FiMVO
Finnish Medicines Verification

The Medicines Verification System in Finland

Maija Gohlke-Kokkonen
General Manager
Finnish Medicines Verification Organisation FiMVO

Agenda

11.00 Overview of the Medicines Verification System

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

11.50 Break

12.00 Introduction from Arvato

Olle Hamskär, Customer Manager Nordics, Arvato Systems

12.30 Building the Verification System in Finland

- timelines
- taking part in the pilot

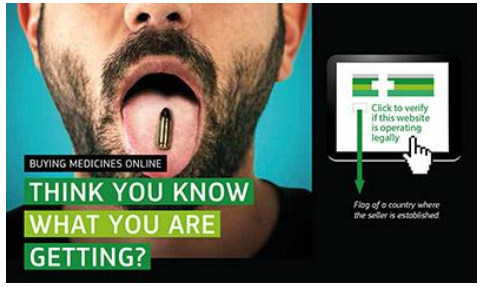
Tim Strässer
Project Manager, Arvato Systems

13.00 Q&A session

14.00 End of 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



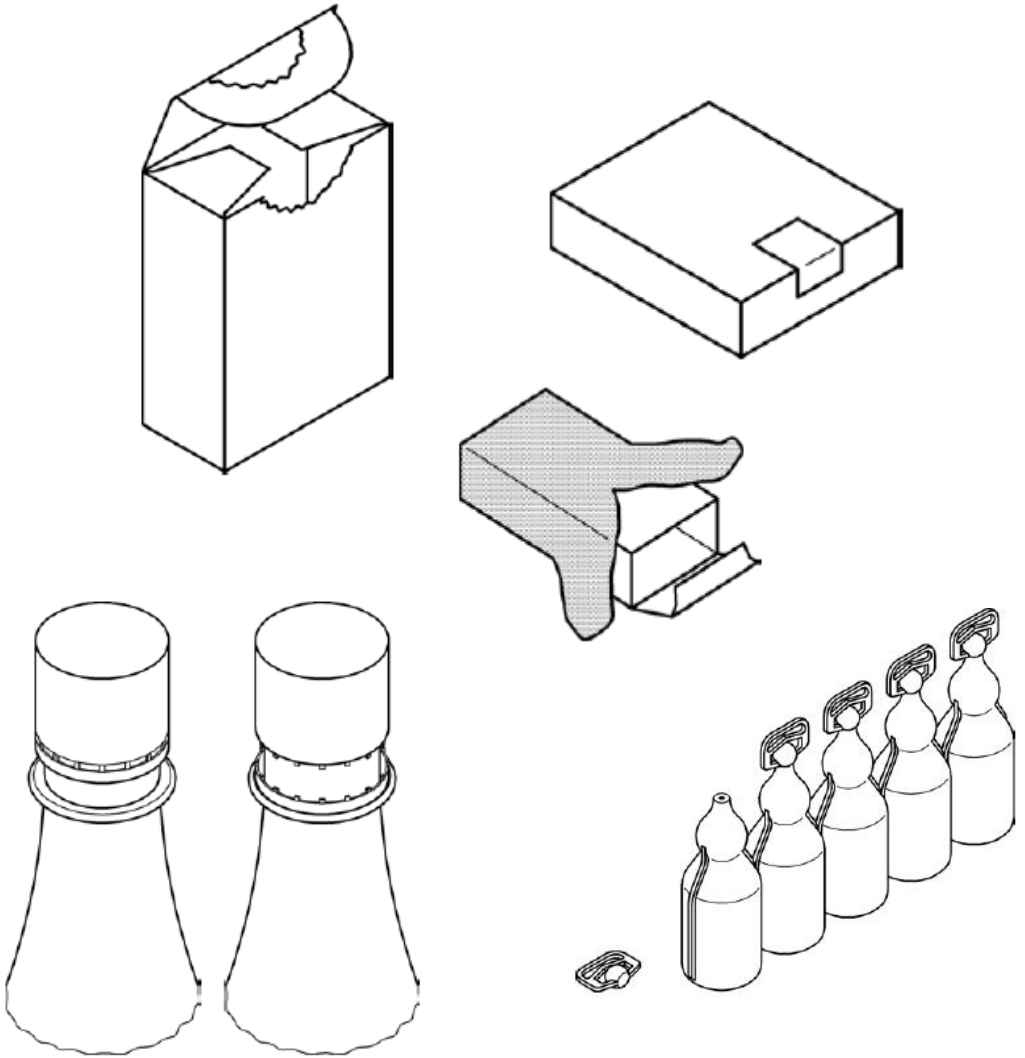
Safety features

- Unique identifier on each pack
  - 2D carrier
    - Product code (GTIN)
    - 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

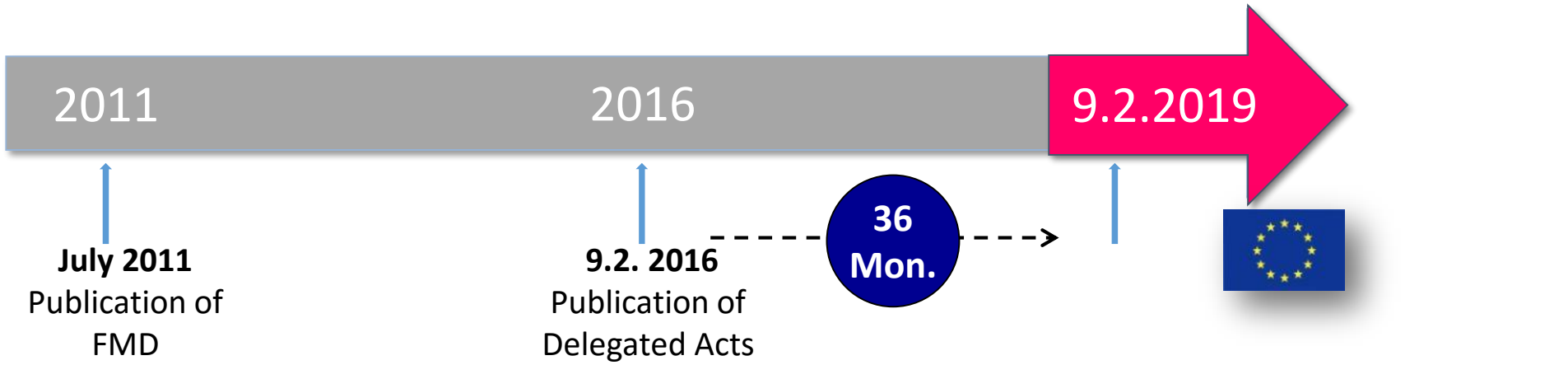
- To be decided by individual companies
- CEN standard prEN 16679 Tamper verification features for medicinal product packaging



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



Implementation time: packs released onto the market before 9.2.2019 do not need to have safety features

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;

