FiMVO

Suomen Lääkevarmennus

Info meeting for MAHs 15.2.2022

Agenda

- Introduction - Maija Gohlke, General Manager
- Contract and Invoice matters - Maija
- Guest speaker: Medicines verification from a pharmacy perspective – Kati Vuorikallas, Pharmaceutical Director from Yliopiston apteekki (University pharmacy)
- Alert Status in Europe & in Finland - Mirka Koski, Service Manager
- Alert Management - Mirka
- Tips for MAHs – Teijo Yrjönen, Quality Manager

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END USER MANAGEMENT
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100%
Users

0,08%
Alerts during weeks 1-5/2022;
the increase is due to technical problems with a end user software

Invoices for 2022 are out!

- We’re still expecting quite a few payments – please check you’re up to date!
- Is your incoiving information up to date?
  - Use this pdf
  - And check out our website

Medicines verification from a pharmacy perspective

Yliopiston Apteekki

Yliopiston Apteekki

Background
- Founded in 1755
- Owned by the University of Helsinki
- Employees 1300
- Sales 333,2 meur (2020)

Business Units
- 17 pharmacies
- ya.fi
- Healthcare services

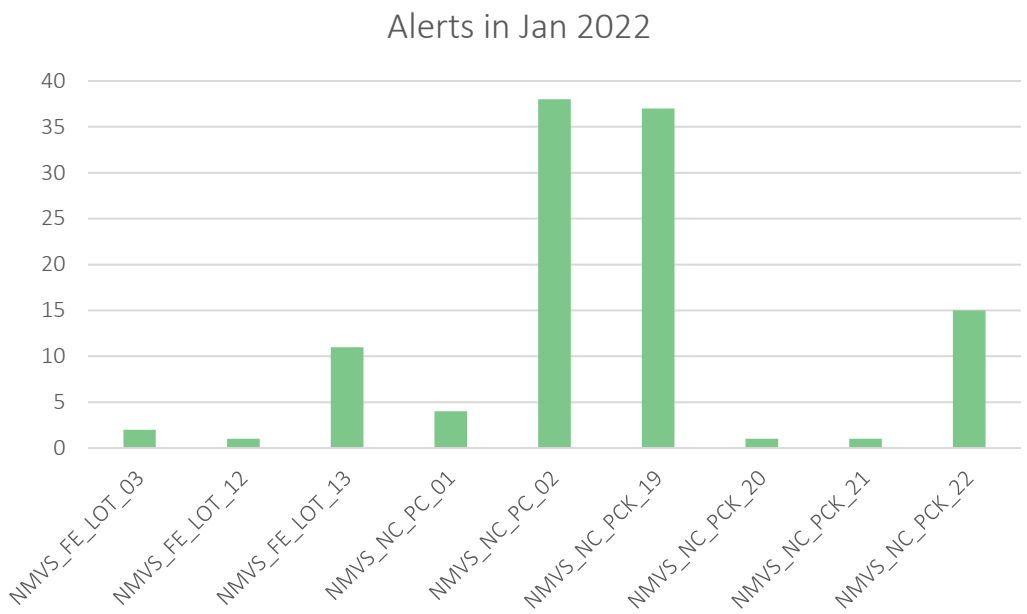
Special responsibilities
- Manufacturing of medicinal products
- Training of pharmacy students
- Research

Medicines verification at Yliopiston Apteekki

- Medicines verification is done in several processes:
  - 17 pharmacies
  - manufacturing unit
  - dose dispencing unit
  - on-line pharmacy
  - logistics

- These units have individual certificates in the NMVS system

Current situation



- In January 2022, 110 alerts
- TOP 3 reasons:
  - NMVS_NC_PC_02 Unknown serial number.
  - NMVS_NC_PCK_19 Property is already set on pack
  - NMVS_NC_PCK_22 Pack is already inactive.
- Divided equally between locations/ processes

Alerts

- All alerts are investigated locally (pharmacy / unit)
- Most common reasons for alerts
  - Double scan
  - Other mistake in scanning
  - Expired products
  - Decommissioning not undone on time
- 3 cases reported to MAH

