

MAH Webinar 14.9.2023 - Agenda

- FiMVO NMVS vendor change project
 - Maija Gohlke, General Manager
- Alert status in Finland
 - Stanley Eklund, Alert Manager
- Contract and Invoice matters
 - Henna Rönkkö, Assistant



FiMVO NMVS vendor change project



New vendor for Finnish Medicines Verification System

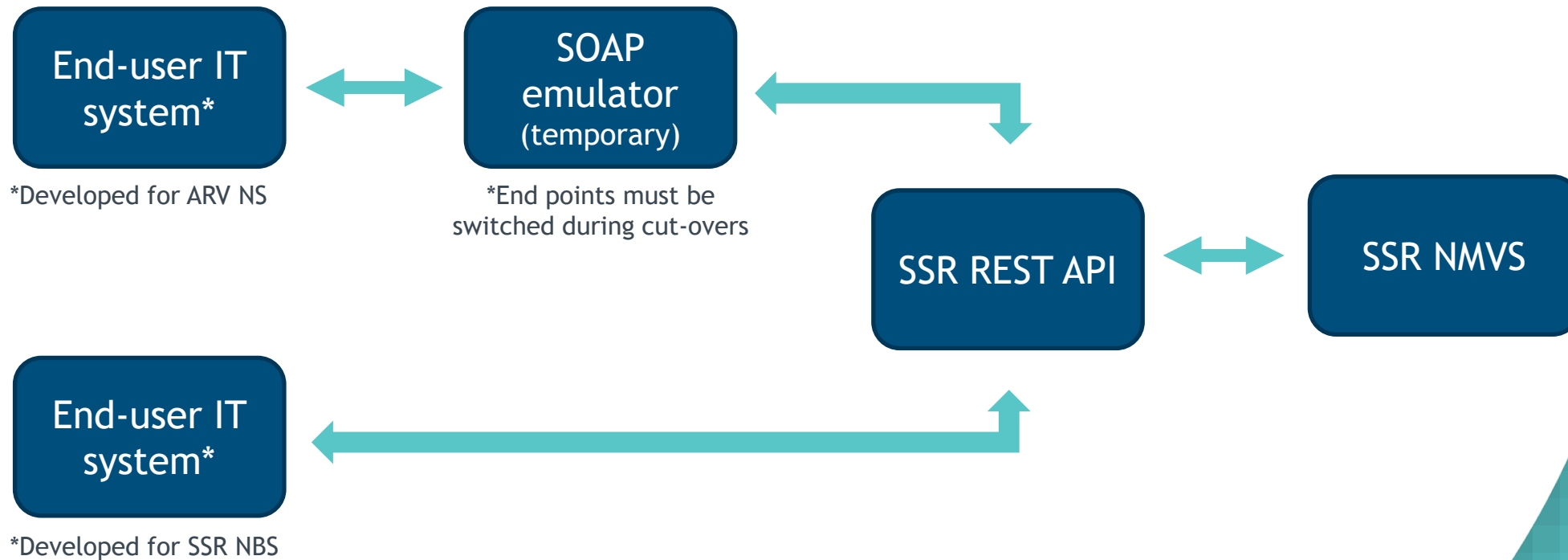
- Solidsoft Reply (SSR) has been chosen as the new system supplier.
- The cutover to SSR NMVS in the test environment (IQE) was performed successfully on August 22nd
- The cutover to SSR NMVS in the production environment (PROD) will happen during **Saturday, November 18th** (evening / night)

No action for OBPs

- Note that the vendor change project does not require any actions or changes from marketing authorization holders/manufacturers or pharmaceutical companies.
- **IMPORTANT!** It is not possible to perform any OPB transactions in the Finnish NMVS via the EU Hub during the cutover on November 18th; any attempt will end up in error and needs to be re-sent after the cutover

FI-NMVS vendor change project

Two alternative ways for End Users to connect after the cutover:



FI-NMVS vendor change project

- Final deadline for SSR REST API (for all end users) is **October 2024**
- Note that the alert codes will change according to SSR NMVS, however, if the end user is still using the temporary SOAP emulator they will receive the current alert codes
 - E.g. Unknown serial number (alert code in the EU Hub = A3)
 - Alert code in the current NMVS: NMVS_NC_PC_02
 - Alert code in the SSR NMVS: 41020001
 - FiMVO has already published the new alert and return codes:
<https://www.laakevarmennus.fi/en/news/fimvo-changes-system-supplier-november-18th-changes-finnish-nmvs-alert-codes>
- FiMVO will update the Alert Handling Guideline (<https://www.laakevarmennus.fi/en/alert-handling-guideline>) also with the new alert codes closer to November 18th