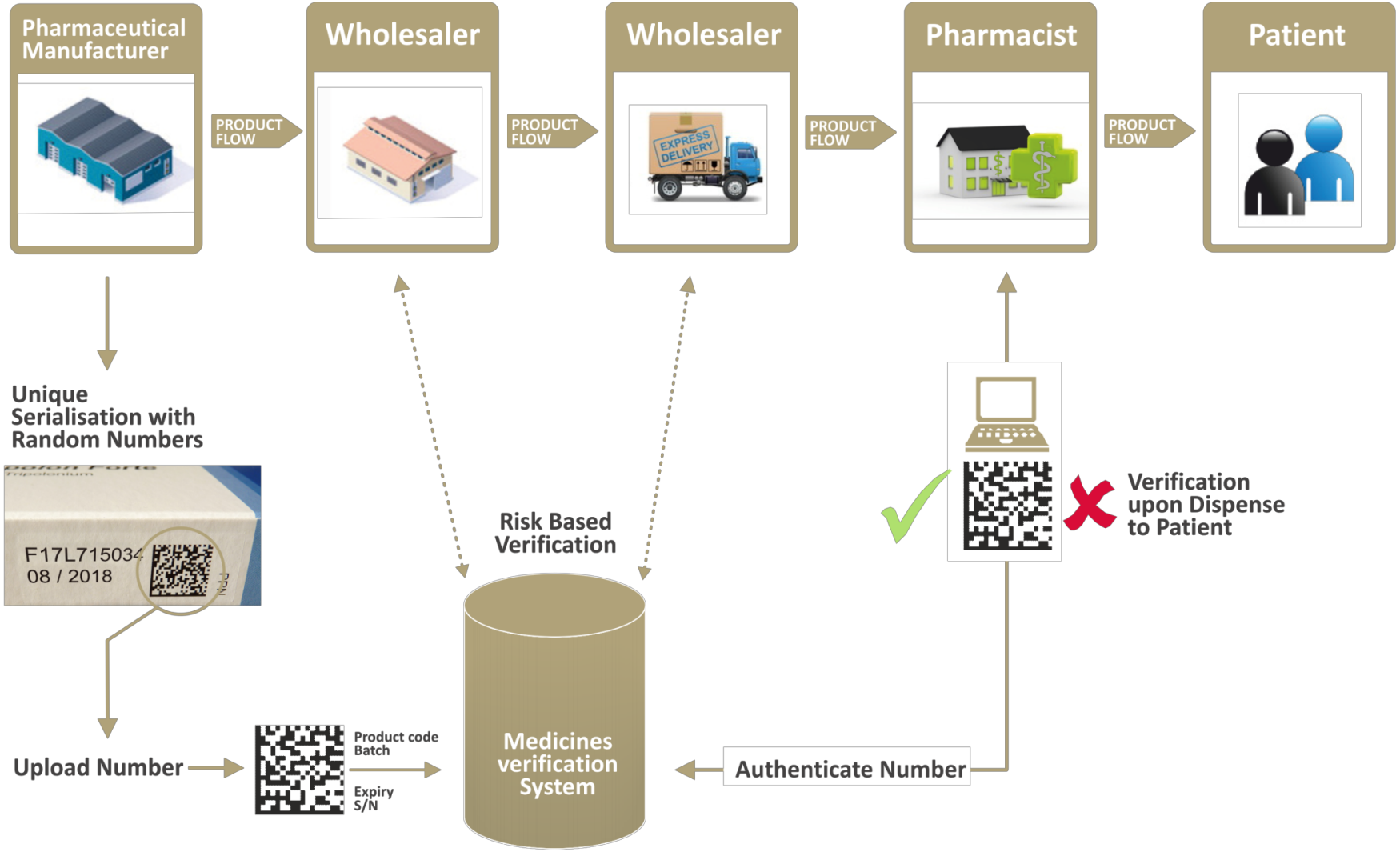
  (c) medicinal products which they supply for subsequent use as authorised