Feedback to MAH’s

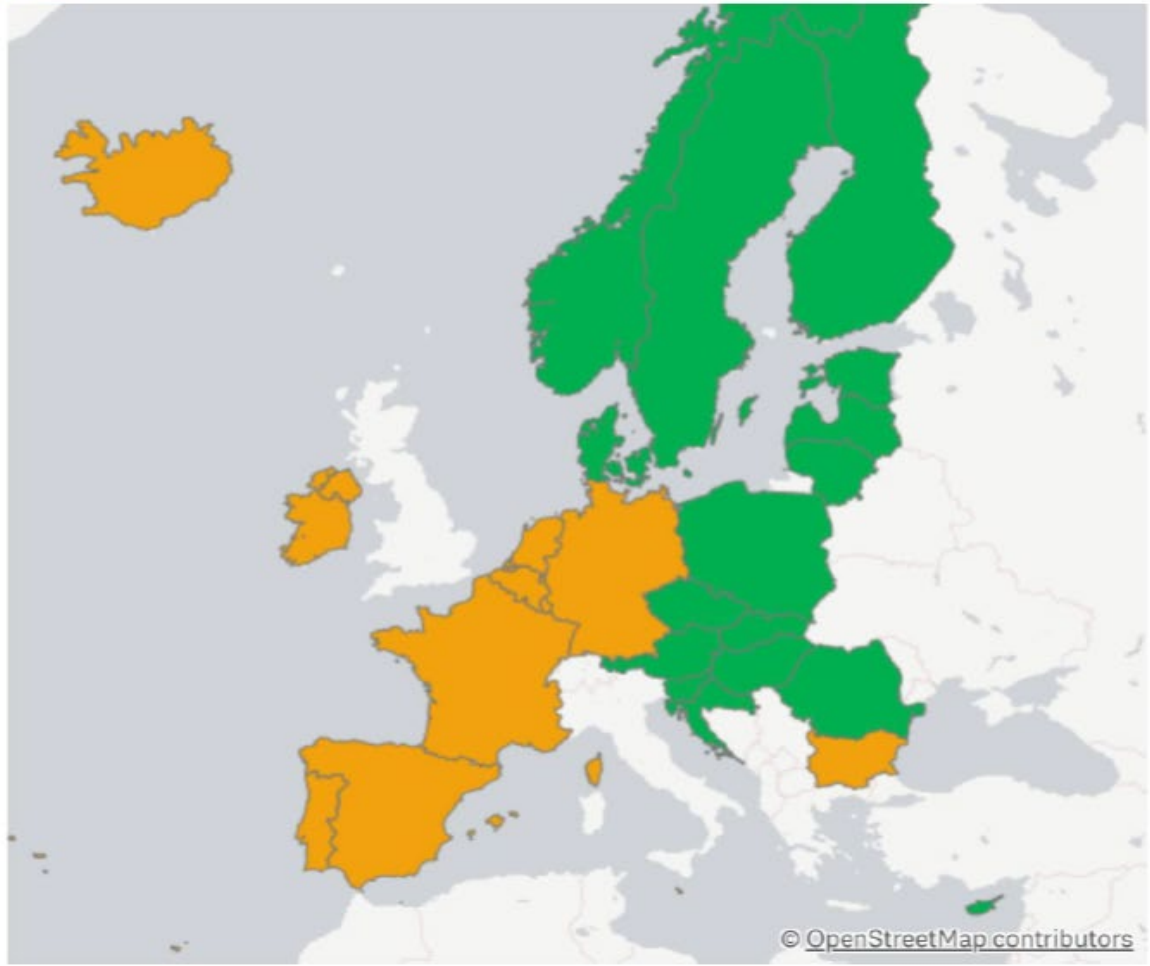
- Overall, the medicines verification process is working well
  - Comments from MAH’s received promptly
- Please remember to notify pharmacies actively in case any issues relating to large amount of packs
- Products not included in the system still on the market

