FIMVO WORKSHOP

Paul Mills – EMVO – June 2019

EUROPEAN HUB UPGRADES

- Two primary topics
- System Stability
- NCA reporting support
- V1.5 (due approx. mid-August)
  - New complete master data report
  - Simplified randomisation checker
  - Support for bulk sample and free sample transactions
  - Support for declaring the national code as mandatory (where requested)
  - Bug fixes and stabilisation changes

PURPOSE OF THIS SESSION

- To see if you have any questions and issues.
- Nothing is out of play – ask anything you want.

MY QUESTIONS…

- I came prepared ☺

- What issues, if any, are you and your OBP having with data loading?
- Are you receiving sufficient information regarding alerts?
- What are the top three items or features you would like to see the EMVS as a whole supporting?
- How well does EMVS support wholesaling operations and what else would you like to see implemented.

MY QUESTIONS…#2

- We have a long term plan to connect with the EMA SPOR system to consume master data and MAH contact details directly from the EMA system.
  Do you see this as a valuable step or something ‘nice to have’?
- Name the top item for EMVS that you feel would help the Finnish market? (anything goes – be bold).

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Medicines verification – The finishing pieces

12 June 2019

Teijo Yrjönen, FiMVO

FiMVO
Suomen Lääkevarmennus

Topics

Status update

a) End users
b) MAHs, Product Master Data & Batch Data

Statistics on alerts in FiMVS

FiMVS – First four months

a) Successes
b) Challenges
c) Way forward

Status update / End users

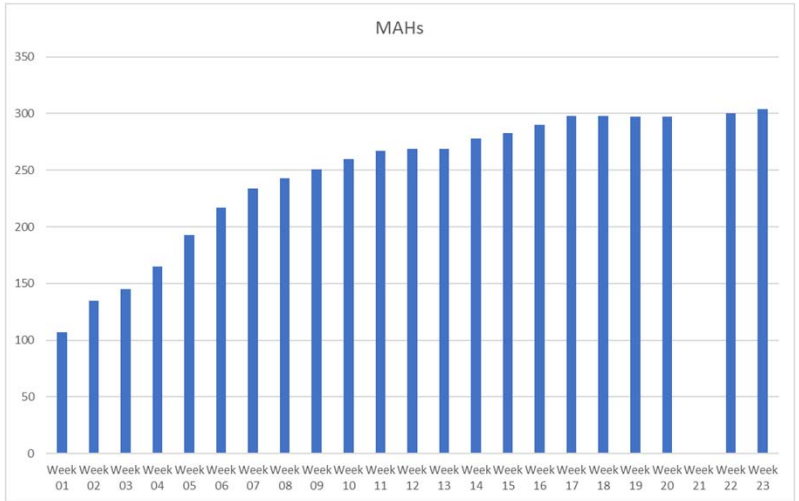
End users created in FiMVS by FiMVO:

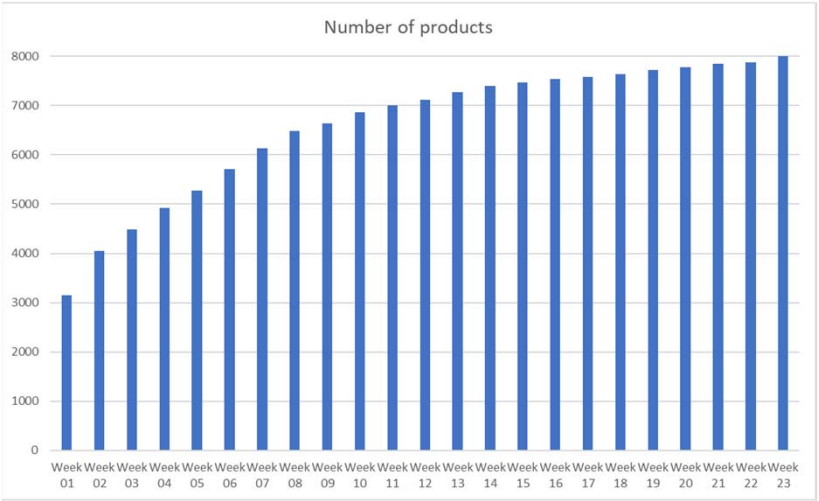
- 821 pharmacies/dose dispensers
- 23 hospital pharmacies
- 58 dispensaries
- 6 wholesalers (Magnum Medical, Medapta, Medifon, Oriola, Tamro & Veripalvelu (Blood service))

