

Welcome!

9.30 Medicines Verification System - general update

Maija Gohlke-Kokkonen, General Manager, FiMVO

- Contracting & fees

10.00 Project status, testing of the Finnish system

Tero Vesa, Technical Project Manager, FiMVO

Tim Strässer, Project Manager, Arvato

10.45 The EU Hub, incl. Q&A session

Paul Mills, Operations Department, EMVO

- Connecting to the EU Hub, gateway solutions
- Role of 3PLs
- Inter Market Transactions
- Master Data

12.15 Lunch

13.00 Medicines Verification in a Pharma Company

Anna Ikonen, Quality Lead Nordics, Bristol-Myers Squibb

- Project status and experiences

13.30 Quality in FiMVO operations

Teijo Yrjönen, QA, FiMVO

14.00 Coffee

14.15 GTIN and Vnr Numbers

Essi Kariaho, Director, Lääketietokeskus (Pharmaceutical Information Centre)

- Moving from NTINs to GTINs
- The role of Vnrs in the future
- Reporting serialized packs in the Vnr service

14.45 News from Fimea (The Finnish Medicines Agency)

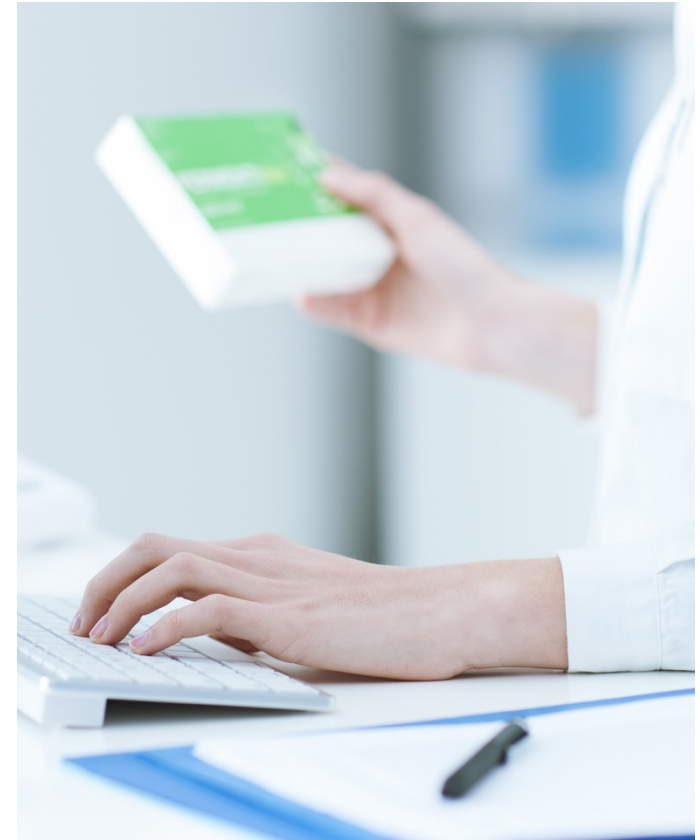
Johanna Linnolahti, Senior Pharmaceutical Inspector, Fimea

15.15 Q&A session

15.30 Close of workshop

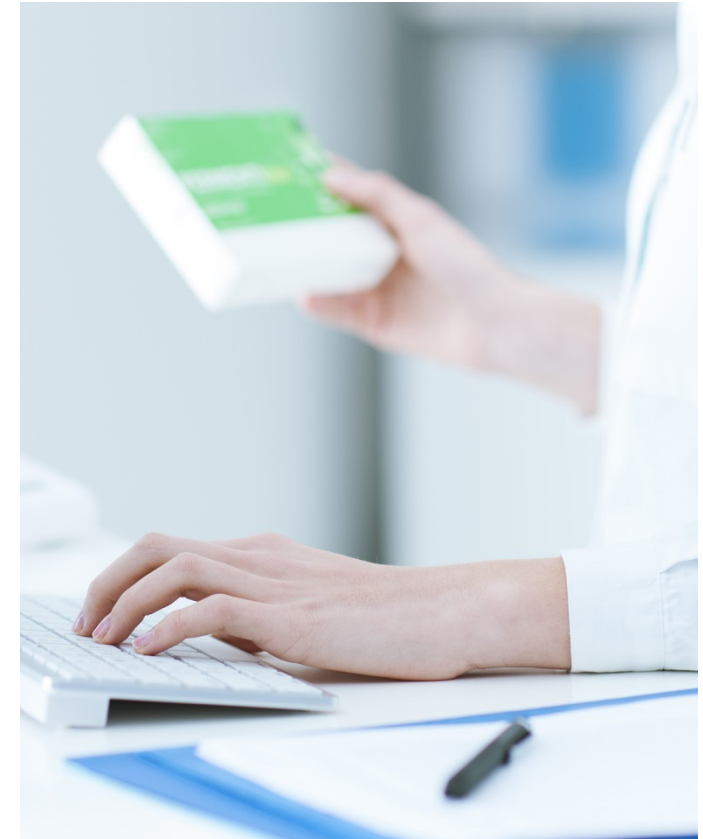
The Finnish Medicines Verification System

Where are we?