Yliopiston Apteekki

Alert Status in Europe & in Finland

ALERT RATE

- < 0,1%
- > 0,1 % and < 1 %
- > 1 %



Note: the objective for the EMVS countries is to reach an alert rate of less than 0,05%

DECEMBER 2021 - READINESS AT NATIONAL LEVEL

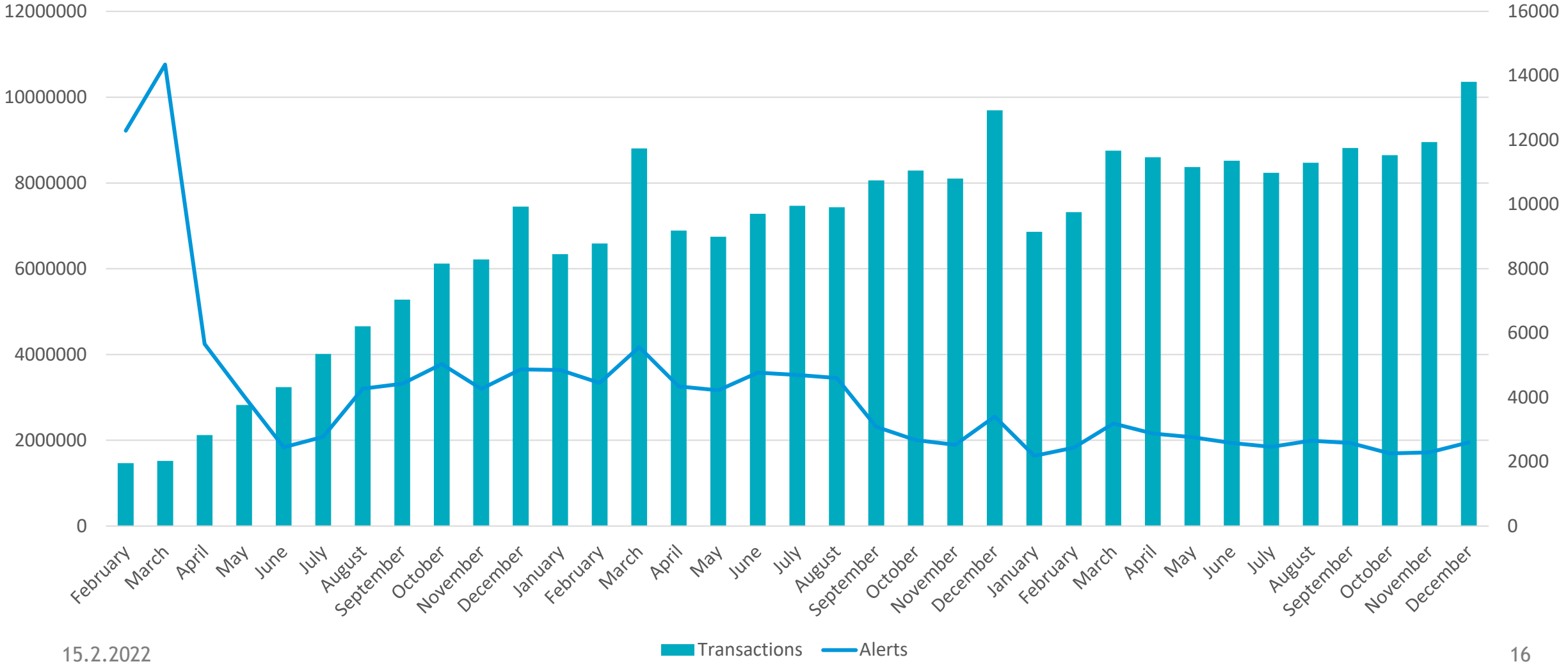
emvo European Medicines Verification Organisation

Source: EMVO (Enhanced Readiness at National Level_Monthly Overview_January 2022_Final.pdf)