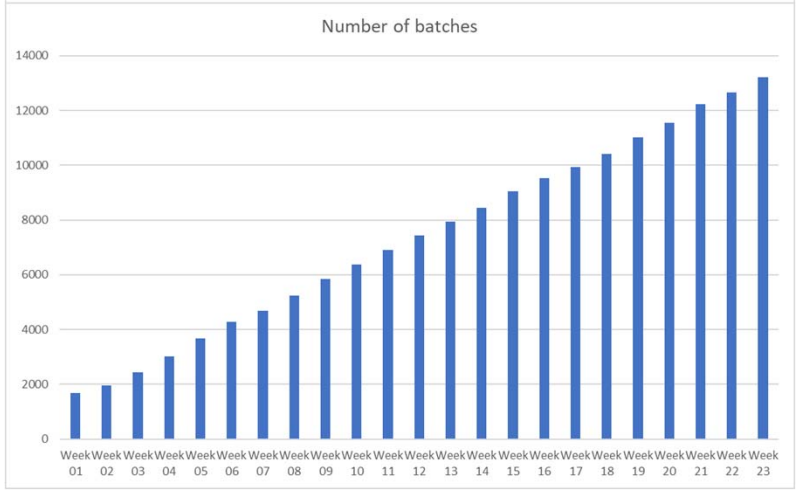
Active users:

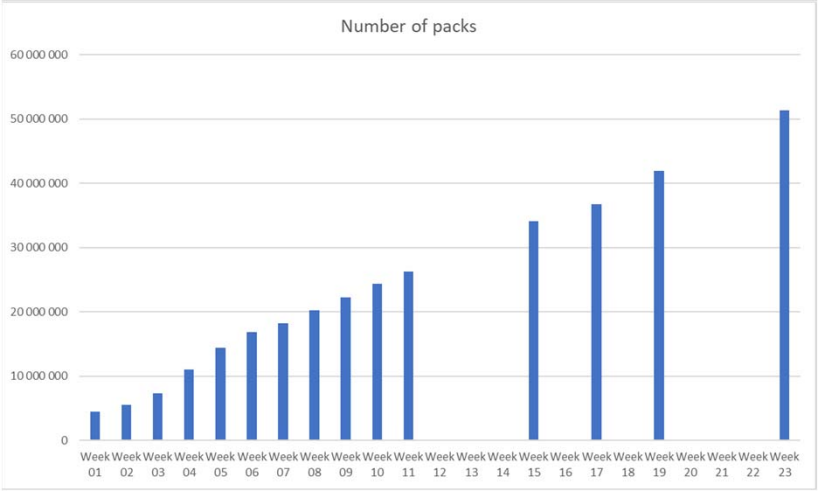
- 821 pharmacies
- 23 hospital pharmacies
- 38 dispensaries
- 5 wholesalers

