences: challenges & way forward

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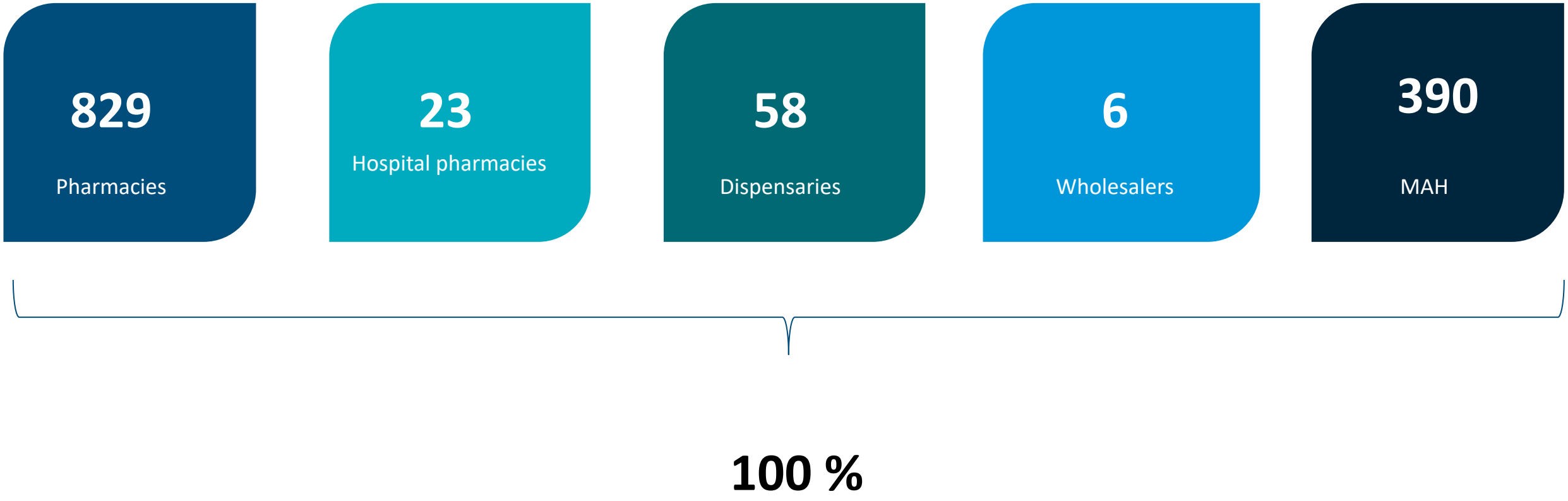
Supply chain summary