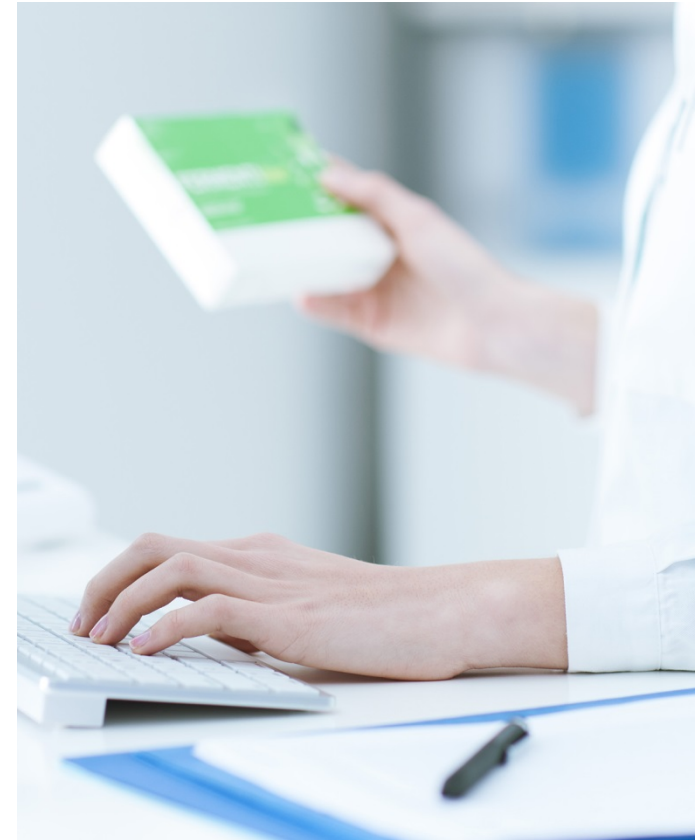
FIVMO

- Non-profit limited company
- Governs the implementation and operation of the Finnish Medicines Verification System (FiMVS)
- Shareholders
 - Pharma Industry Finland (~74%)
 - Orion Corporation (~13 %)
 - Finnish Generic Pharmaceutical Association (~10%)
 - Suppliers of Parallel Imported Medicines of Finland (~3%)
 - The Association of Finnish Pharmacies (0,1%)
 - The Association of Pharmaceutical Distributors (0,1%)
- Hospital pharmacies represented in the Project Steering Group



FiMVO decision making

- Consensus is sought but Shareholder's Agreement gives industry representatives power to make decisions regarding
 - FiMVO fees and fee increases
 - Investments
 - Annual operating plan (when the plan incurs costs)



What's important for pharma industry in Finland now?

- Taking part in testing FiMVS
- Contracts with FiMVO
 - Contract is non-negotiable
 - Whenever possible, local representation signs for all its MAH's (listed in Annex 2)
 - If MAH has no products on market it does not have to be listed (no obligation to pay)
 - MAH must keep Annex 2 updated
 - If one MAH is represented by several companies - one payment is sufficient - internal decision who pays
 - If you haven't yet, please return signed contract asap to katriina.newton-kolehmainen@fimvo.fi
 - Have you informed us of your Single Point of Contact?



Structure for financing the Verification System in Finland

Ramp-up costs

2017-2018

Loan from
Industry
Shareholders

- **Covers:** IT-provider + FiMVO governance
- **Lenders:** Industry shareholders in proportion to Rx sales in 2016

Ramp-up payments

2019 - 2020

Estimated range
5 000 – 8 000 €
/MAH*

- **Covers:** Ramp-up loans with 4% interest
- **Method:** Flat-fee/MAH
- Paid in two instalments (2019 and 2020)

