



**FIMVO**

Suomen Lääkevarmennus

**Info meeting for MAHs 5.10.2021**

# Agenda

- Introduction - Maija Gohlke, General Manager
- Contract and Invoice matters - Maija
- Alert Status in Europe & in Finland - Mirka Koski, Service Manager
- Alert Management - Mirka
- Tips for MAHs - Mirka
- Final words - Maija



## Board



PHARMA INDUSTRY FINLAND  
Nina Ekholm-Wenberg,  
Janssen-Cilag



FINNISH GENERICS ASSOCIATION  
Heikki Bothas



ORION PHARMA  
Juho Hellman



WHOLESALE ASSOCIATION  
Kai Kaasalainen, Tamro



PHARMACY ASSOCIATION  
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FINNISH PARALLEL TRADERS  
Tia Geijer

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Maija Gohlke



QUALITY MANAGER  
Teijo Yrjönen



SERVICE MANAGER  
Mirka Koski



ASSISTANT  
Henna Rönkkö

END USER MANAGEMENT  
Susanna Sunila-Eklund

ALERT MANAGEMENT  
Stanley Eklund



100%  
Users

0,03%  
Alerts





# Soon it's time for invoicing - what should you do?

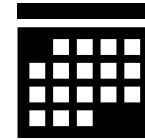
- Do you need a PO number? Let us know by **15th November** [with this pdf](#) (fill in all the details)
- Is your invoicing information up to date?
  - [Use this pdf](#)
  - [And check out our website](#)



# What are you paying and when?

€

5 250



1/2022

## Heads up!

- We are building a new CRM - next year you'll be able to update your information via a web portal