  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

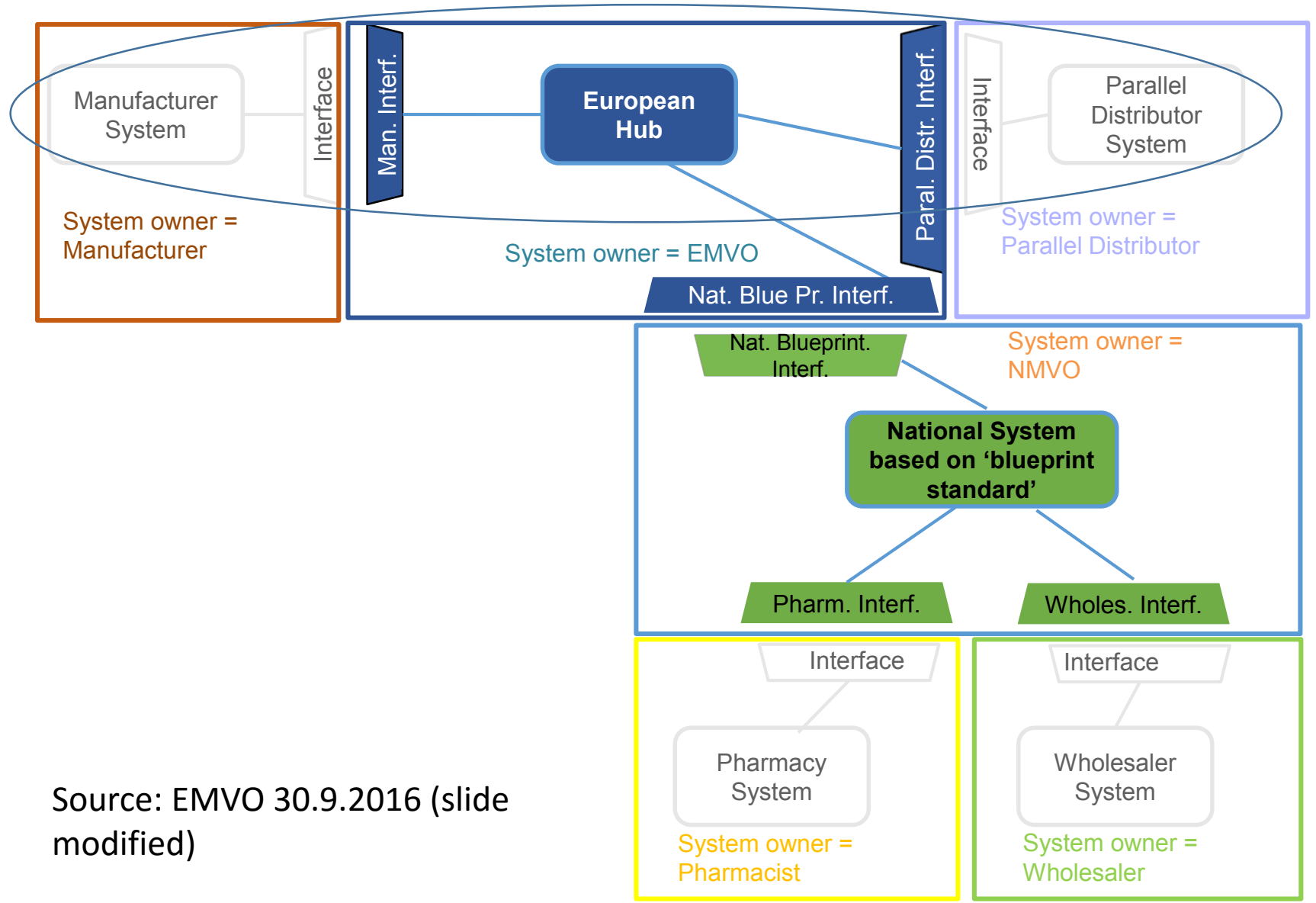
Responsibilites

- 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)

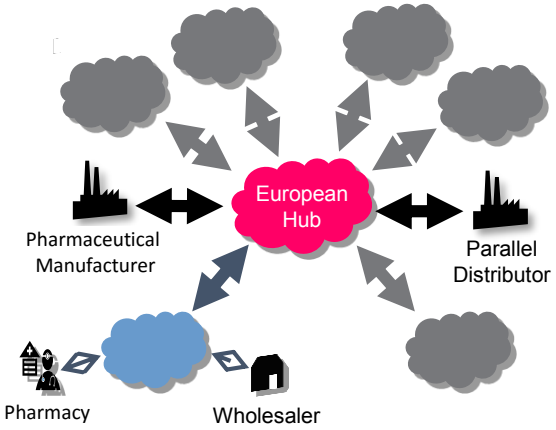
FiMVO

- Not-for profit limited company
- Shareholders (according to Rx market share):
  - 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 mentioned above
- 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, …**

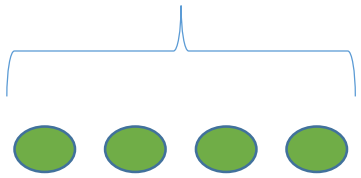
Financing the Verification System

- Ramp-up phase of the system 2017-2018
  - Initially financed through loans by the shareholders according to shares in FiMVO
  - Amount of ramp-up costs (+ 4% interest) will be charged to all users of the system during 5 years (2019-2023)
    - Loans will then be repaid to shareholders
    - Charge will be based on a flat fee for each marketing authorisation holder
- Operational phase costs covered by all users of the system (start end of 2018)
    - Costs will be divided as a flat fee per marketing authorisation holders