Yearly operational costs

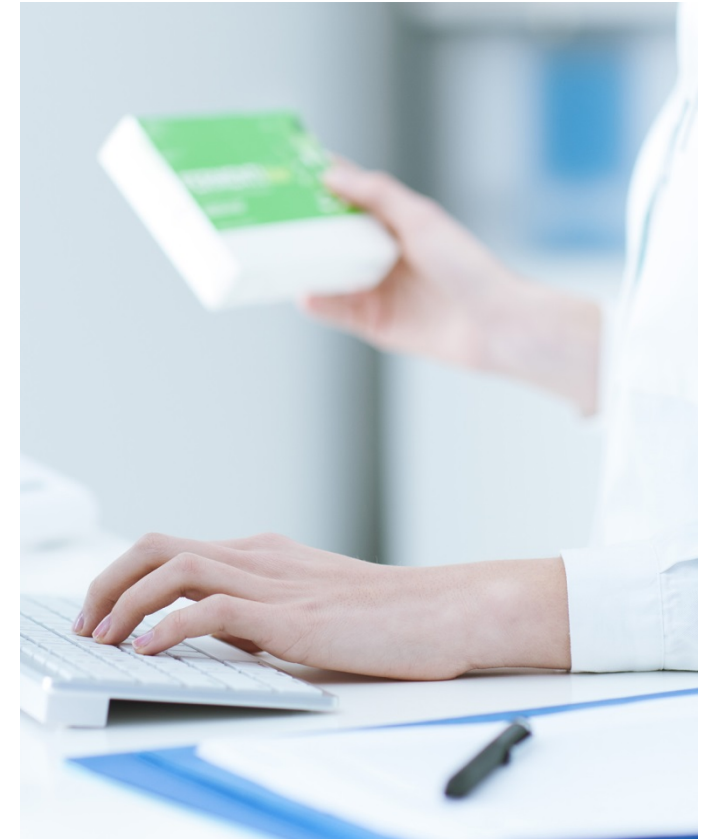
9/2018 ->

Estimated range
5 000 – 10 000 €/MAH*

- **Covers:** IT-system + FiMVO governance + Hub share
- **Method:** Flat fee/MAH

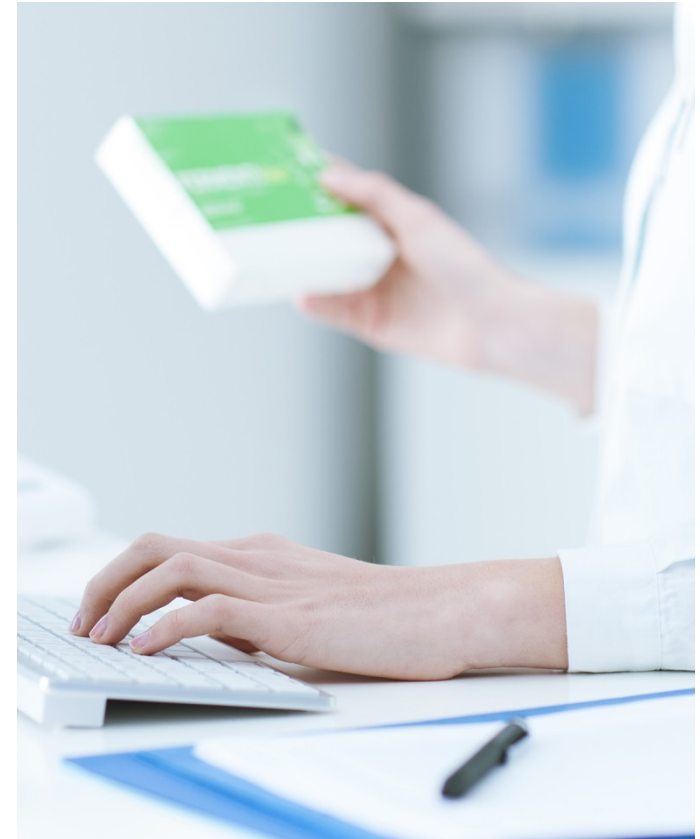
*Please note:
current estimates are based on 310 MAHs on FI market.
Number will be lower!

- Operational fees will start running in 9/2018
 - Invoicing starts in 8/2018
 - Pre-production phase and related costs start running in 11/2018
 - System must be up and running in time before implementation, we cannot risk failure
 - FiMVO's sole income are MAH fees - it takes time to ensure sufficient funds
 - Q4 2018 and 2019 will be covered in same invoice
- Costs of the ramp-up phase will be charged in two installments (2019 and 2020)
 - After receipt of ramp-up fees loans to Industry Shareholders will be paid back by PIF
 - PIF members note! All PIF members must also pay ramp-up fee
 - Ramp-up fee and PIF loans are two different issues



Operational fees

- Include:
 - System running costs (Arvato)
 - Finland's share of Hub costs (1%)
 - FiMVO administrative costs
- Predictable:
 - FiMVO is a limited company and legislation binds
 - Must operate in an efficient manner
 - Board can order audit at its discretion
- Unpredictable
 - Changes in number of MAHs
 - Changes to technical requirements
 - Changes from Commission or national authorities
 - Changes in Hub Fees



Additional information

- www.laakevarmennus.fi
- www.fimvo.fi
- LinkedIn
<https://www.linkedin.com/company/fimvo-finnish-medicines-verification-organisation/>