Alert status in Finland

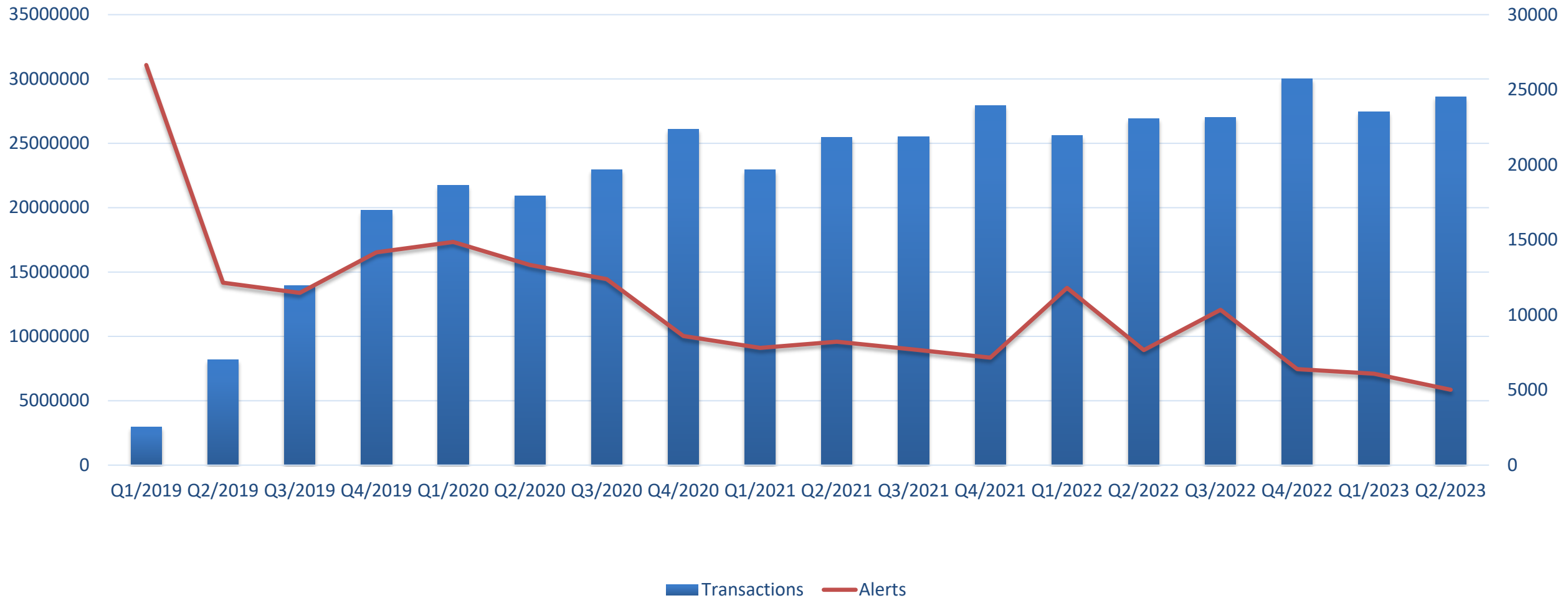


FiMVO's alert statistics

- 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



The number of transactions and alerts quarterly from February 2019



Most common alert types and root causes in FiMVS

A68 The batch ID does not match serial number

A3 Unknown serial number

A7 Property is already set on pack

- We have a low alert rate (0,02%)
- We can still improve! Everyone throughout the supply chain needs to check their processes and make quick corrective actions when errors arise