Structure for financing the Verification System

2017-2018

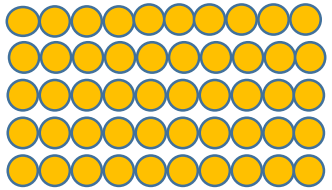
Ramp-up: estimation 1.5M €



- **Covers**: IT-provider + FiMVO governance
- **Financing method**: loan
- **Lenders**: industry shareholders in proportion to their market share

2019 -2023

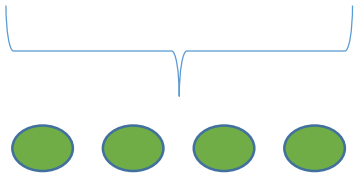
Covering ramp-up costs



- All companies pay a share of ramp-up costs
- **Basis:** Flat-fee/MAH
- **Estimation: 4 700/ramp-up***

2019 - 2023

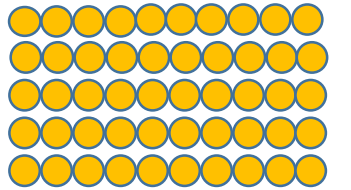
Loan repayment



- Ramp-up loan repaid with interest (4 %)

Q4/2018 ->

Operational costs: Estimation 1M p.a.



- **Covers:** IT-system + FiMVO governance, Hub share
- **Financing method:** usage fees
- **Basis:** Flat fee
- **Estimation:** 3 200 €/MAH/p.a.*

Please note: currently 320 MAH's on FI market. Number may change!

What you need to do now

- Make sure that each package has a unique product code (GTIN)
- Ensure technical readiness to create a unique serial number according to the requirements of the Delegated Act
- Ensure that production lines are fully equipped to fulfill the requirements of legislation
- Get ready for the new legislation by renewing the lay-out of the packages when necessary
- Ensure that onboarding the Hub is started as soon as possible

How to connect to the Hub

- https://www.emvo-medicines.eu/wp-content/uploads/2016/09/OBP-On-boarding-Guideline.pdf
- https://www.emvo-medicines.eu/wp-content/uploads/2016/09/On-Boarding-Presentation.pdf
- https://www.emvo-medicines.eu/wp-content/uploads/2016/09/OBP-Non-Disclosure-Agreement-SAMPLE.pdf
- https://www.emvo-medicines.eu/wp-content/uploads/2016/09/OBP-Participation-Agreement-SAMPLE.pdf