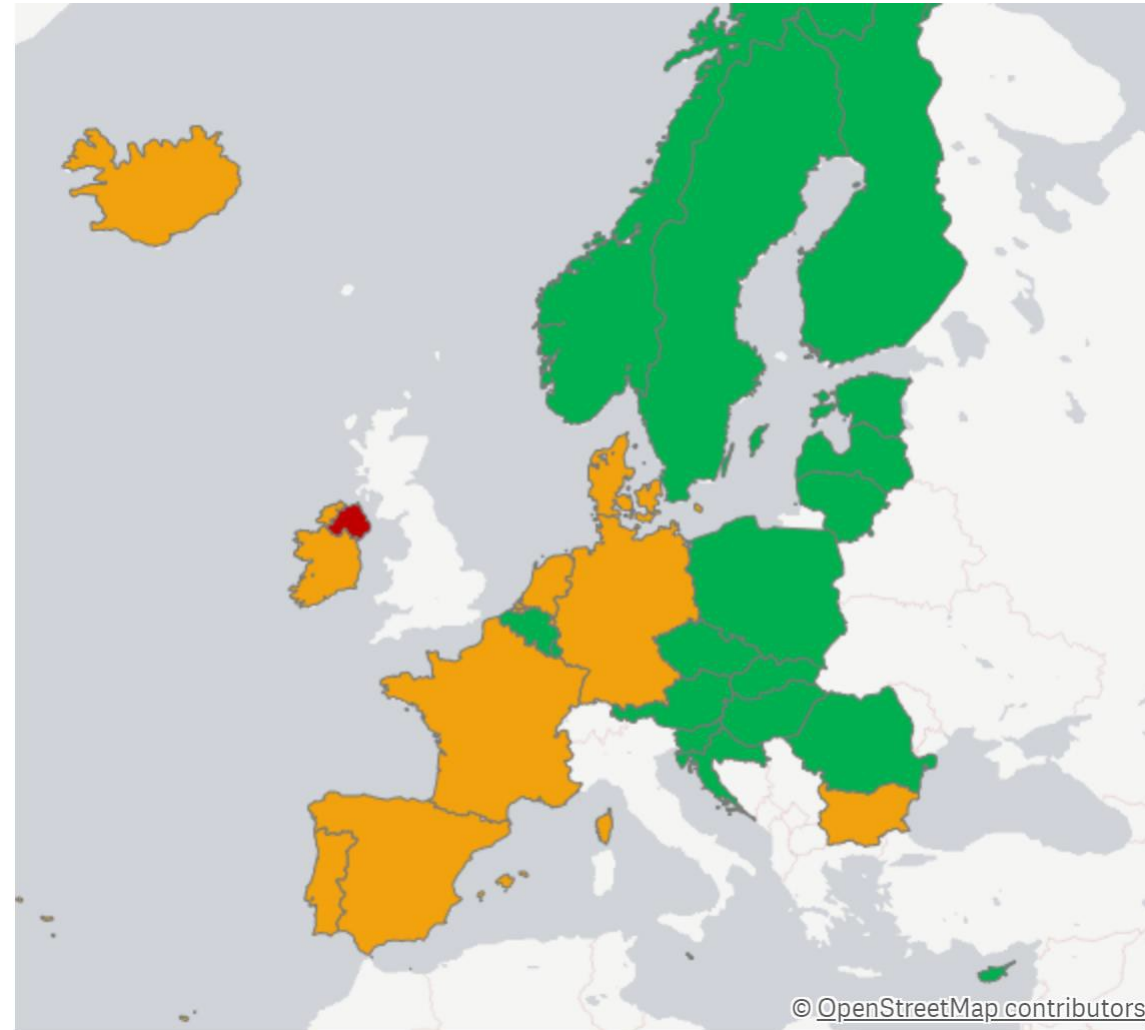


# Alert Status in Europe & in Finland



# ALERT RATE

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



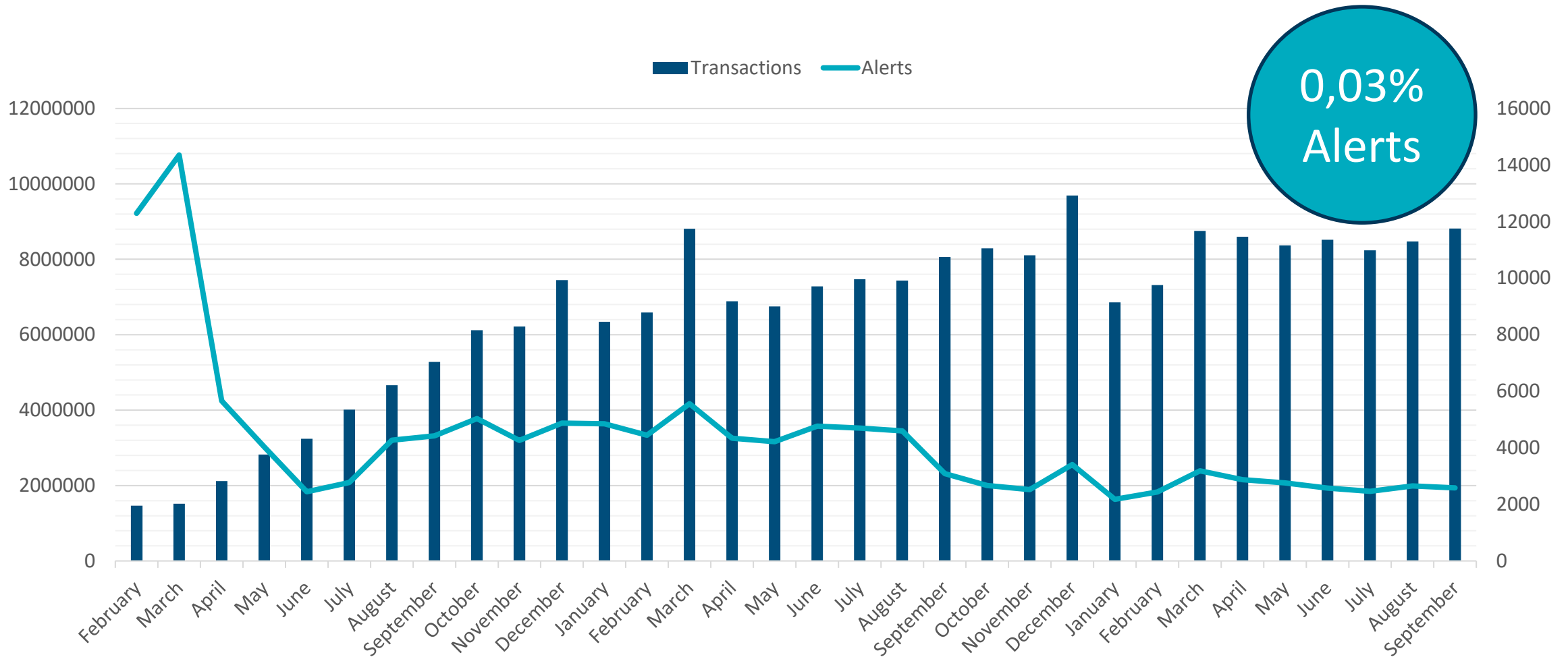
Note: the objective for the EMVS countries is to reach an alert rate of less than 0,05%