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

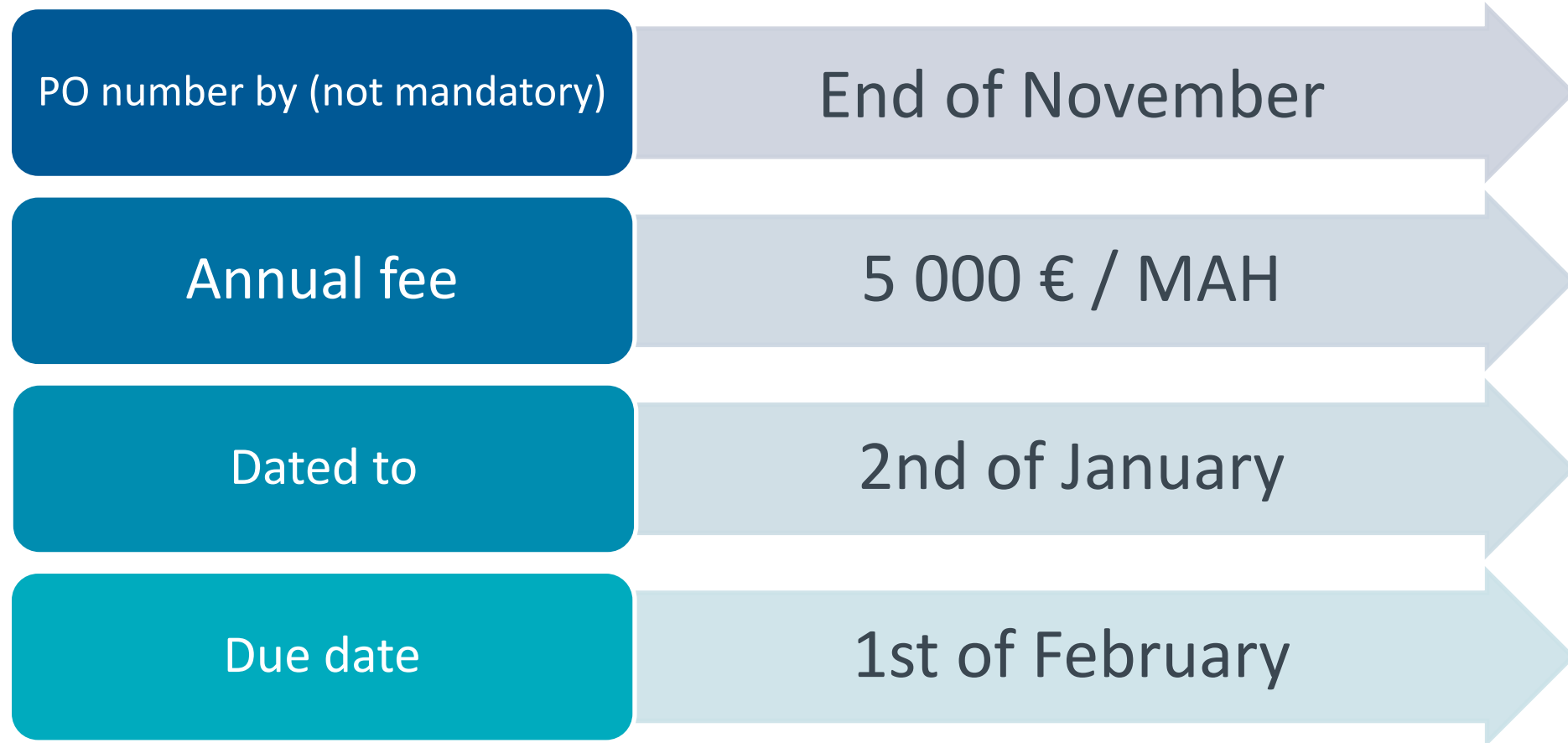
- NAMS project is on hold due to the FI-NMVS vendor change project this year
- FiMVO also follows the progress of the EAMS project within the EMVS community





Contract and Invoice matters







Updating Appendix 1 and Appendix 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:

Signatures

This Contract Update has been drawn up and executed in two (2) identical copies (which may also be in electronic format) of which each Party has received one (1) copy.

Company:

Name:

Title:

Suomen Lääkevarmennus Oy

Maija Gohlke

General Manager

Save Form

If you need a PO number on the invoice

- Fill in **whole** the Appendix I and II form
- Save and send it back to us (info@fimvo.fi)
- Appendix needs to be signed by both parties
 - Let us know your signer's email and we'll send an invitation for signing on VismaSign



WE PROTECT FINNISH PATIENTS FROM FALSIFIED MEDICINES

we build a safe medicines supply

FiMVO changes system supplier
November 18th: changes in the Finnish NMVS alert codes

Autumn brings great changes for
FiMVO - Newsletter 4/2023

Welcome to the MAH Webinar on 14th
of September!