Status update / MAHs, PMD, PPD

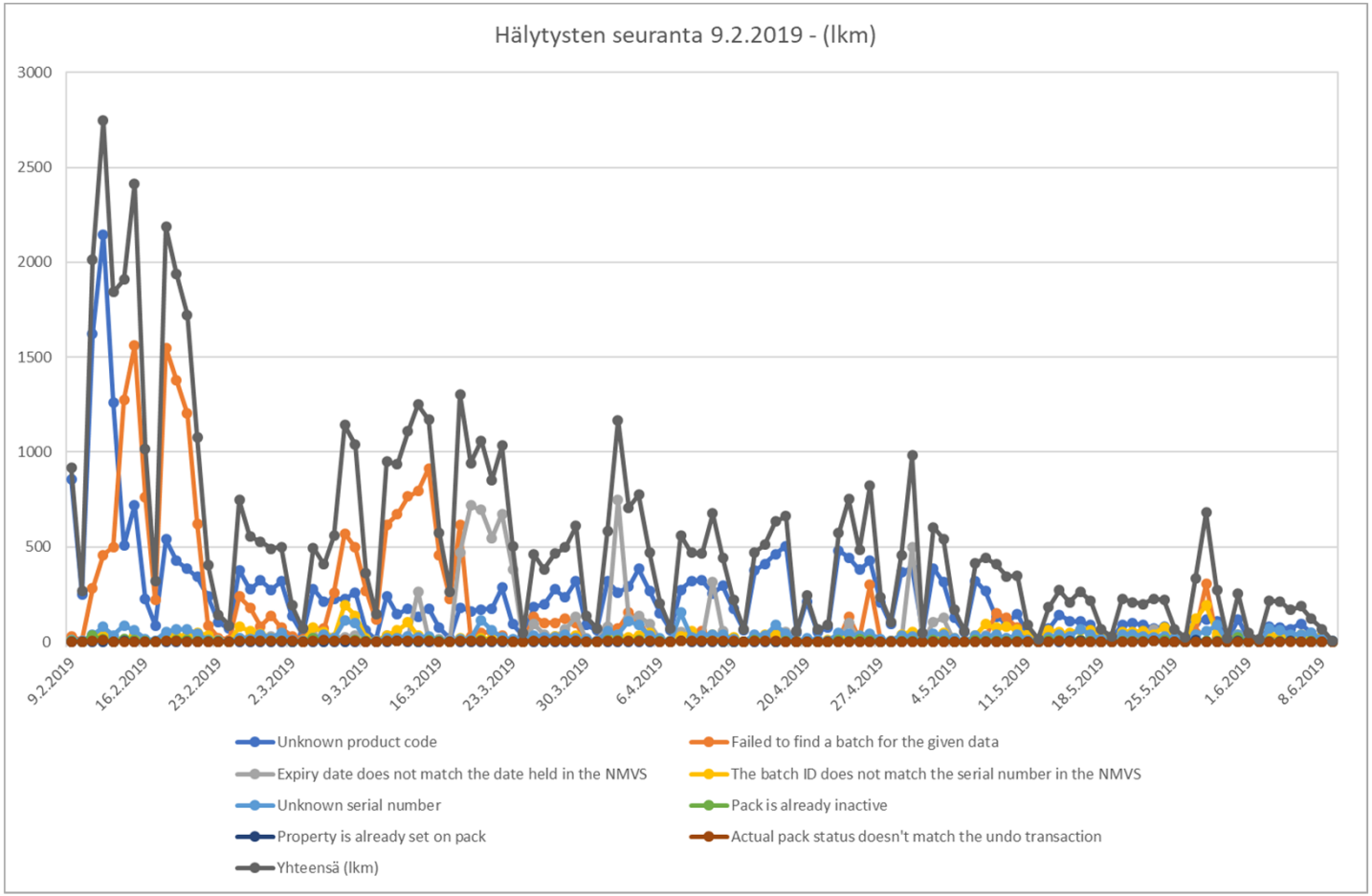




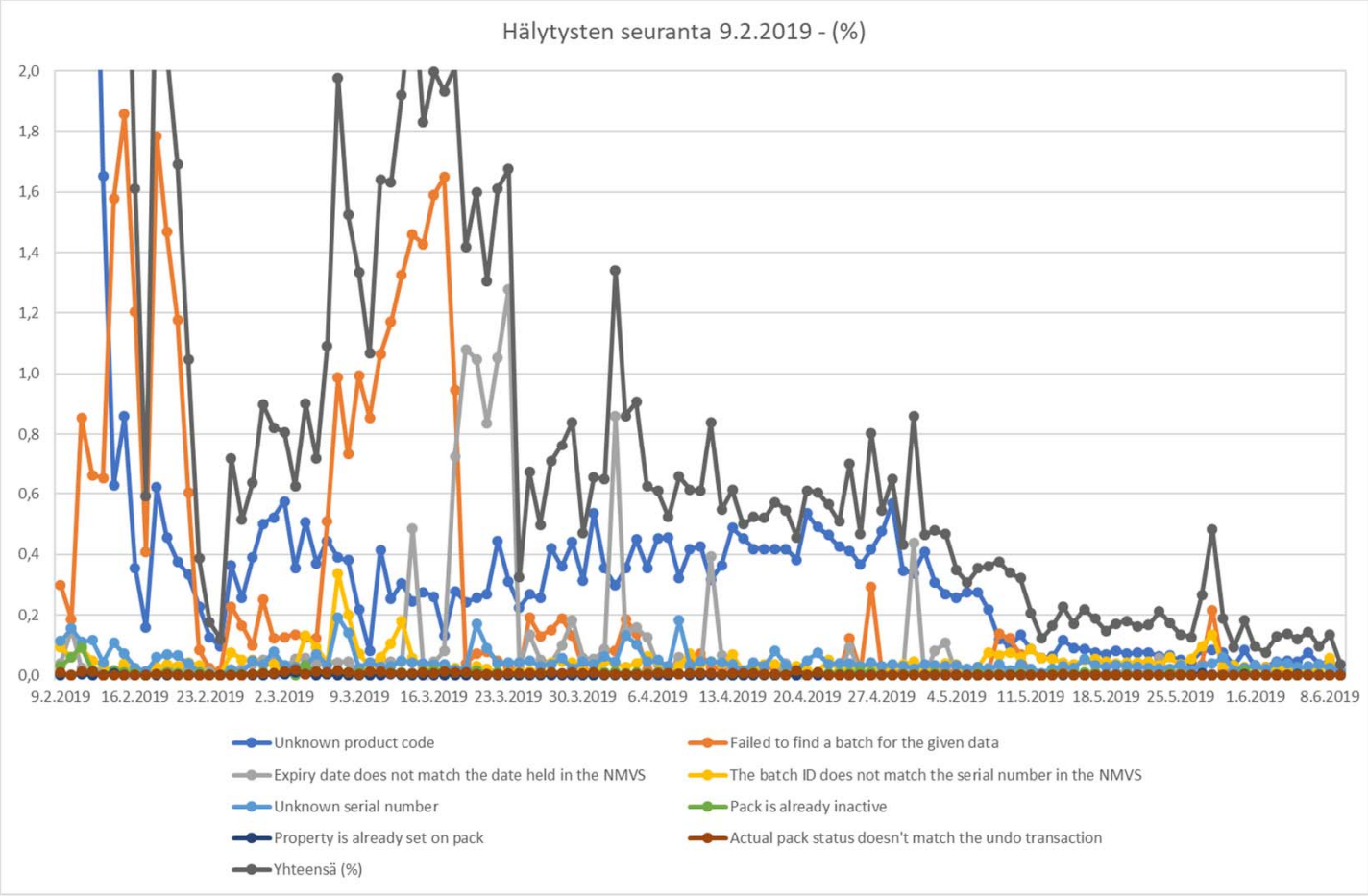




Statistics on alerts in FiMVS



Statistics on alerts in FiMVS



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Statistics on alerts in FiMVS

- Unknown product code
  - A majority of these alerts are caused by non-EU-serialized packs (”Indian packs” with incorrect GTIN in the 2D data matrix)
- Failed to find a batch
  - Also 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)
- Expiry date mismatch
  - No longer an issue, only one product batch with known mismatch
  - Mismatch between 2D data matrix and FiMVS, in some cases shelf life has been incorrectly printed on packs

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Statistics on alerts in FiMVS

- Batch ID does not match serial number in FiMVS
  - Approx. 35% of these alerts are caused by one product with incorrectly uploaded batch ID (OBP data entry error)
  - The rest caused by random scanning errors
- Unknown serial number
  - Usually scanning errors
  - In some cases a part of the batch data has not been uploaded in FiMVS
- Pack is already inactive
  - Caused by the end user performing a Dispense transaction for the same pack many times
  - FiMVS allows the end user to perfom the Dispense transaction by scanning the 2D data matrix four consecutive times before raising an alert (double dispense functionality)
  - If, however, the pack is first dispensed by scanning and then by manual transaction (or vice versa), FiMVS alerts immediately after the second Dispense transaction