100 %

Data summary

9908

Products

50 144

Batches

300 000

Transactions/weekday

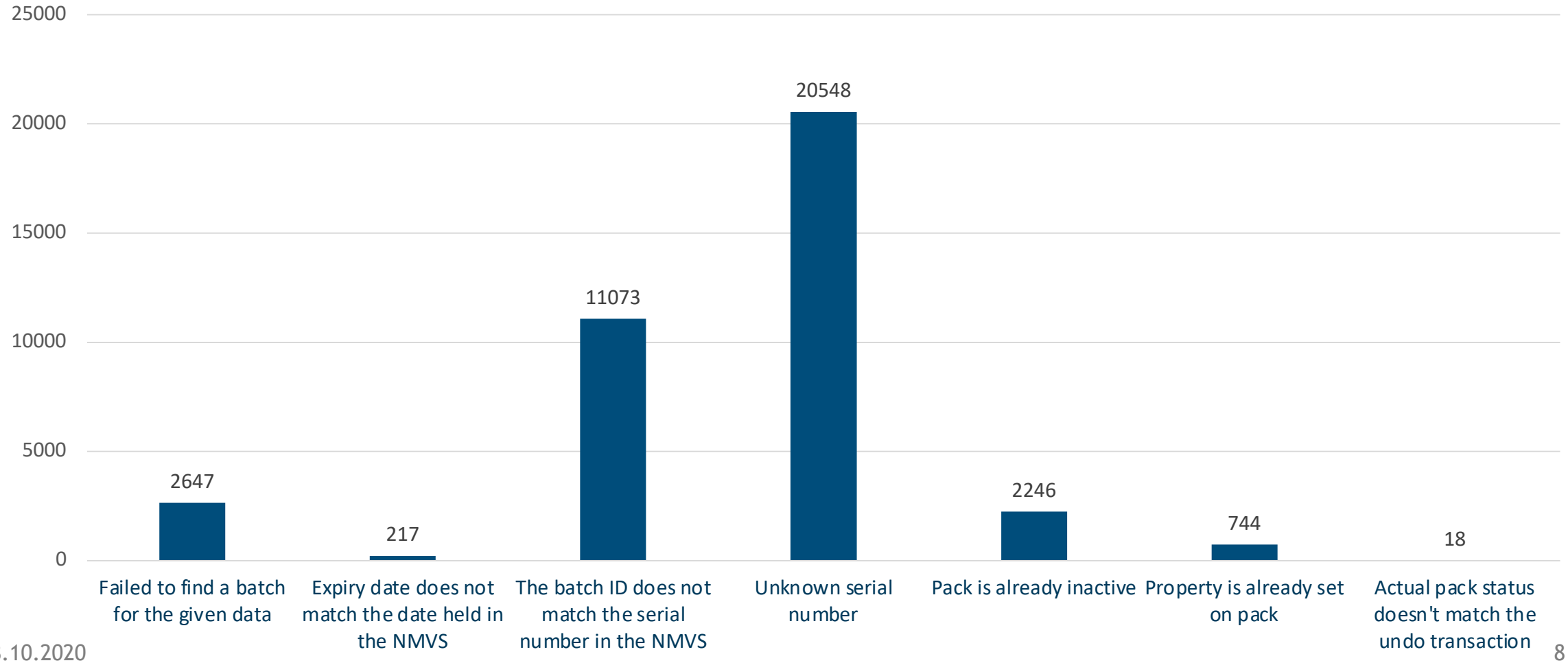
200

Number of alerts/ weekday

Statistics on alerts in FiMVS

The number of transactions and alerts per month Feb 2019 - Aug 2020

The number of alerts by type in 2020



Most common alert types and root causes / 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)
- Failed to find a batch
  - Some of these alerts are caused non-EU-serialized packs (”Indian packs” with correct NTIN/GTIN in the 2D data matrix)
  - Occasional failures by OBPs to upload Product Pack Data to FiMVS (will be detected by the wholesaler)

Most common alert types and root causes / FiMVS

- Pack is already inactive
  - Caused usually by the end user performing a decommission transaction for the same pack several times or the same end user has already decommissioned the pack for some time earlier
  - Another end user has already decommissioned the pack from the system – these situations are often generated due to the borrowing of packs between pharmacies, dispensaries and hospital pharmacies or the return of a borrowed pack
  - In some rare cases it has been detected that two different packs with the same identical identifiers have been distributed by the manufacturer by mistake
  - MAH/OBP has made a bulk decommission to a certain batch and the packs create alerts when dispending the packs by the end user (pharmacy / hospital pharmacy / dispensary)

Main principles of alert management at FiMVO

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 management process at FiMVO

- FiMVO monitors exceptions and alerts daily and proactively contacts the end user or MAH if needed (e.g. to request clarification regarding a pack audit trail or to request a reason for bulk transactions that have caused a large amount of alerts)
- FiMVO does not use any external and separate national alert management system
- For more information:
  - FiMVO has published a guideline on handling the alerts from both end user and from the MAH/OBP point of view
  - The guideline is available in Finnish, Swedish and English: https://www.laakevarmennus.fi/en/news/updated-guideline-handling-alert-system-published

FiMVO’s experiences: challenges & way forward

Challenges & way forward

- Data management by OBPs
- Non-EU-serialized packs
- Open sharing of information and experiences among the stakeholders
- Fine-tuning of barcode scanners
- Development of end user IT systems so that the user can easily see the information content of the request that was sent to FiMVS and the reply from FiMVS and can distinguish between a deviation and an alert
- The entire supply chain should have enough information about the reasons for different alerts and of their solutions => guideline on handling the alerts has been published

Contact us!

- www.fimvo.fi
- https://www.linkedin.com/company/fimvo-finnish-medicines-verification-organisation

- 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!

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