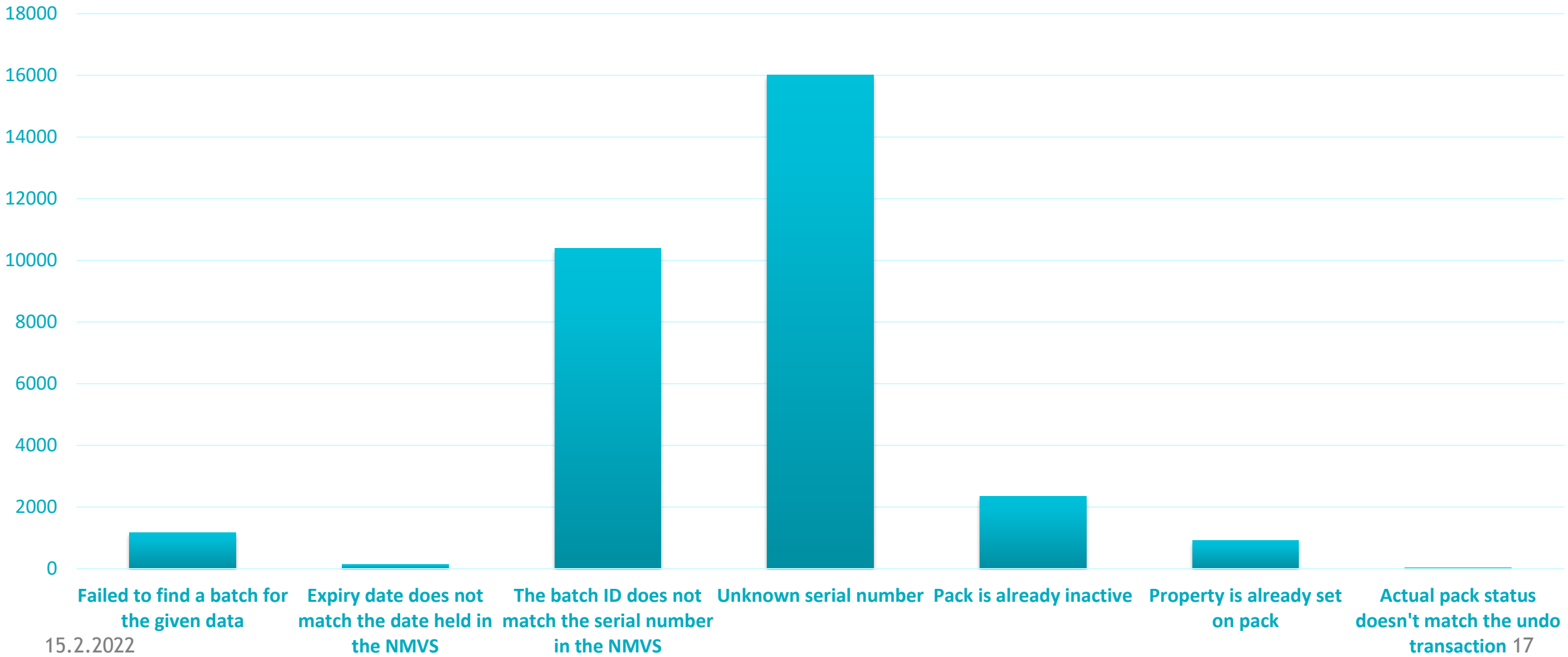
FiMVO statistics until December 2021

- Please note that our alert statistics 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 alerts are filtered according the unique serial number (no doubles)
- **FiMVO is implementing some changes to the statistics starting this year**

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



The number of alerts by type in January - December 2021



The two most common alert types and root causes in FiMVS

- A3 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 the OBP

- A68 The batch ID does not match serial number
  - 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 are not needed by the supply chain anymore – the 2D-matrix is sufficient)**

