FiMVO
Suomen Lääkevarmennus

Fighting
falsified medicines

Building a safe medicines supply

3

MAH Training 20.9.2022 – Agenda

- Introduction
  - Maija Gohlke, General Manager
- Contract and Invoice matters
  - Henna Rönkkö, Assistant
- Guest speaker: Medicines verification from a hospital pharmacy perspective
  - Tiina Miettinen, Pharmacist from HUS Apteekki (the Hospital District of Helsinki and Uusimaa)
- Alert Status and Alert Management in Finland
  - Mirka Koski, Service Manager
- Tips for MAHs
  - Teijo Yrjönen, Quality Manager

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Board

Pharma Industry Finland
Nina Ekholm-Wenberg, Janssen-Cilag

Finnish Generic Pharmaceutical Association
Heikki Bothas

Orion Pharma
Juho Hellman

The Association of Pharmaceutical Distributors
Kai Kaasalainen, Tamro

The Association of Finnish Pharmacies
Charlotta Sandler

Suppliers of Parallel Imported Medicines of Finland
Tia Geijer

Office

General Manager
Maija Gohlke

QA Manager
Teijo Yrjönen

Service Manager
Mirka Koski

Finance and administration manager
Taina Tummavuori

Assistant
Henna Rönkkö

Alert Management
Stanley Eklund

End User Management
Susanna Sunila-Eklund

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100%
Users

0,04%
Alerts

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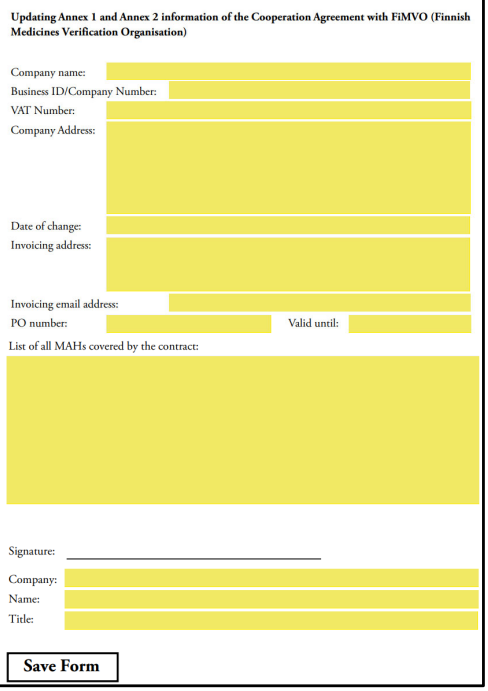
Contract and Invoice matters

€	Invoices sent on	Due date
5 000 € / MAH	2nd of January	1st of February

If you need a PO number

- Please fill in the Annex I and II form
- Sign it
- Send it back to us (info@fimvo.fi)

- **Let us know by 14th of October**



Updating Annex 1 and Annex 2 information of the Cooperation Agreement with FiMVO (Finnish Medicines Verification Organisation)

Company name:
Business ID/Company Number:
VAT Number:
Company Address:
Date of change:
Invoicing address:
Invoicing email address:
PO number:
Valid until:
List of all MAHs covered by the contract:

Signature: _____
Company:
Name:
Title:

Save Form

If your company information changes

- Update Annex I and II form

If your SPOC changes

- Inform us by sending email to info@fimvo.fi

- Check our website for more info: https://www.laakevarmennus.fi/en/sign-fimvo

MEDICINES VERIFICATION IN HOSPITAL PHARMACY

20.9.2022 Tiina Miettinen / HUS Pharmacy

OUR HOSPITAL IN BRIEF

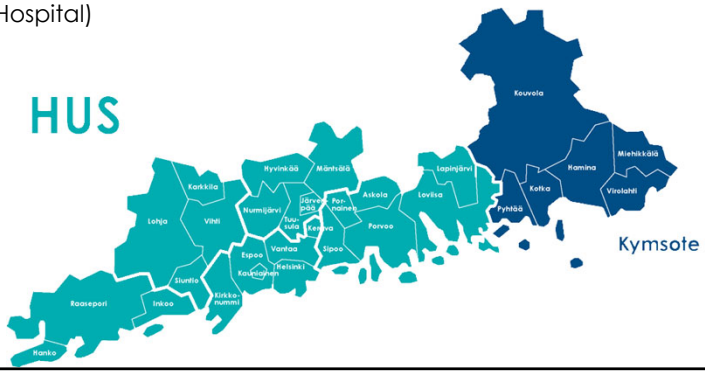
- Every year, about 680,000 patients are treated at the HUS Helsinki University Hospital.
- HUS employs 27,000 professionals to serve all patients' best interests.
- We are responsible for specialized medical care for the residents of 24 member municipalities. In addition, we provide nationally centralized care for many rare and severe diseases.
- HUS is the biggest health care provider and the second-largest employer in Finland.
- Our expertise is internationally recognized and accredited.
- As a university hospital, we constantly study and develop our treatment methods and activities.


HUS
HUS PHARMACY

SERVICE NETWORK AND COOPERATION WITH MEMBER MUNICIPALITIES

We have four service locations:

- Helsinki (Meilahti)
- Jorvi (Jorvi Hospital Pharmacy)
- Hyvinkää (dispensary of Hyvinkää Hospital)
- Kymenlaakso (hospital pharmacy of Kymenlaakso Central Hospital)



HUS

Pharmaceutical services to HUS's 24 member municipalities and to all of Kymsote.

HUS's member municipalities have almost 1.7 million residents and Kymsote approximately 160,000 residents

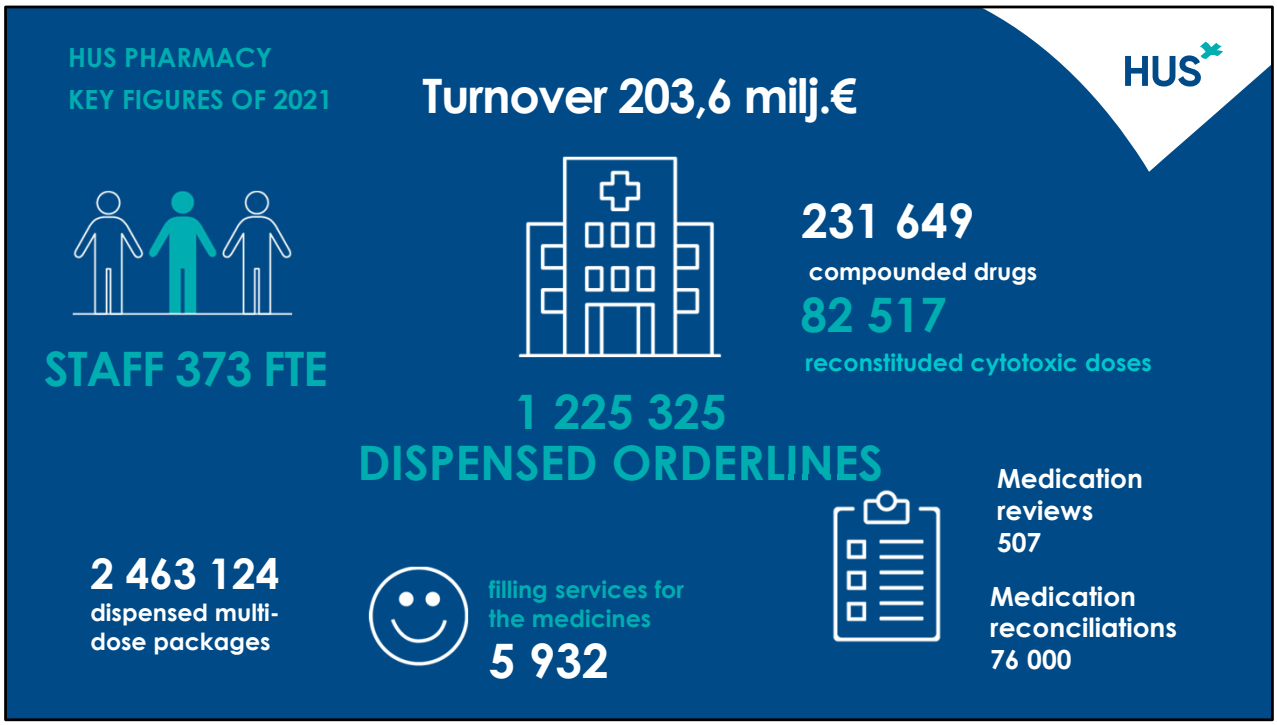
OUR CUSTOMERS

Internal customers:

- HUS Hospital districts
- HUS Profit areas
- HUS Subsidiaries

External customers include:

- Customers of primary health care
- Patients with communicable diseases
- Finnish Defence Forces
- Customers of clinical trials
- Others


HUS PHARMACY
KEY FIGURES OF 2021
Turnover 203,6 milj.€
HUS
231 649
compounded drugs
82 517
reconstituded cytotoxic doses
STAFF 373 FTE
1 225 325
DISPENSED ORDERLINES
Medication reviews
507
Medication reconciliations
76 000
2 463 124
dispensed multi-dose packages
filling services for the medicines
5 932

MEDICINES VERIFICATION IN HUS PHARMACY

- Medicines verification is done upon arrival in each location
  - On special occasions the verification can be postponed and done on more suitable time

- In past 12 months the average of alerts: 0,01% (not including COVID-vaccines)
  - Most common reasons for alerts
    - Scanning related issues
    - Expired products (COVID-vaccines!)

CURRENT CHALLENGES AND IMPROVEMENT PROPOSALS FOR MAH'S

- Expiration date differences on package vs 2D codes cause problems in hospital environment
- Post production changes on expiration dates are problematic
- 2D codes should be easily scannable

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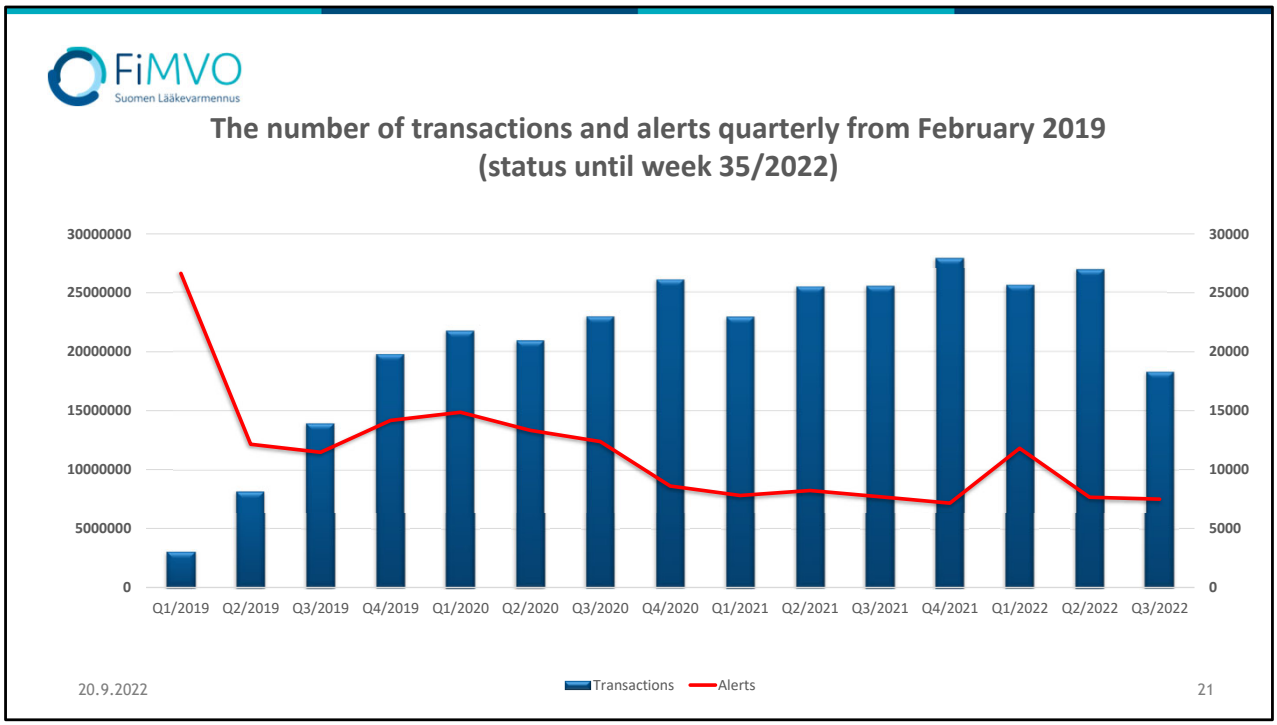
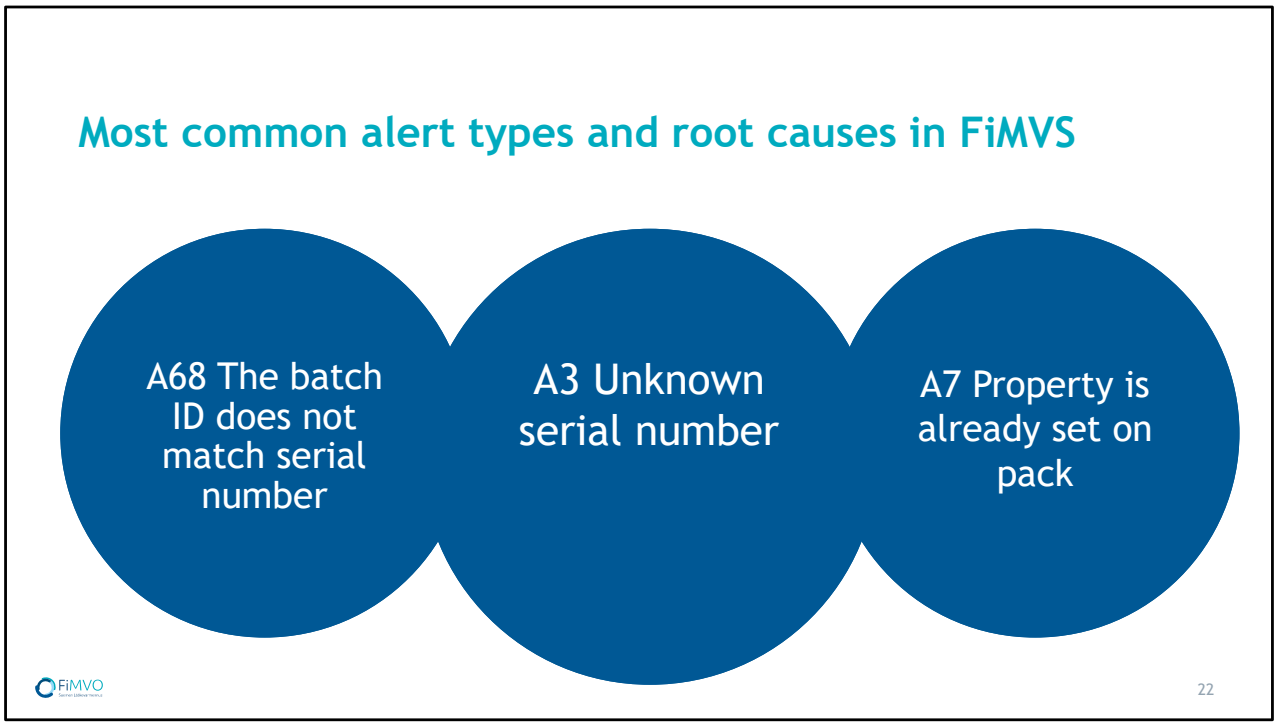
Alert Status in Finland

FiMVO's alert 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



~300 000 transactions per day
~120 alerts per day
~915 end users



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)

A7 Property is already set on pack

- The same or another end user has already decommissioned the pack with the same transaction. (NOTE. Before the alert is generated the end user will receive the error message “NMVS_NC_PCK_23 Re-setting of the property via double scan is registered” three times).
- In some rare cases it is possible that two packs with identical identifiers have been released on the market by the MAH/OBP.
- 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

- We have a low alert rate (0,04%)
- We can still improve! Everyone throughout the supply chain needs to check their processes and make quick corrective actions when errors arise