## FiMVO statistics

- 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)



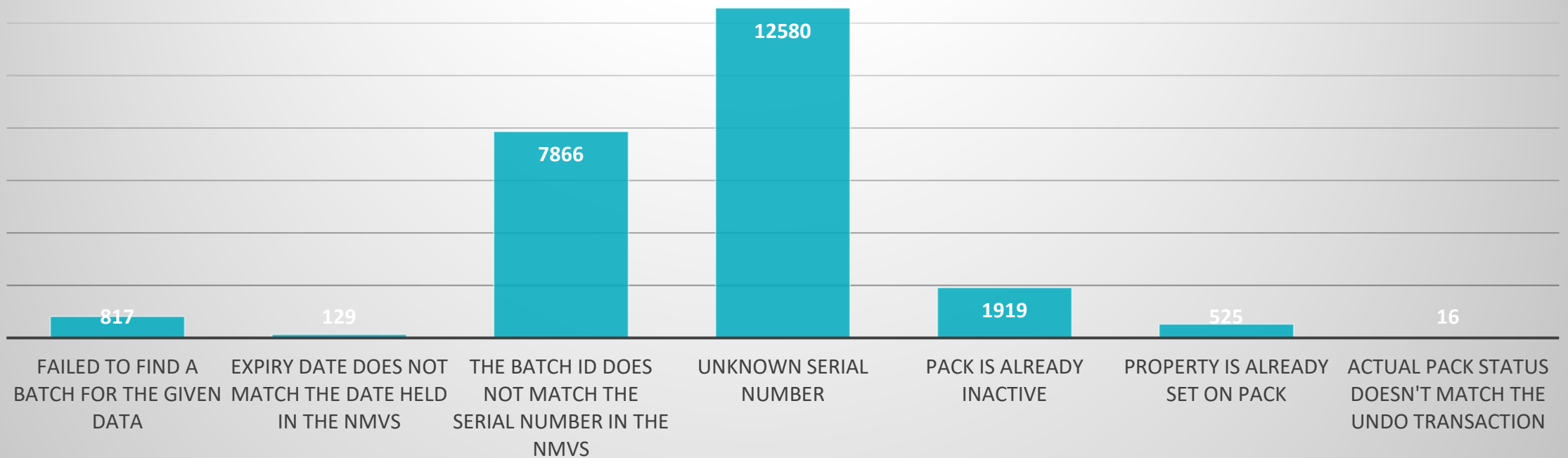
# The number of transactions and alerts per month Feb 2019 - Sep 2021



0,03% Alerts



## The number of alerts by type in January - September 2021



## 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 => the error is created in the end user software because the product information is missing from the Nordic Product Number (Vnr) service
  - 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>
- 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
- The pack is already inactive
  - The end user is not able to investigate who has done the decommission previously => FiMVO has to check the audit trail of the pack and to provide guidance