FiMVS – First four months

Successes:

- FiMVS was successfully taken into use
  - All users have been connected and use the system
  - No interruptions on the supply of prescription medicines
- Users, FiMVO and OBPs all have gained experience on how to use the system and how to identify and correct various issues that may arise
- End user IT systems have functioned relatively well and there have been no major incompatibility issues or other technical issues
- The soft launch approach has ensured a stable supply of medicines without any major interruptions or issues

FiMVS – First four months

Challenges:

- Tight implementation schedule
  - Certain technical issues with the EU Hub and national systems some of which were corrected in December 2018, some later
  - Some OBPs were late
  - Solutions developed by many Gateway Providers were not completely ready on time
  - End user IT systems implemented very late (pharmacies, hospital pharmacies, dispensaries)
  - Not enough training by the users
- Common ways of working to be defined
- Data management by OBPs
  - Expiry dates on packs and in FiMVS
- Non-EU-serialized packs
- Barcode scanners (configuration, lighting, placement of 2D data matrix adjacent to linear barcode,…)

FiMVS – First four months

Possible solutions:

- Open sharing of information and experiences among the stakeholders
- Updating of packaging materials: removal of linear barcode or placing it on the opposite side of the carton than the 2D data matrix
- 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

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Thank you!

Any questions or comments?

Medicines Verification – Wholesaler perspectives

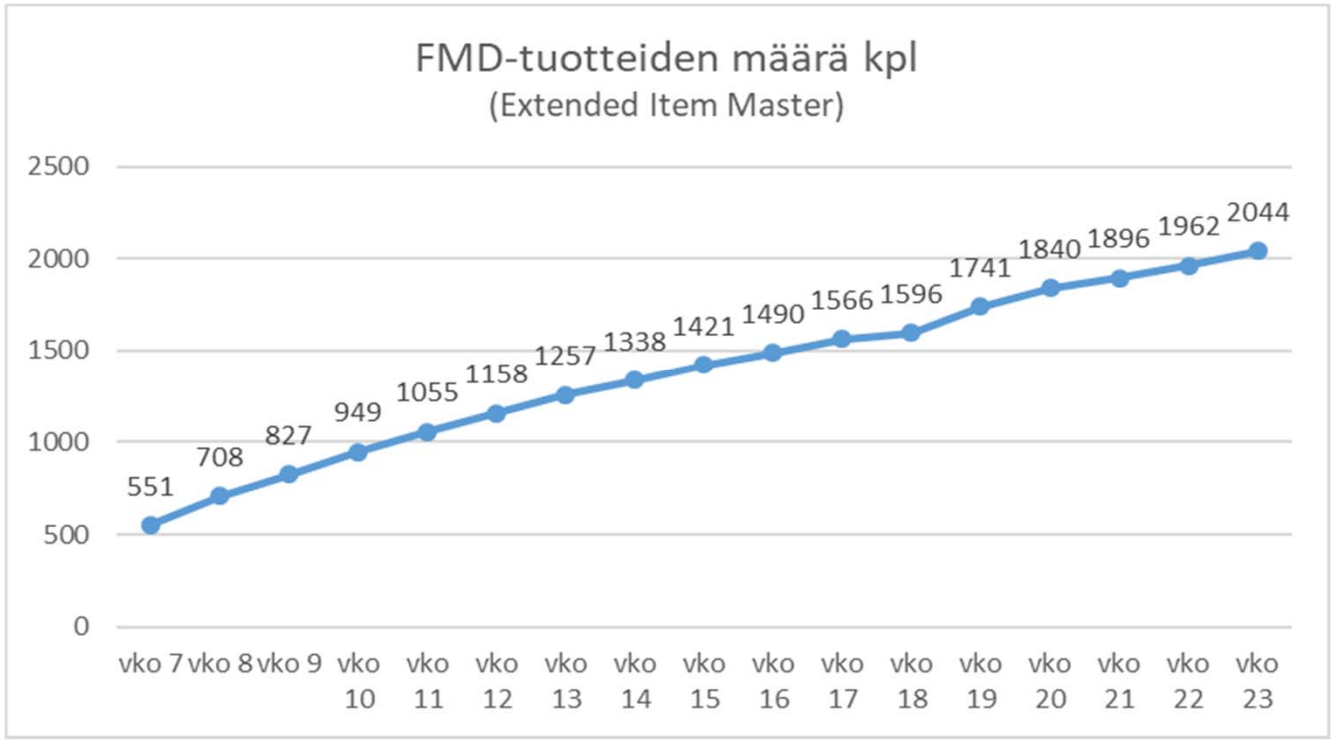
Kati Vuorikallas
Quality and Development Director
@kativuorikallas