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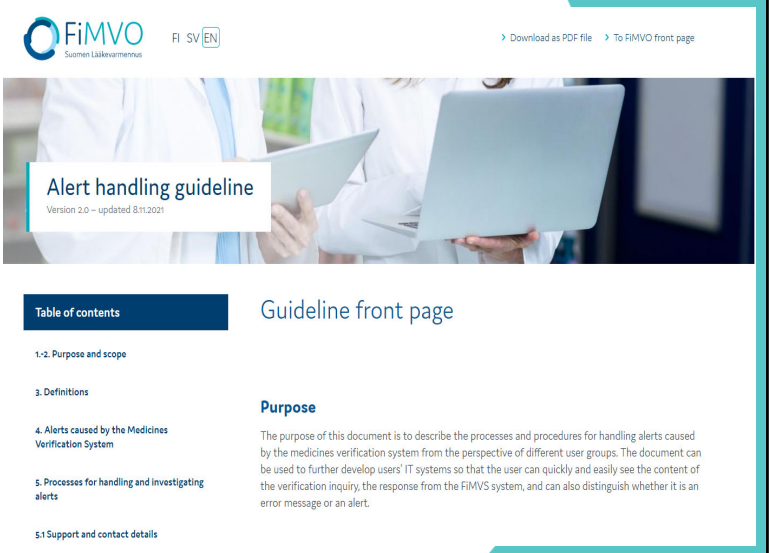
Alert Management in Finland

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): https://www.laakevarmennus.fi/en/alert-handling-guideline



Alignment from the Finnish NCA (Fimea): all alerts must be investigated as soon as possible, without any delay.

National Alert Management System (NAMS) in Finland / Current status

- NAMS project is on hold
- Discussions with the Finnish end users and stakeholders about the needs and expectations for an AMS are ongoing – no final decision from the supply chain yet
- FiMVO also follows the progress of the AMS project within the EMVS community

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Tips for MAHs

Upload of batch data

- MAHs must ensure that batch data has been successfully uploaded in the NMVS prior to releasing the batch for sale or distribution, refer to DR (EU) 2016/161, Art. 33
- Failure to do so may cause harm to patients as it may prevent or delay their access to the prescribed medication
- Furthermore, failure to upload batch data or a significant proportion of UIs belonging to a particular batch is considered a product defect -> same rules apply as for any other type of product defect
- Wholesalers, pharmacies and hospital pharmacies must be notified of the issue and advised what to do

Product Master Data: Market

- MAH is responsible for uploading PMD and PPD in **all** repositories (NMVSs) where the product is intended to be placed on the market, refer to DR (EU) 2016/161, Art. 33
- Besides violating the requirements of the DR, failure to upload data in all relevant NMVSs:
  - Constitutes a misuse of the IMT functionality (increased number of IMTs -> higher maintenance costs of the EMVS, higher likelihood of technical issues)
  - Complicates alert monitoring and alert investigations as e.g. the pack audit trail is not available for review in the initiating market
- Likewise, MAH should not upload PMD and PPD in any NMVS where the product is not intended to be placed on the market

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Product Master Data: MAH Name

- ‘MAH Name’ in PMD should be the same as in the approved MA for the product
- This means that ‘MAH Name’ should be kept constantly the same over time (if there are no MAH changes), and for all the products with the same MAH
- FiMVO annual fees are MAH-specific and the use of incorrect MAH names in PMD leads to unnecessary queries addressed to the MAH or MAH representative by FiMVO

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 20, June 2022)
  - The document is available on EC website: https://health.ec.europa.eu/system/files/2022-06/qa_safetyfeature_en_0.pdf
- 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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Final reminders

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

Join our training "Verification basics for MAHs" on October 27th

- We welcome you to our new training event Verification Basics for MAHs on October 27th at 10 CEST. In this training we will cover all the basics you need to know about medicines verification as an MAH. **If you're new to medicines verification or want to refresh your knowledge, this training is for you!**
- As a special guest speaker, we have Paul Mills, who will guide you through the ABC of medicines verification.
- Register for the event here: https://www.lyyti.fi/reg/Basics_for_MAHs_4527

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Thank You!