# Alert Management

# Alert Handling Guideline by FiMVO

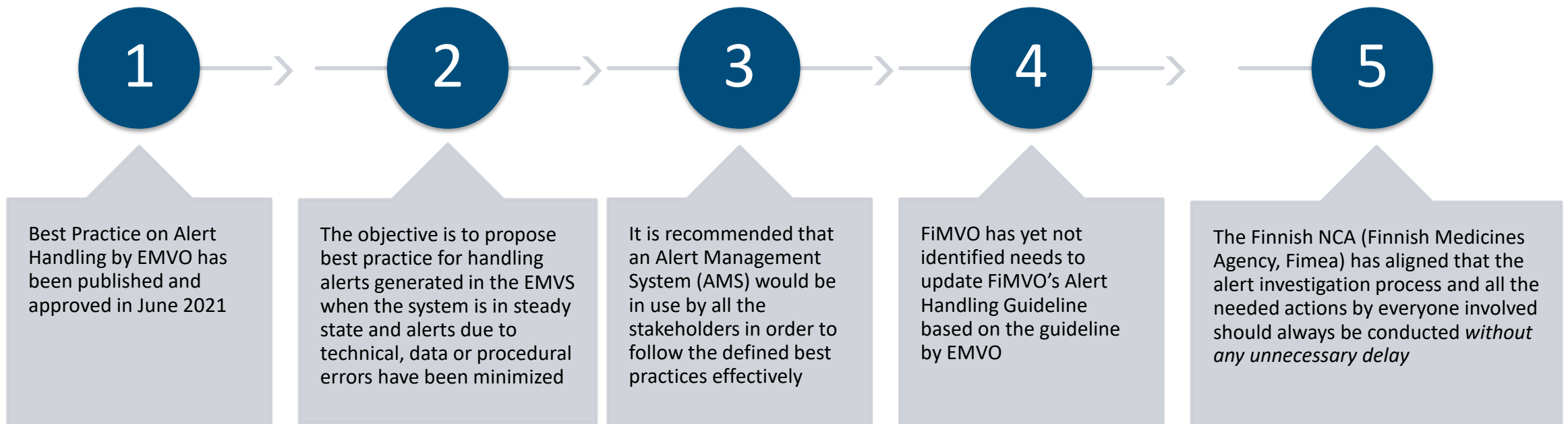
- FiMVO has published a guideline on handling the alerts from both end user and from the MAH/OBP point of view
- The guideline is available in Finnish, Swedish and English:
  - [Lääkevarmennusjärjestelmän hälytysten käsittelyohje järjestelmän käyttäjille](#)
  - [Anvisning för hantering av läkemedelsverifikationssystemets larm](#)
  - [Alert Handling Guideline for Medicines Verification System for System Users](#)
- The different chapters of the guideline will be embedded on FiMVO’s website during the upcoming months (this will enable stakeholders to utilize direct links to guidelines)

|   |   |              |
|---|---|--------------|
|  | SOP – Alert Handling Guideline for Medicines Verification System for System Users |              |
|   | Document Number: NMVO-0049  | Version: 1.0 |
|   | Effective date: 04-Dec-2020   | Page 2 of 24 |

## Table of Contents

|  |    |
|--|----|
| 1. Purpose .....   | 3  |
| 2. Scope .....   | 3  |
| 3. Definitions.....  | 4  |
| 4. Alerts caused by the Medicines Verification System .....  | 5  |
| 5. Processes for handling and investigating alerts .....   | 8  |
| 5.1 Support and contact details .....  | 9  |
| 5.2 Failed to find a batch for the given data (NMVS_FE_LOT_03) .....                                   | 10 |
| 5.3 Expiry date does not match the date held in the NMVS (NMVS_FE_LOT_12) .....                        | 12 |
| 5.4 The batch ID does not match the serial number in the NMVS (NMVS_FE_LOT_13) .....                   | 14 |
| 5.5 Unknown serial number (NMVS_NC_PC_02) .....  | 16 |
| 5.6 Property is already set on pack (NMVS_NC_PCK_19) .....   | 18 |
| 5.7 Pack is already inactive (NMVS_NC_PCK_22) .....  | 19 |
| 5.8 Defined timeframe between setting this property and the undo was exceeded (NMVS_NC_PCK_20) .....   | 20 |
| 5.9 Undo can only be executed by the same user who previously set the attribute (NMVS_NC_PCK_21) ..... | 21 |
| 5.10 Actual pack status doesn't match the undo transaction (NMVS_NC_PCK_06) .....                      | 22 |
| 5.11 Status change could not be performed (NMVS_NC_PCK_27) .....                                       | 23 |
| 6. Roles & Responsibilities .....  | 24 |
| 7. Reference documents .....   | 24 |

