FiMVO
Finnish Medicines Verification

The Medicines Verification System in Finland

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General Manager
Finnish Medicines Verification Organisation FiMVO

Agenda

9.00 Overview of the Medicines Verification System

Maija Gohlke-Kokkonen, General Manager
Finnish Medicines Verification Organisation/Suomen Lääkevarmennus Oy

9.30 Introduction from Arvato

Olle Hamskär, Customer Manager Nordics, Arvato Systems

9.50 Overview of the technical implementation

Tim Strässer, Project Manager, Arvato Systems

10.30 Break

10.45 Workshop, Detailed technical solution

Tim Strässer, Project Manager and Christian Classes, System Architect NMVS, Arvato Systems

12.00 Break

Possibility to have lunch at own expense

12.30 Detailed technical solution, continues

- timelines
- taking part in the pilot

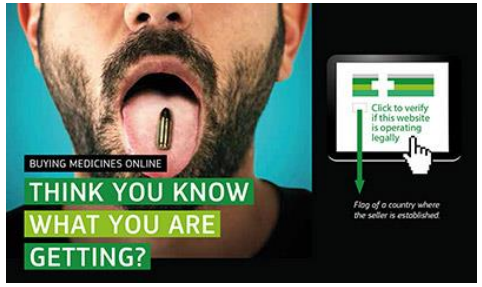
Tim Strässer, Project Manager and Christian Classes, System Architect NMVS, Arvato Systems

13.30 Q&A session

14.00 End of the meeting

Objective

- Protecting patients from falsified medicines in the legal supply chain
- Falsified Medicines Directive 2011/62/EU
  - Commission Delegated Regulation (EU) 2016/161
  - Commission Q&A document
    - http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm#framework
- Falsifications are a global threat
  - Falsifications have also been found in the Finnish legal supply chain