Most common questions to FiMVO from the End Users

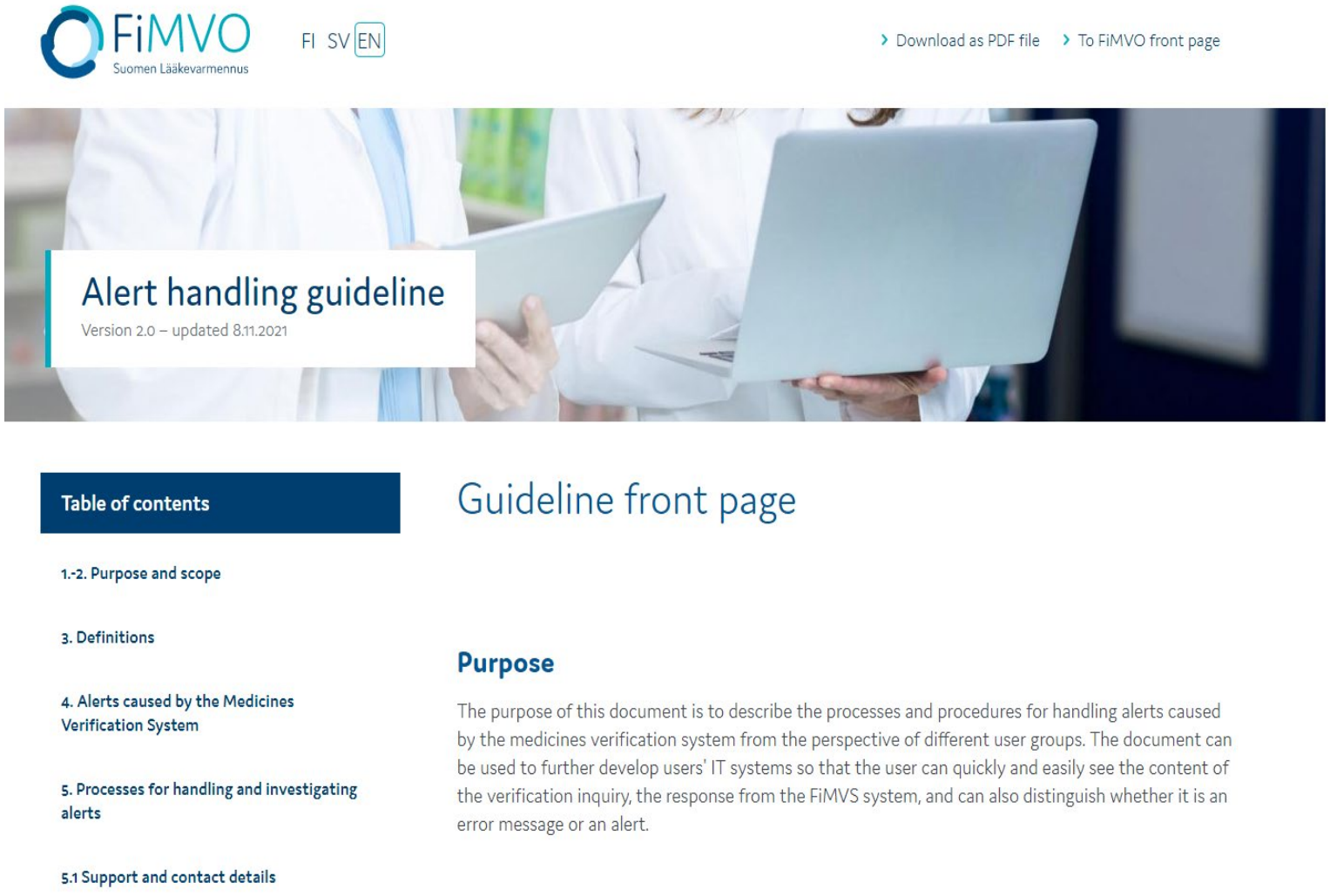
- Product not found
  - This is NOT an NMVS error ‘A1 Unknown product code’ => this similar ‘Product not found’ error is created in the end user software because the correct product information is missing from the Nordic Product Number (Vnr) service => the verification cannot be performed
  - A kind reminder to the MAHs: please keep the Nordic Vnr-numbers and product notifications always up-to-date: https://www.laaketietokeskus.fi/en/pharmaceutical-information/vnr-services
- A3 Unknown serial number
  - In some cases a part of the batch data has not been uploaded in FiMVS by the OBP
  - The end user requests guidance from FiMVO
- A7 Property is already set on pack / A24 The pack is already inactive
  - The end user is not able to investigate who has done the decommission previously in all cases => FiMVO has to check the audit trail of the pack and to provide guidance