First of all… thank you !

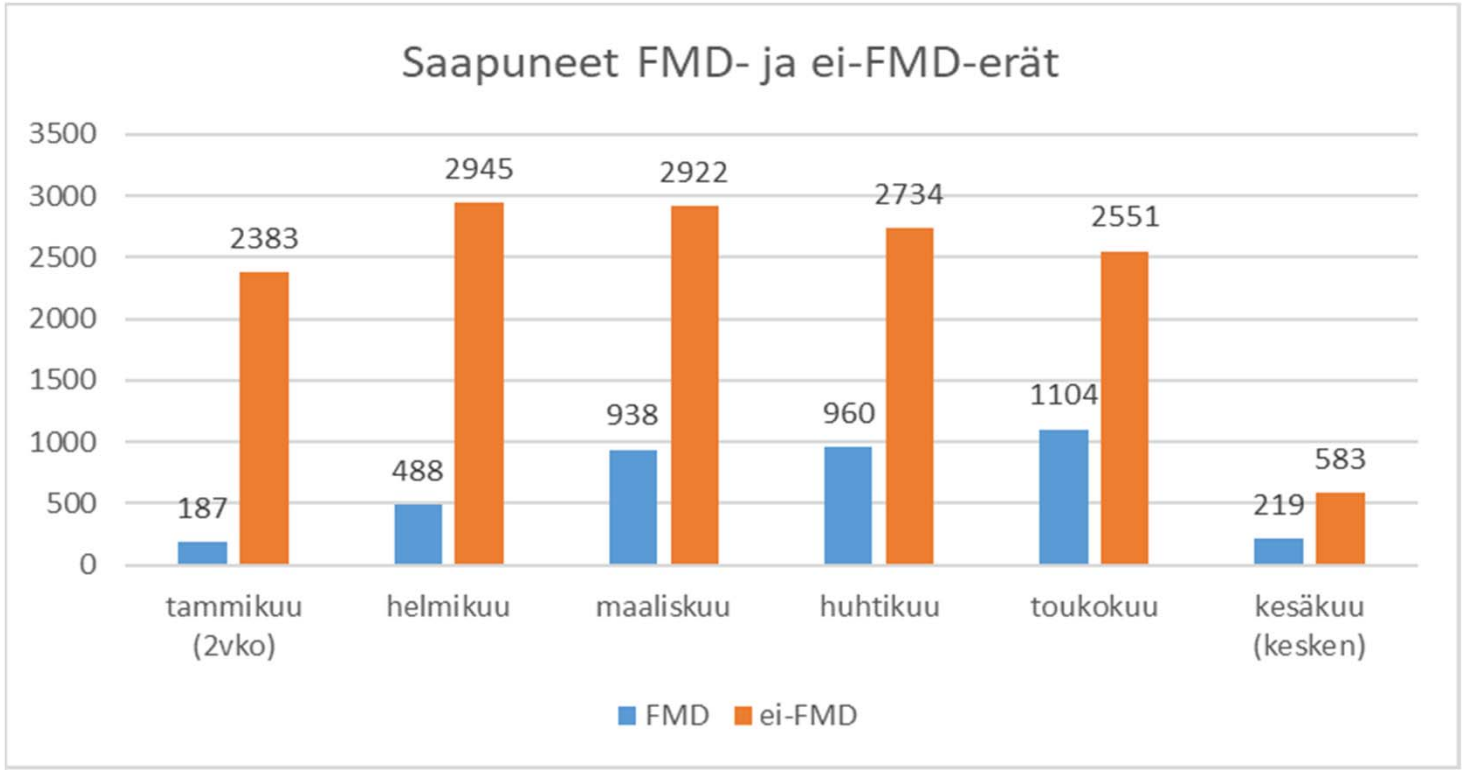
- Stakeholder co-opeartion has been excellent throughout the implementation
- Quick response times to wholesaler questions / issues