Who connects to the Hub

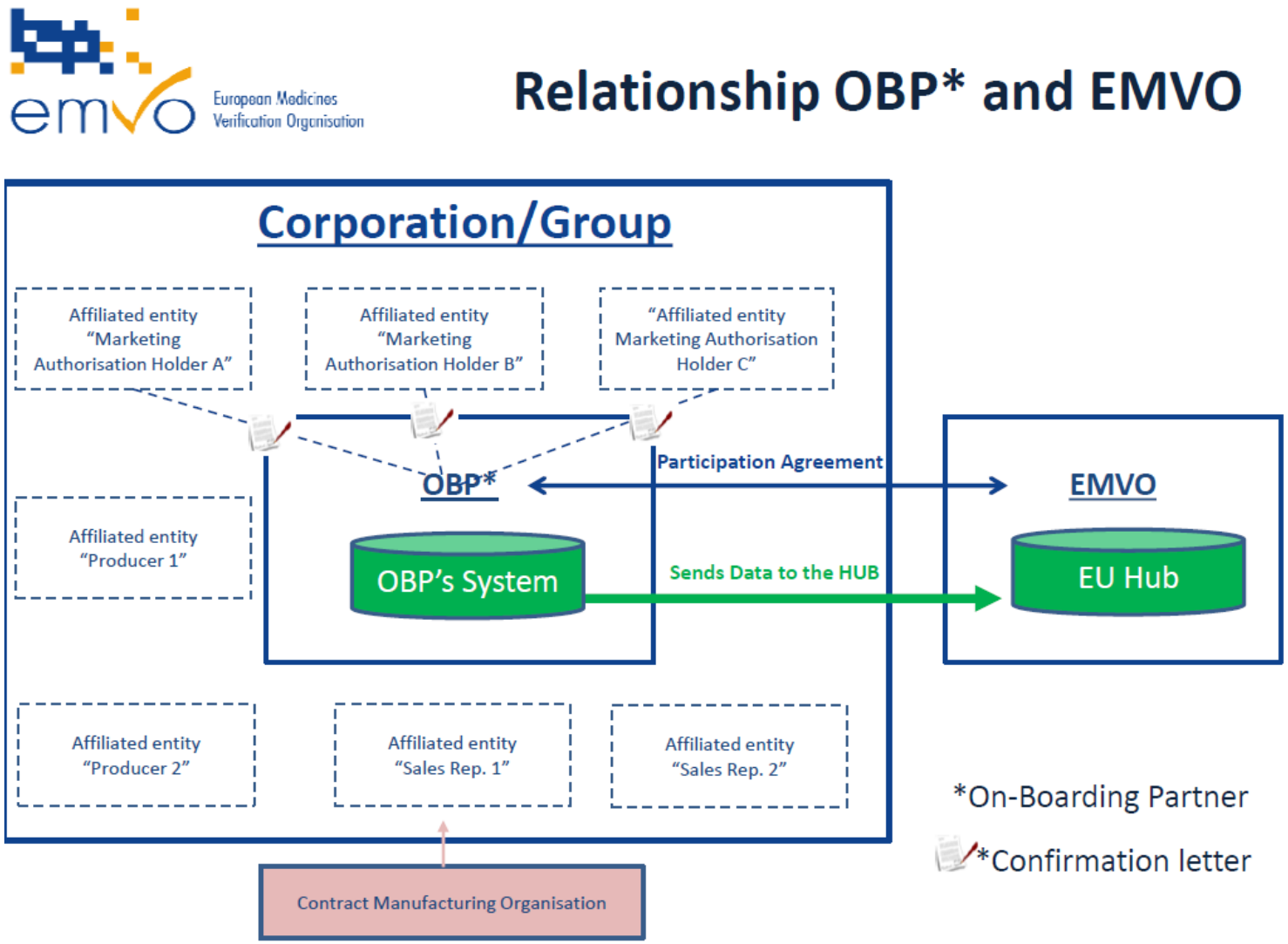
European Medicines Verification Organisation

What is an "OBP"?

- OBP means **O**n-**B**oarding **P**artner and is the contracting party of EMVO and concludes the non-disclosure agreement (NDA) and participation agreement (PA).
- The OBP is legally authorized to sign on behalf of a MAH/a group of MAHs.
- The OBP has to be affiliated (*) to a MAH/a group of MAHs

(*) Affiliate shall mean, in relation to a Party, any other person affiliated with such Party within the meaning of Article 11 of the Belgian Code of Companies (it being understood, for the avoidance of doubt, that the definition set out in said Article 11 is agreed to also apply to non-Belgian persons).

Who connects to the Hub



Connecting to the Hub - costs

One-Time Fee per OBP

OBPs with more than 12 MAHs in Europe	20,000 €
OBPs with 6 to12 MAHs in Europe	10,000 €
OBPs with 3 to 5 MAHs in Europe	8,000 €
OBPs with 2 MAHs in Europe	6,000 €
OBPs with 1 MAH in Europe	3,000 €

Contacts

- Governance and general issues:
  - General Manager Maija Gohlke-Kokkonen
  - Maija.gohlke-kokkonen@laakevarmennus.fi
  - +358 40 700 1655
- Technical issues
  - Project manager Tero Vesa
  - Tero.vesa@laakevarmennus.f
  - +358 400 416698

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