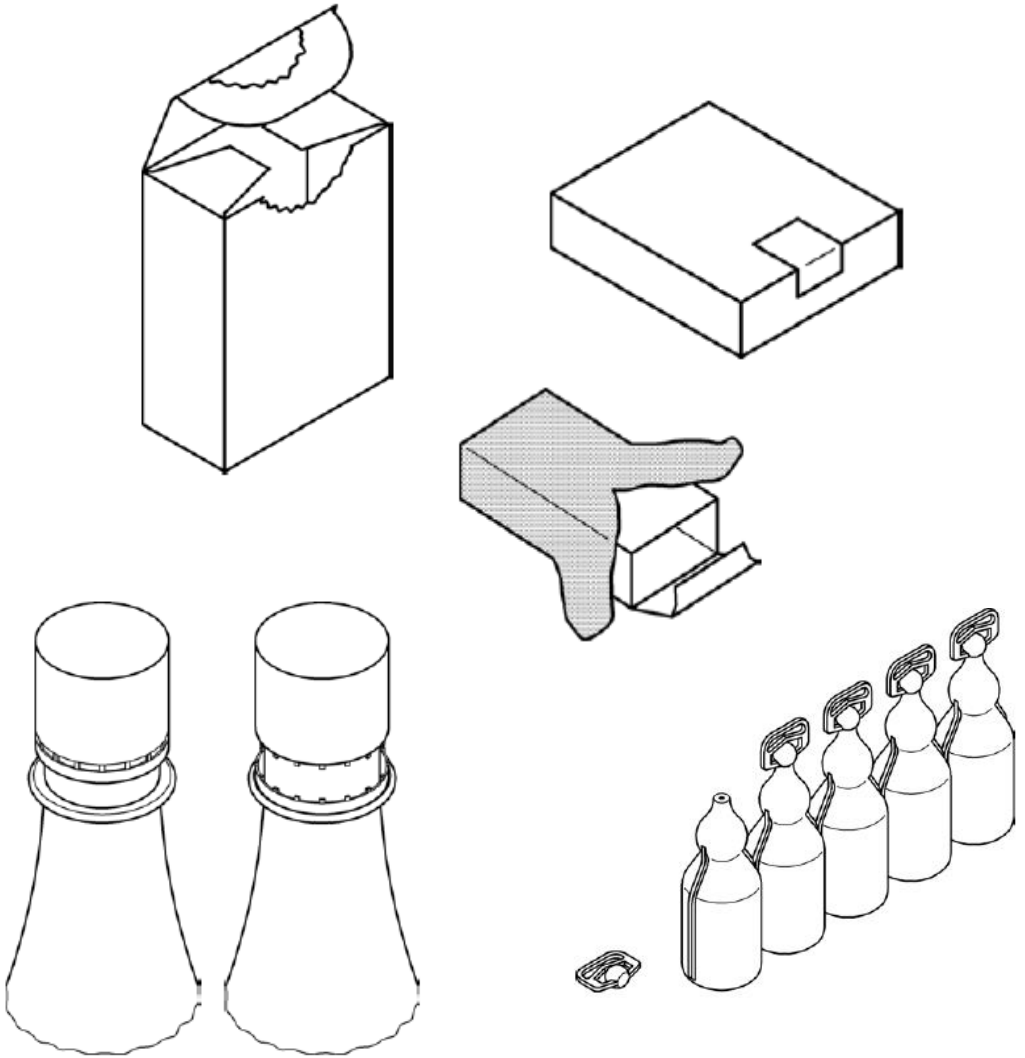
Safety features

- Unique identifier on each pack
  - 2D carrier
    - Product code
    - Serial number
    - Batch number
    - Expiry date
    - (National reimbursement number)
- Tamper evidence on packages

PC: (01)09876543210982
SN: (21)12345AZRQF1234567890
Batch: (10)A1C2E3G4I5
Expiry: (17)140531

Anti-tampering devices

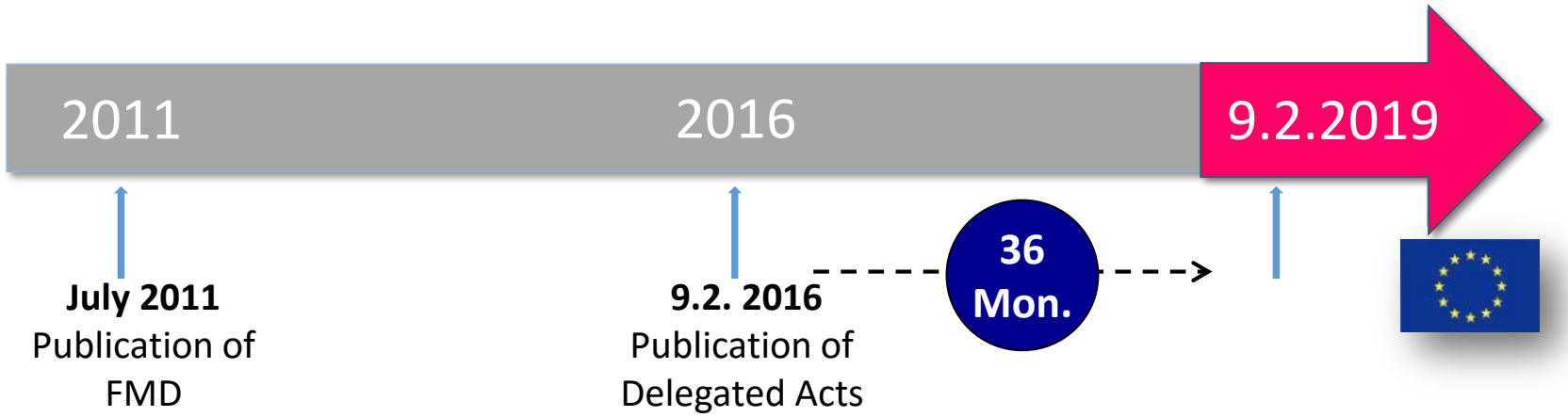
- To be decided by individual companies
- CEN standard prEN 16679 Tamper verification features for medicinal product packaging



Scope

- Applies to prescription medicines
  - Some exceptions (e.g. radionuclide generators, medicinal gases)
- Self-care medicines on a risk-based approach
  - At the moment only one active substance
    - 20 mg omeprazole capsules
- Applies to all parts of the supply chain

Timeframe


2011
2016
9.2.2019
July 2011
Publication of
FMD
9.2. 2016
Publication of
Delegated Acts
36
Mon.

