Aktivitātes saistībā ar Falsified Medicines Directive ieviešanu Latvijā

2016.gada 20.aprīlis Rīga

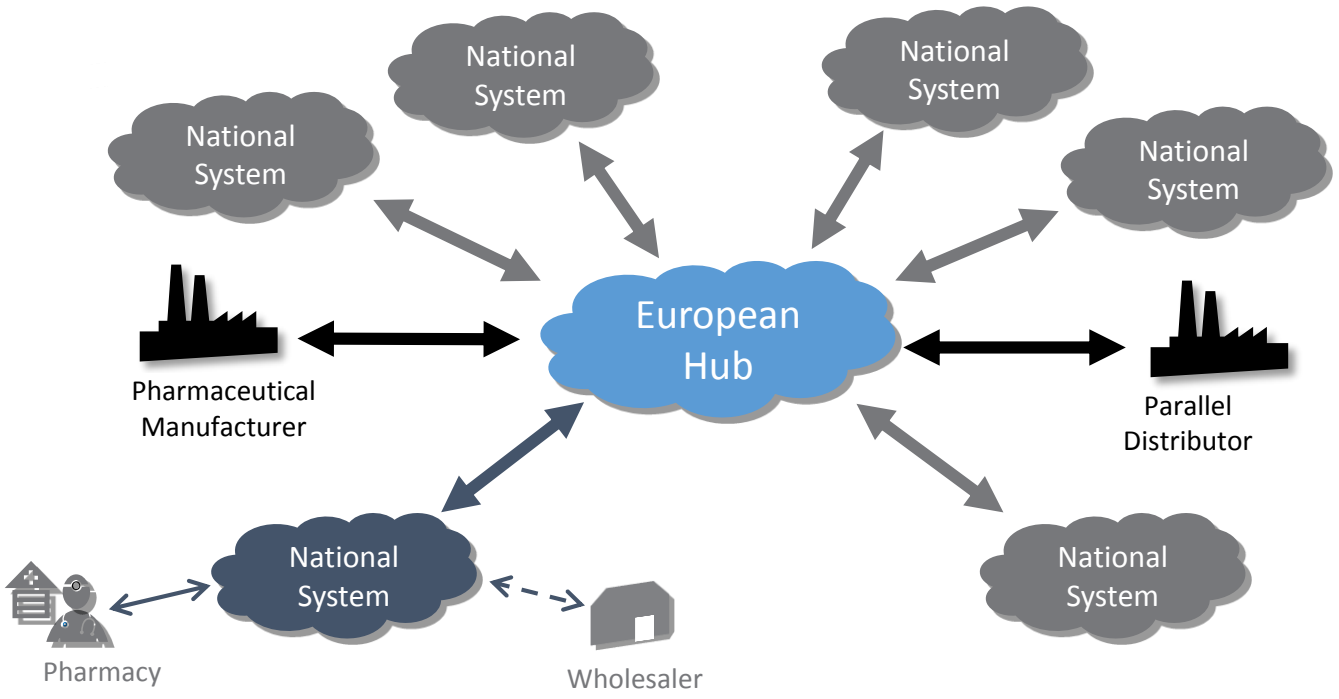
Pamatinformācija par *Falsified Medicines Directive (FMD)*

- **Objective:**
  - Protection of patients from counterfeited medicines in the legal distribution chain.
- **Idea:**
  - Pan-European system to verify the authenticity of medicinal products

- **Timeline:**
  - Official publication of FMD: **2011**
  - Delegated Regulation (DR), published: **2016**
  - The European Medicines Verification Organisation (EMVO) has developed an **Implementation Package** to support its members
  - Implementation **process** in a country will take **2 years**. With an extra **6 months** testing period after implementation
  - Implementation of the FMD is required **until 2018**
  - The complete verification system has to be up and running **by 9 February 2019** (except Belgium, Italy, Greece: 9 February 2025)