Current status – products

- < 50% of arriving SKU's are FMD ready
- Increases steadily

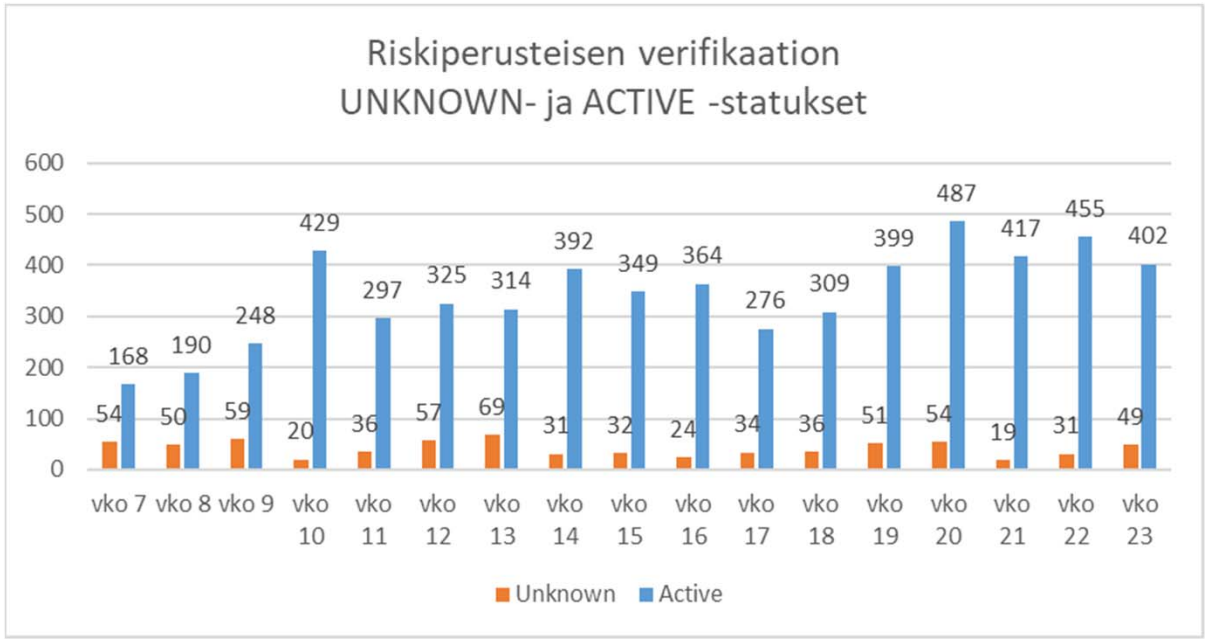


Current status – incoming batches



Current status –verification

- Soft lauch verification
- 1 product / batch
- Unknown – status remains steady



Success

- IT systems have worked well
- Incoming goods process has functioned well
- Personnel well trained
- Change control and risk management appropriately done
- No need for 100% verification, master data updated

What have we learnt so far?

- Readiness level varied between the companies

- Data loading issues
  - Products in quarantine
  - Slowed down incoming goods checks

- Expiry dates
  - Differences between the expiry printed on the packaging vs 2-D matrix information
  - Standard format for expiry date MM/YYYY

Continuous improvement

- Data should be uploaded and verification tested before products are sent to wholesaler
  - Part of product certification?
- Safety features
  - Robust enough
- Handling of exceptions
  - Products with MA but foreign packages
  - Products with another product status in country of origin (special license)

Thank You!

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