PHARMACIES

WHOLESALERS

PHARMACEUTICAL
COMPANIES

PHARMACEUTICAL
IT-PARTNERS

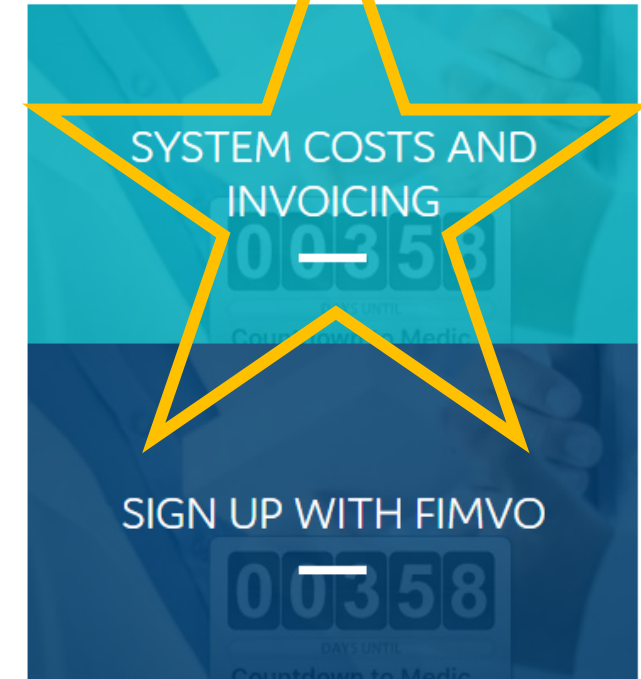
CONSUMERS

PHARMACEUTICAL COMPANIES

How do pharma companies prevent falsified medicines with the verification system

- Pharma companies (manufactures or parallel distributors) on-board the system through the European repository (Hub). On-boarding the Hub is a prerequisite for the company to be able to upload information about their medicines into the repository and bring serialized packs to the market. You can find more information about on-boarding on [EMVO's website](#).
- Pharma companies equip their prescription medicine packs with the safety features required by [legislation](#). The safety features consist of the unique identifier (serial number and product code) and an anti-tamper device on the package. There are some exceptions in the [Delegated Regulation](#) regarding the products in scope.

The unique identifier is added to the medicine pack in the form of a 2D matrix. In addition to the unique serial number and product code (GTIN), the 2D matrix must include the batch number and expiry date.



THE SYSTEM COSTS

Legislation states that the pharmaceutical industry is responsible for the cost of setting up the medicines verification system. This includes the costs of the Hub, as well as the national repositories. In addition, pharmaceutical companies have had to make investments to upgrade their production lines and data systems to meet the requirements of the legislation.

Wholesalers and pharmacies bear the costs of updating their own data systems as well as the acquisition of any needed equipment such as scanners.

FiMVO and the Finnish medicines verification system are funded with annual fees from MAH's

We apply a flat fee which is based on MAHs, not marketing authorisations. If a company represents more than one MAH, the fee will be charged according to the number of MAHs. If an MAH does not have any data in our system, no fee will be applied.

The fees are defined annually according to the FiMVO budget. For 2023 the annual fee will be 5 000 EUR / MAH.

If you need to update your invoicing details, please fill in Appendix I and II template and return it to us in pdf format with a e-signature or pdf signature.

How to sign up with FiMVO?

 FiMVO's Vendor Details

 FiMVO Invoicing Q&A

When do you need to update the contract?

- Use the Appendix I and II form
- Deletion or addition of an MAH
- Merging of MAHs

NB. Write the MAH name, not the product name to "List of all MAHs covered by the contract". If there is only one MAH represented in the contract (with the same name as the company) still, please write the MAH to the list.

- Invoicing information
- Company information (address, company name...)
- PO number (if needed)

-> info@fimvo.fi

- Please let us know the changes as soon as possible, especially when coming closer to the end of the year / sending the invoices



More about the Appendix

- Always fill completely
- "PO number" and "Valid until" are not mandatory
- Save and send to info@fimvo.fi
- Appendix needs to be signed by both parties
 - Let us know your signer's email and we'll send an invitation for signing on VismaSign

Updating Appendix 1 and Appendix 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:

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List of all MAHs covered by the contract:

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Title:

Suomen Lääkevarmennus Oy

Majja Gohlke

General Manager

Save Form

If your SPOC (or Alert SPOC) changes?

- Inform us by sending email to info@fimvo.fi
- We recommend the new SPOC to [subscribe to our newsletter](#)
- Follow FiMVO on [LinkedIn](#) (FiMVO Finnish Medicines Verification Organisation) and [X/Twitter](#) (@fi_mvov)

Follow the news and contact us!

- Social media: [FiMVO.fi](https://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
- For contracts and invoicing, please use: info@fimvo.fi



Thank You!