Pamatinformācija *FMD*

- **Pan-European System: National Systems connected by the European Hub:**



Pamatinformācija *FMD*

- Requirements for safety features
  - **Unique identifier**
    - Data-Matrix Code
    - Randomised serial number

Code (‘safety feature’)

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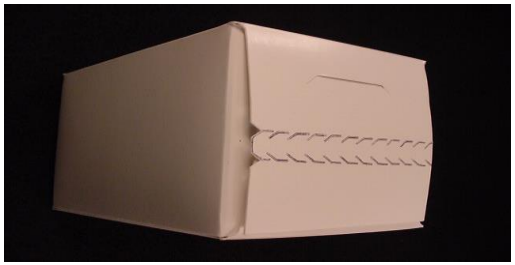
Tamper evidence



Product #:	09876543210982
Batch:	A1C2E3G4I5
Expiry:	140531
S/N:	12345AZRQF1234567890

Pamatinformācija *FMD*

- Verification at point of dispense

Serialization by manufacturer

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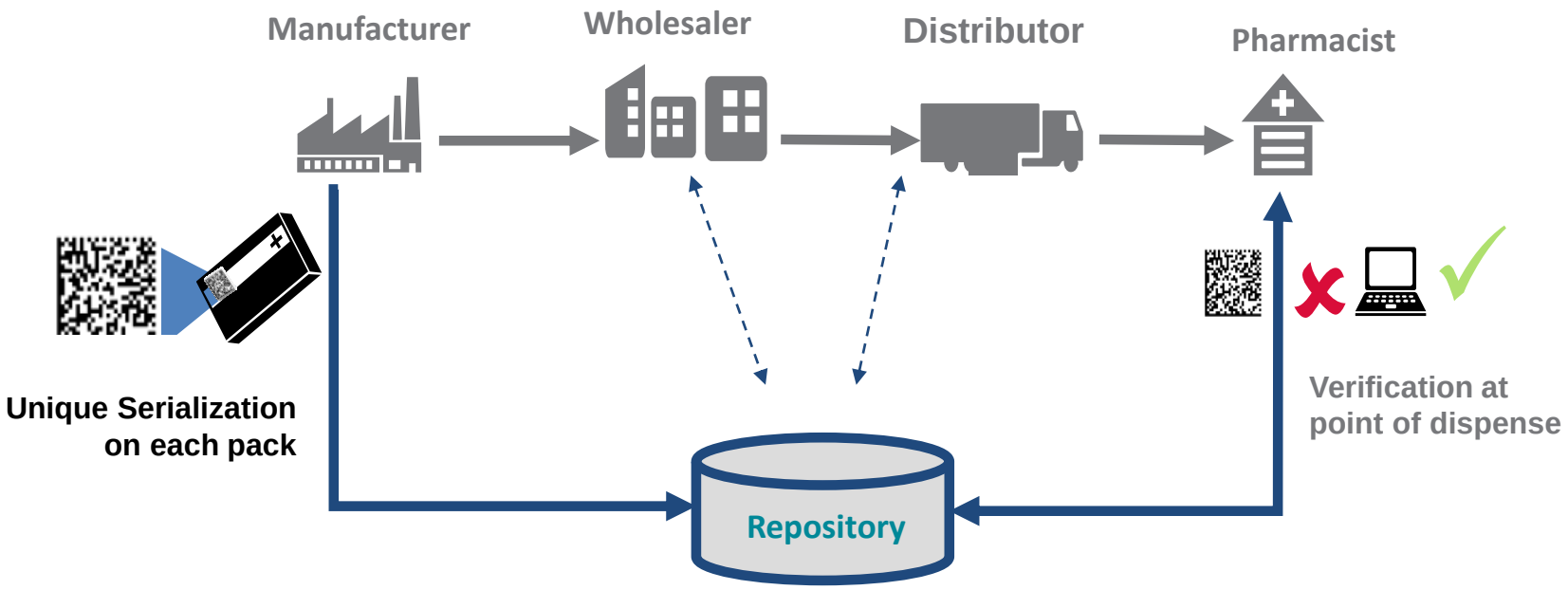
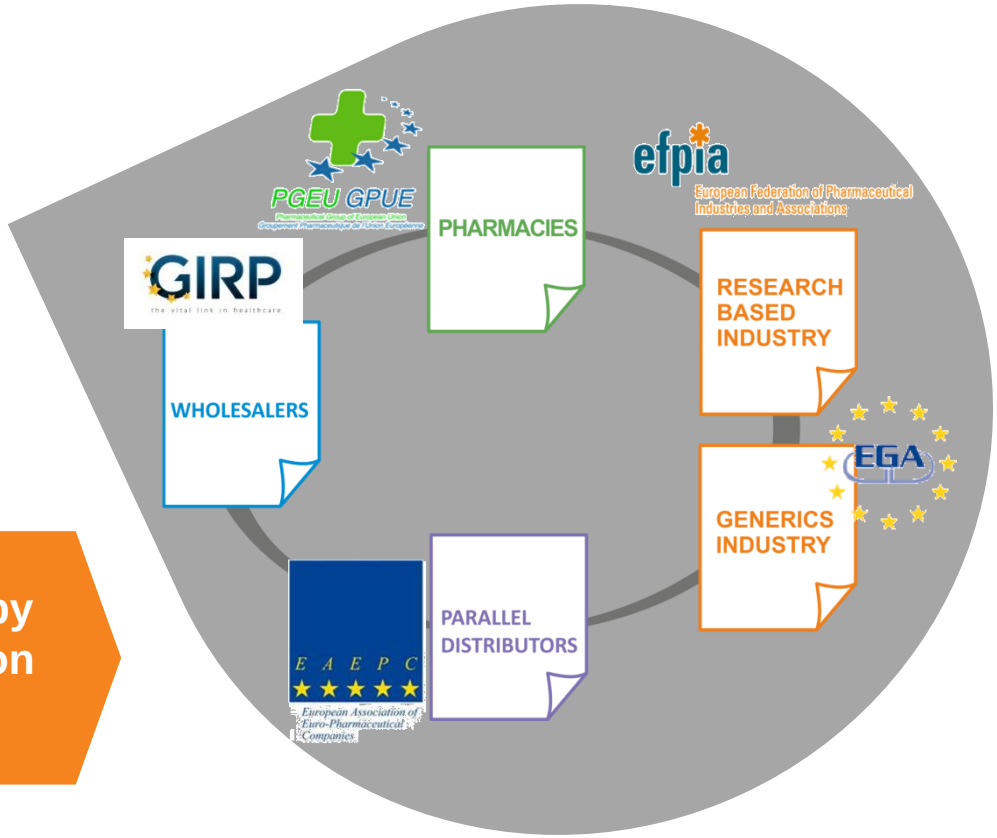
Verification at point of dispense



Pamatinformācija *FMD*

EMVO-members are allocated to a constituency



System set up and governed by stakeholders under supervision of authorities

Aktivitātes saistībā ar FMD ieviešanu Latvijā

- ***Saprašanās memorands (MoU):***
  - Sadarbība ar EFPIA institūcijām
  - MoU parakstīts (Sifffa; LPMA; BRAL; LAĶĪFA)
  - MoU pievienojas citas ieinteresētās organizācijas

- ***The National Medicines Verification Organisation (NMVO) dibināšana Latvijā***
  - Šobrīd tiek strādāts pie NMVO dibināšanas (statūti, dokumentācija utt.)
  - Līdz ar NMVO izveidi sāktos kopsadarbība ar iesaistītajām pusēm.

- ***IT pakalpojumu nodrošinājums:***
  - Blueprint piedāvājumu noklausīšanās
  - Blueprint nodrošinātāja izvēle

- ***Sadarbība ar valsts iestādēm***

PALDIES PAR UZMANĪBU!