# Best Practice on Alert Handling by EMVO





# 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 planning and the software assessment processes

# 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 based on the investigation done by the MAH

Regarding many alerts, especially #A68 The batch ID does not match the SN & #A3 Unknown serial number, 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)




## 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 also possible (please remember to update also the PMD if needed).
- EMVO has published a Letter of Announcement about the Irreversible transactions:  
[https://emvo-medicines.eu/new/wp-content/uploads/EMVO\\_LoA\\_0200\\_20210921\\_Irreversible\\_transactions.pdf](https://emvo-medicines.eu/new/wp-content/uploads/EMVO_LoA_0200_20210921_Irreversible_transactions.pdf)
- All the LoAs can be found on EMVO's website in the [Documents Overview] > [Letters of Announcement] section of the Knowledge Base (please note: OBPs are always informed via email by EMVO)



helpdesk@emvo-medicines.eu

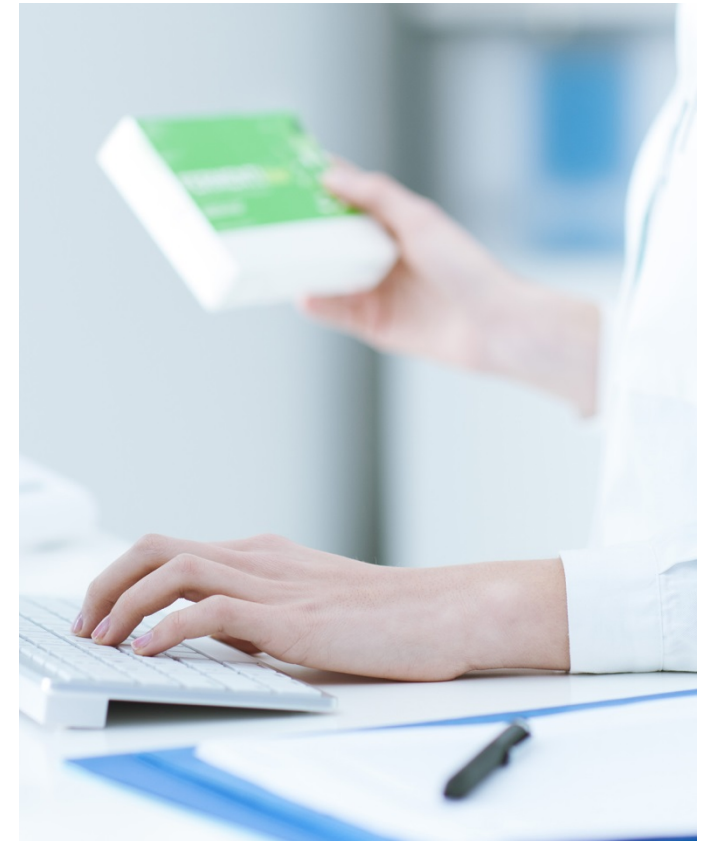


<https://emvo-medicines.eu/knowledge-database/>



## A few additional reminders to OBPs

- Packs must not be verified when not at hand (excluding cases of alert investigation) - please see the latest LoA from EMVO:  
[https://emvo-medicines.eu/new/wp-content/uploads/EMVO\\_LoA\\_0201\\_20210929\\_Verifications\\_of\\_packs\\_under\\_physical\\_possession\\_of\\_an\\_OBP.pdf](https://emvo-medicines.eu/new/wp-content/uploads/EMVO_LoA_0201_20210929_Verifications_of_packs_under_physical_possession_of_an_OBP.pdf)
- 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





## Follow the news and contact us!

- Social media: [FiMVO.fi](https://www.fimvo.fi) | [LinkedIn](#) | [Twitter](#)
- Subscribe to FiMVO's newsletter: <https://uutiskirje.fimvo.fi/>
- For alerts, system and data related inquiries and support, please use: [nmvs@fimvo.fi](mailto:nmvs@fimvo.fi)
- For contracts and invoicing, please use: [info@fimvo.fi](mailto:info@fimvo.fi)





# Thank You!

The Finnish Medicines Verification Organisation FiMVO