Responsibilities

- Pharmaceutical industry responsible for
  - Placing the unique identifier on the package
    - With related responsibilites such as record keeping
  - Equalent unique identifier must be placed in parallel trading
  - Setting up and financing the system
    - All stakeholders in supply chain involved!

Responsibilities

- Wholesalers verify code on a risk based approach
  - returned products
  - products received from another wholesaler not commissioned by the MAH
- Wholesalers verify and decommission

  “(a) products which he intends to distribute outside of the Union;

  (b) products which have been returned to him by persons authorised or entitled to supply medicinal products to the public or another wholesaler and cannot be returned to saleable stock;

  (c) products which are intended for destruction;

  (d) products which, while in his physical possession, are requested as a sample by competent authorities;

  (e) products which he intends to distribute to the persons or institutions referred to in Article 23, where required by national legislation in accordance with the same Article”

Responsibilities

- Article 23: Member states may require wholesalers to verify and decommission the code before the product is supplied to:
  (a) persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;
  (b) veterinarians and retailers of veterinary medicinal products;
  (c) dental practitioners;
  (d) optometrists and opticians;
  (e) paramedics and emergency medical practitioner
  (f) armed forces, police and other governmental i
  medicinal products for the purposes of civil prote
  (g) universities and other higher education establ
  products for the purposes of research and educat
  healthcare institutions;
  (h) prisons;
  (i) schools;
  (j) hospices;
  (k) nursing homes.

Not in Finnish legislation yet BUT
FiMVO opinion:

Only b) applies for Finnish wholesalers, all other entities buy their medicines from pharmacies or hospital pharmacies

Responsibilities

- Pharmacies decommission code when dispensing the medicine to the patient
  - Exceptions to hospital pharmacies – code may be decommissioned earlier (and in most cases will be)
  - Also tamper evidence must be checked
- Pharmacies also verify and decommission in certain cases:

  "(a) medicinal products in their physical possession that cannot be returned to wholesalers or manufacturers;

  (b) medicinal products that, while in their physical possession, are requested as samples by competent authorities, in accordance with national legislation;

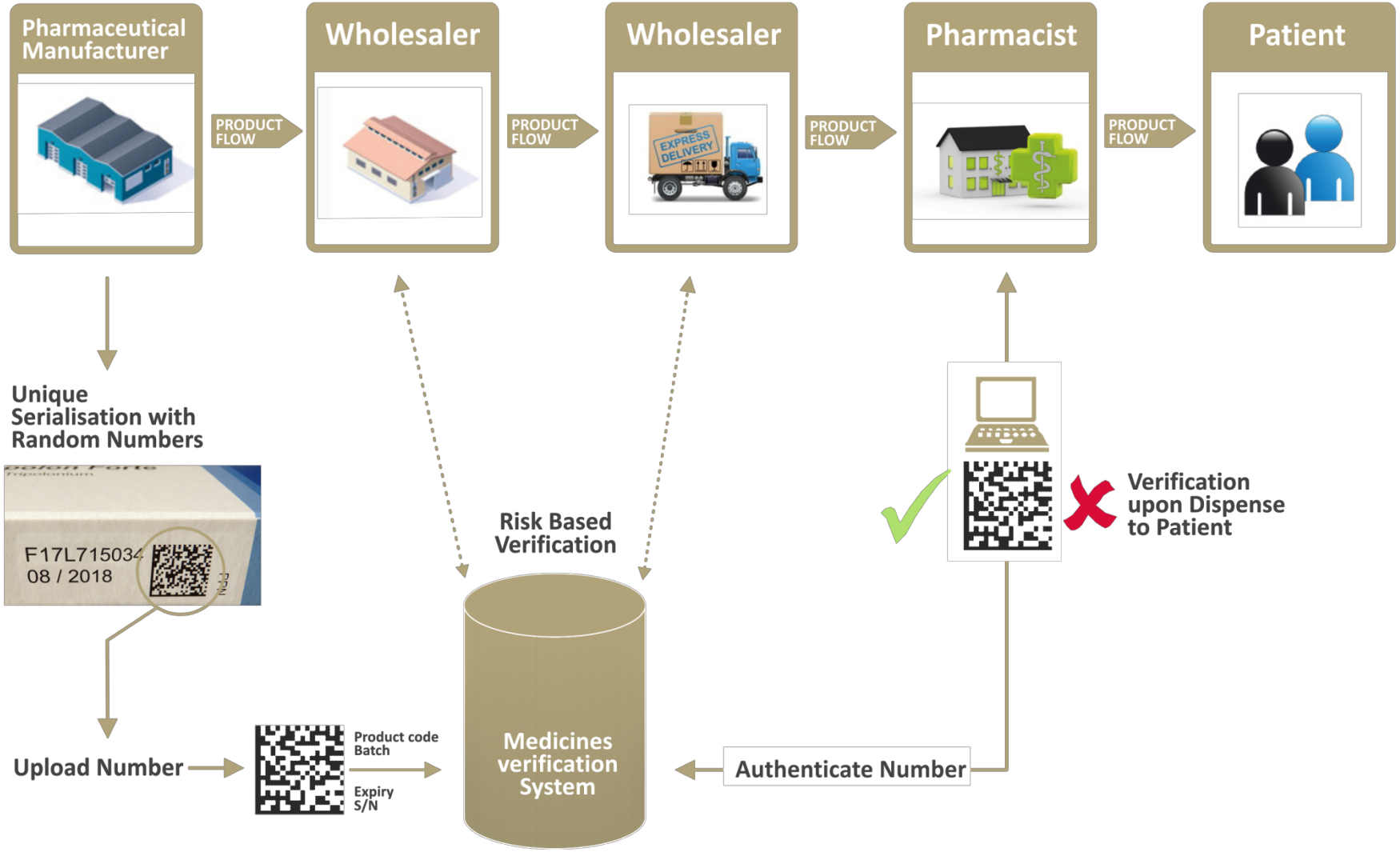
  (c) medicinal products which they supply for subsequent use as authorised