Alert Management

Alert Handling Guideline by FiMVO

- FiMVO has published a guideline on handling the alerts from both the end user and from the MAH/OBP point of view (available in Finnish, Swedish and English)

- **The guideline has also been embedded on FiMVO's website (this will enable stakeholders to utilize direct links to different chapters of the guideline):** https://www.laakevarmennus.fi/en/alert-handling-guideline



National Alert Management System (AMS) in Finland: Current status

- FiMVO Board has had a discussion of this topic in June 2021 and a go decision was made regarding the implementation of an AMS **internally** at FiMVO
- Discussions with Finnish End Users about the needs and expectations for an AMS are ongoing – no final decision from the supply chain yet
- FiMVO will continue the discussions with the stakeholders in Finland
- FiMVO also follows actively the progress of the AMS project inside the EMVS community

Tips for MAHs

Product Master Data: Name

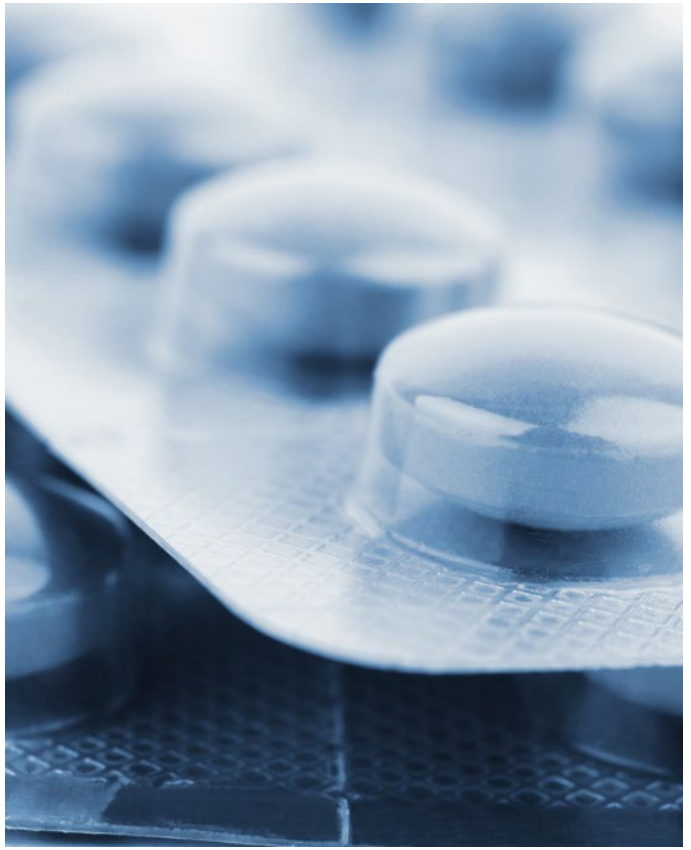
- Data element ’Name’ in PMD should include:
  - The invented name of the product
  - The strength of the product
  - The pharmaceutical form of the product
- See: https://emvo-medicines.eu/new/wp-content/uploads/EMVS-Master-Data-Guide_updated.pdf
- Currently this is not the case for many products!
- In the future, FiMVS will return also the name of the product when the end user performs a transaction

Product Master Data: Name

- If FiMVS returns a product name which does not match the pack at hand, this may lead to unnecessary investigations and delays in patients receiving their medication
- Most common errors in ‘Name’:
  - Name only includes the invented name (i.e. brand name)
  - Name only includes common name (i.e. INN, generic name)
  - Pharmaceutical form is missing
  - Pack size and/or target country abbreviations are included in the name
  - Name contains internal SKU numbers, seemingly random strings of characters or abbreviations, or is written in non-latin alphabets
- In some cases, the name uploaded with PMD can be very misleading and/or confusing as shown on the next slide