  investigational medicinal products or authorised auxiliary medicinal products as defined in Articles 2(2)(9) and (10) of Regulation (EU) No 536/2014."
- Code can be entered back into the system within 10 days if product hasn't been removed from premises

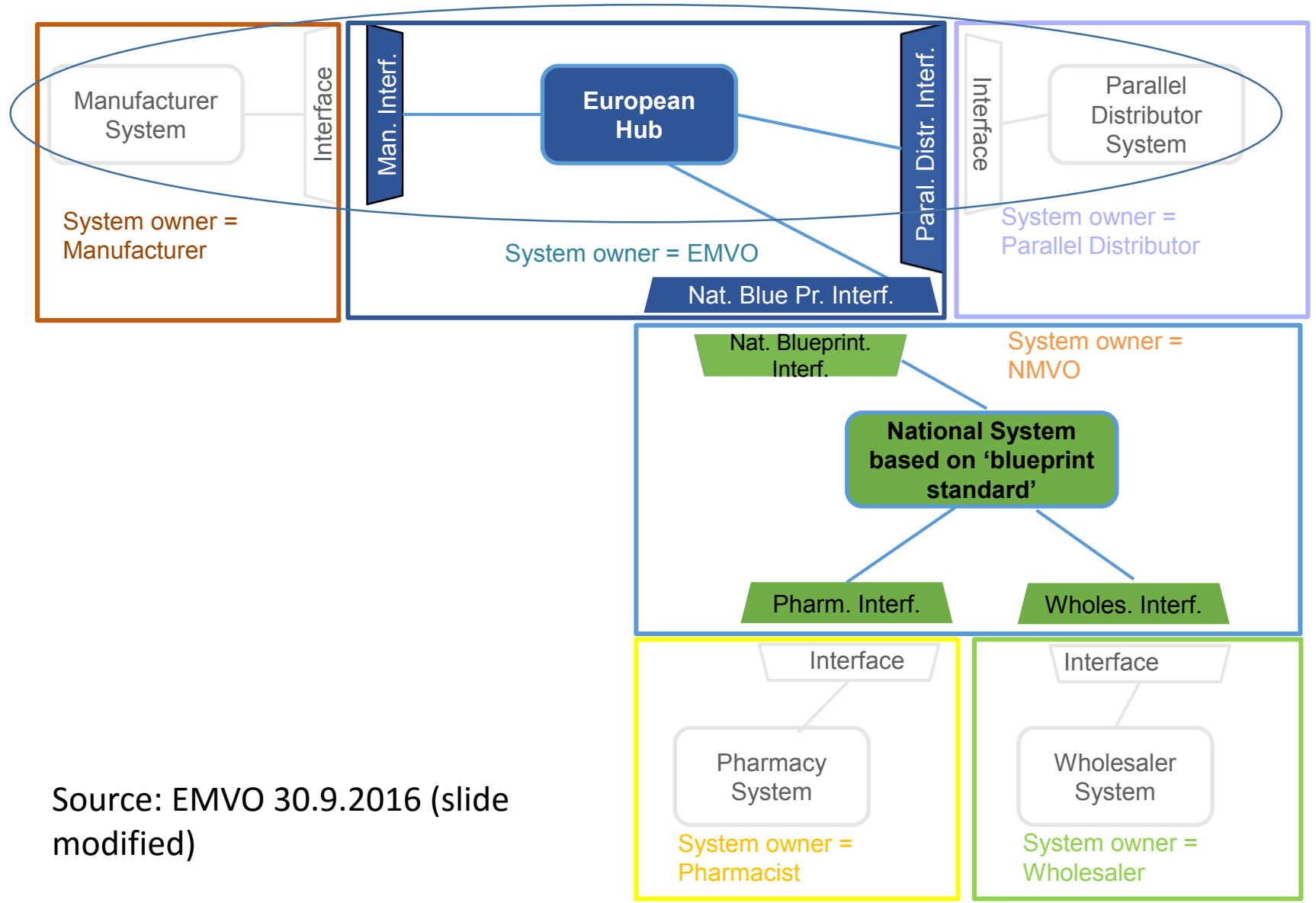
Responsibilites

- National Competent Authorities
  - Make available information about products in scope
  - Supervise the repositories system
    - Participate in the board of the national organisation, if choose so
      - Finnish authorities will not use this option

Point of dispense verification



System Landscape



Source: EMVO 30.9.2016 (slide modified)

14

Governance

GENERAL PRINCIPLE
System management and governance by not-for-profit organisation under supervision of relevant competent authority

EU LEVEL

emvo European Medicines Verification Organisation

NATIONAL LEVEL
National Medicines Verification Organisations (NMVO)

In Finland: The Finnish Medicines Verification Organisation (Suomen Lääkevarmennus Oy)

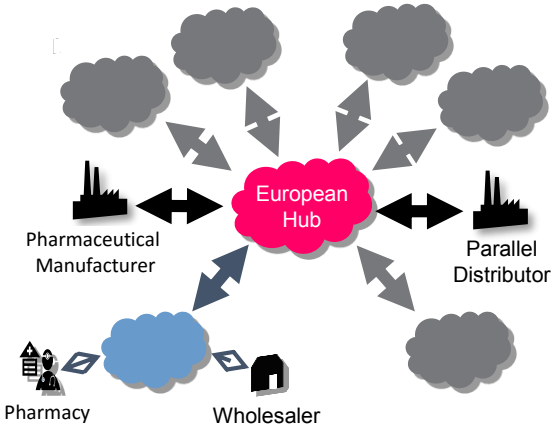
FiMVO

- Not-for profit limited company
- 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 (0,10%)
  - The Association of Pharmaceutical Distributors(0,1%)
- Also hospital pharmacies represented in the Steering Group of the project

FiMVO tasks

- Establish and manage national system
- Ensure interoperability with European Hub
- Conclude agreements with all national users
  - All pharmacies, hospital pharmacies and dispensaries
  - All wholesalers
  - All IT-providers for the above mentioned
- Analyse exceptional events at national level

Who will pay?

Repository system (Hub & national systems)	Installations for pack coding	Installations for pack verification
		
Pharmaceutical Industry	**Pharmaceutical Industry**	**Pharmacists, wholesalers, …**

Contacts

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- www.laakevarmennus.fi /www.fimvo.fi operational in May, until then www.laaketeollisuus.fi