Product Master Data: Name

- Real examples of product names in FiMVS PRD:
  - DEFAULT BRAND 200mg Tablet
  - Filgrastim 48MU
  - Fusidic Acid
  - LEVETIRACETAM
  - ME-MS260-NORD
  - METRONIDAZOLE
  - OTHER AI/COMBO EYE 5.0 ML 6000.000 IU/ML
  - QVM149 INHA 90.0 ST 0.050 MG/PC
- All these products are on the market in FI, and their invented names do not contain the INN



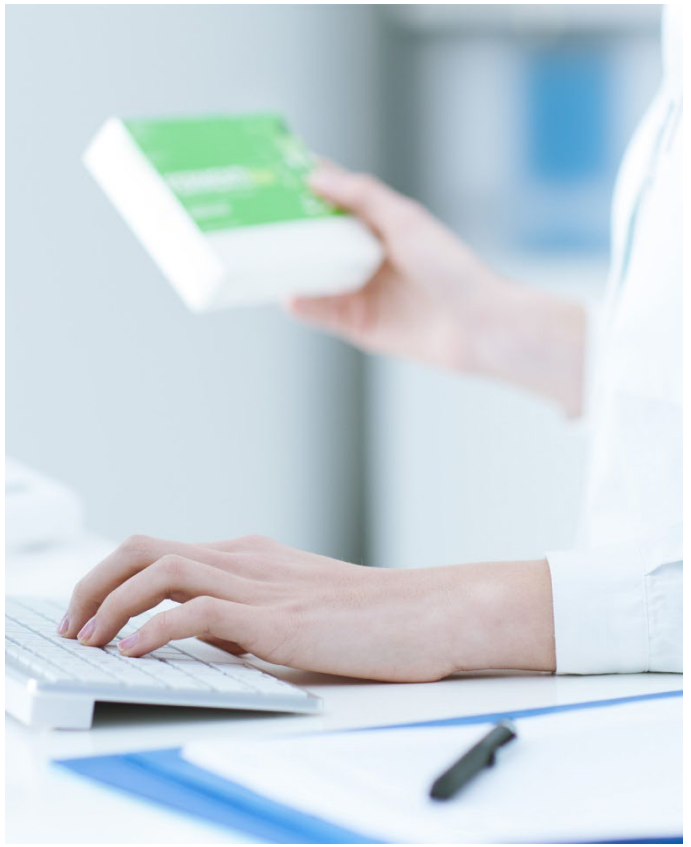
Batch Data: Expiry date

- Some OBPs upload expiry dates which are not the last day of the month e.g., 240115 (=15-Jan-2024)
- On packs the expiry dates are typically printed as MM/YYYY or MM-YYYY which is interpreted as the last day of that particular month, e.g., 01/2024 (=31-Jan-2024)
- This leads to a discrepancy which affects e.g., stock management and, furthermore, the expiry date on the packs extends the approved shelf life of the product
- Calculation of the expiry date of a batch:
  - Date when the manufacturing of the batch was started (API added) e.g., 15-Jan-2022
  - Approved shelf life of the product e.g., 24 months
  - Correct expiry date of the batch would be 12/2023 (=31-Dec-2023), not 01/2024 (=31-Jan-2024)
- Even though the day of the month is no longer decisive in the expiry date of a batch in FiMVS (or any NMVS), the information in FiMVS and on the carton should be the same
- The recommended procedure in this example case would be to upload the expiry date of 231231 or 231200 for the batch and print 12/2023 or 12-2023 on the packs

A few additional reminders to OBPs

- The European Commission released an updated Q&A document regarding Safety Features for Medicinal Products for Human Use (version 19, December 2021)
  - The document is available on EC website: https://ec.europa.eu/health/medicinal-products/falsified-medicines_en

- Please keep 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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