SAFER EUROPE WITHOUT FALSIFIED MEDICINES

European Commission

EU2017.EE Estonian Presidency of the Council of the European Union

The Falsified Medicines Directive: Safer Medicines for Europe

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European Commission

"Safer Europe without Falsified Medicines"

8 November 2017
Tallin

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EU Legislation against Falsified Medicines

Directive 2011/62/EU (the FMD)

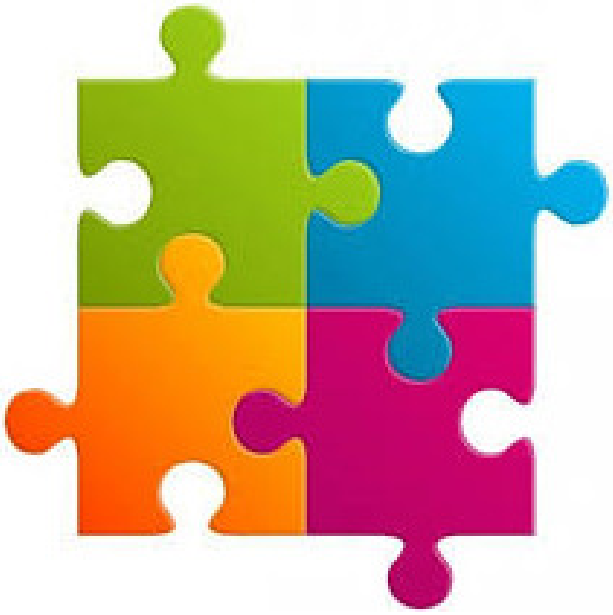
4 Pillars

1. Safety features

Mandatory identification and authentication of individual medicine packs.

2. Reinforcing the distribution chain

Strengthened GDP and requirements for wholesale distributors



3. Active substances

Tougher rules on importation of APIs; reinforced controls and inspections of API manufacturers.

4. Internet sales

A common, EU-wide logo to identify legal online pharmacies.

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GDP

Reinforced Distribution Chain

- Improved **GDP guidelines** for *medicinal products* and *APIs*
- EU database of distributors ⇨ **EudraGMDP**
- Mandatory **registration of** API distributors

Safer Active Ingredients

API

- Import from outside the EU only if:
  - **Written confirmation** of equivalent GMP for API; or
  - Exporting country is **"listed"** as equivalent by the Commission; or
  - **EU GMP** certificate.
- New requirements for API manufacturers (registration, audits, inspections, GMP)

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EU logo

Safer Internet Sales of Medicines

EU common logo for online pharmacies

- Since 1 July 2015, a **EU common logo** identifies all websites legally selling medicinal products in the EU;

Click to verify if the website is operating legally

→ **Buyer takes informed decision!**

- Awareness campaigns to inform on the **risks of buying from illegal websites**.

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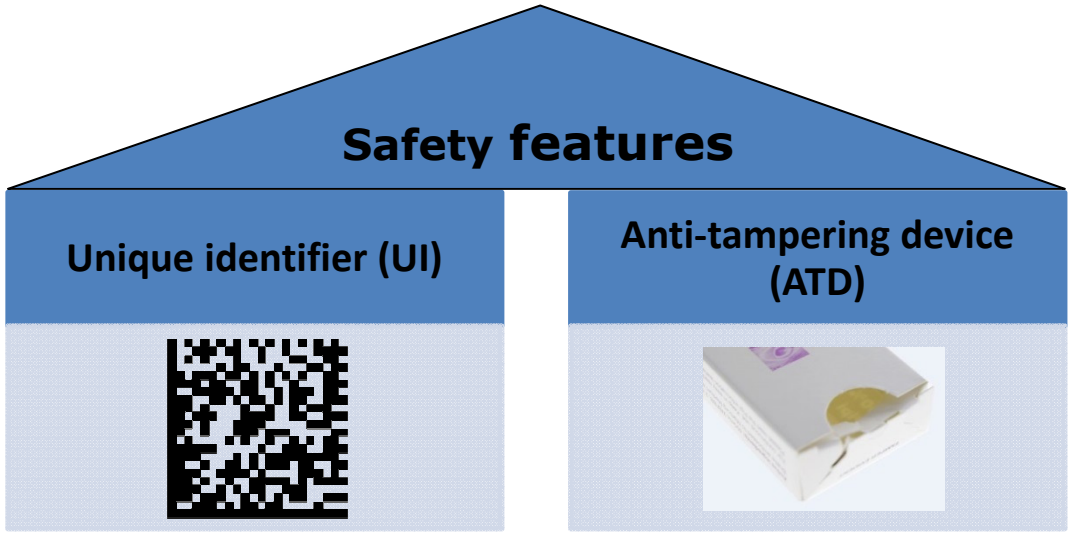
Safety Features for Medicine Verification

Safety Features

Delegated Regulation (EU) No 2016/161



Unique Identifier

Anti-tampering Device

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The Unique Identifier

PC:	09876543210982
SN:	12345AZRQF1234567890
NN:	(optional)
Batch:	A1C2E3G4I5
Expiry:	032021

Illustrative example – not binding

- A unique code on each pack
- carried by a 2D barcode (Data Matrix ECC200)
- Minimum printing quality
- Human-readable format

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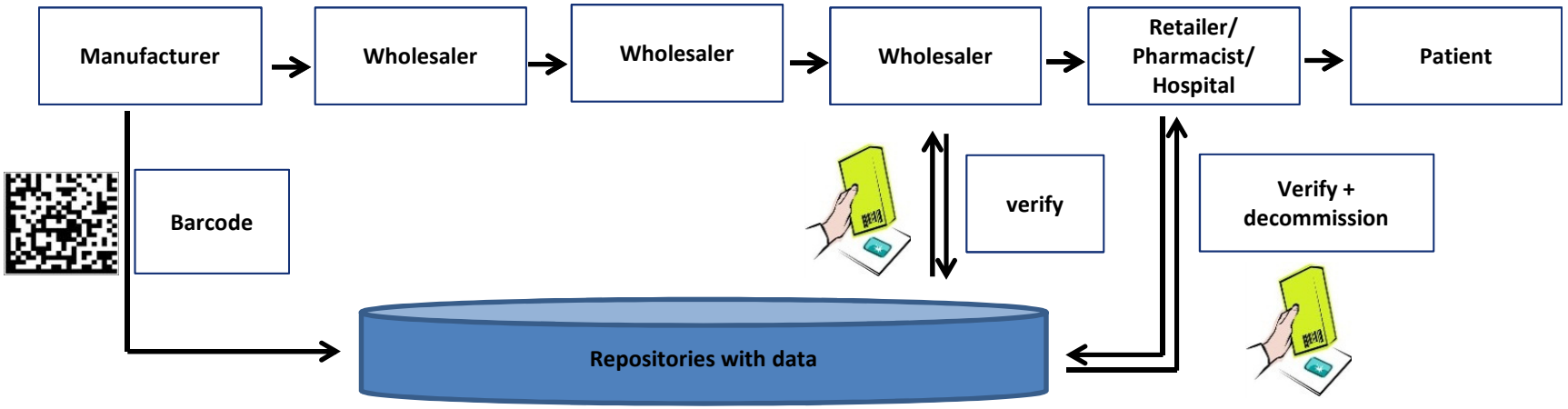
Verification of the safety features

End-to-end verification system + risk based verifications



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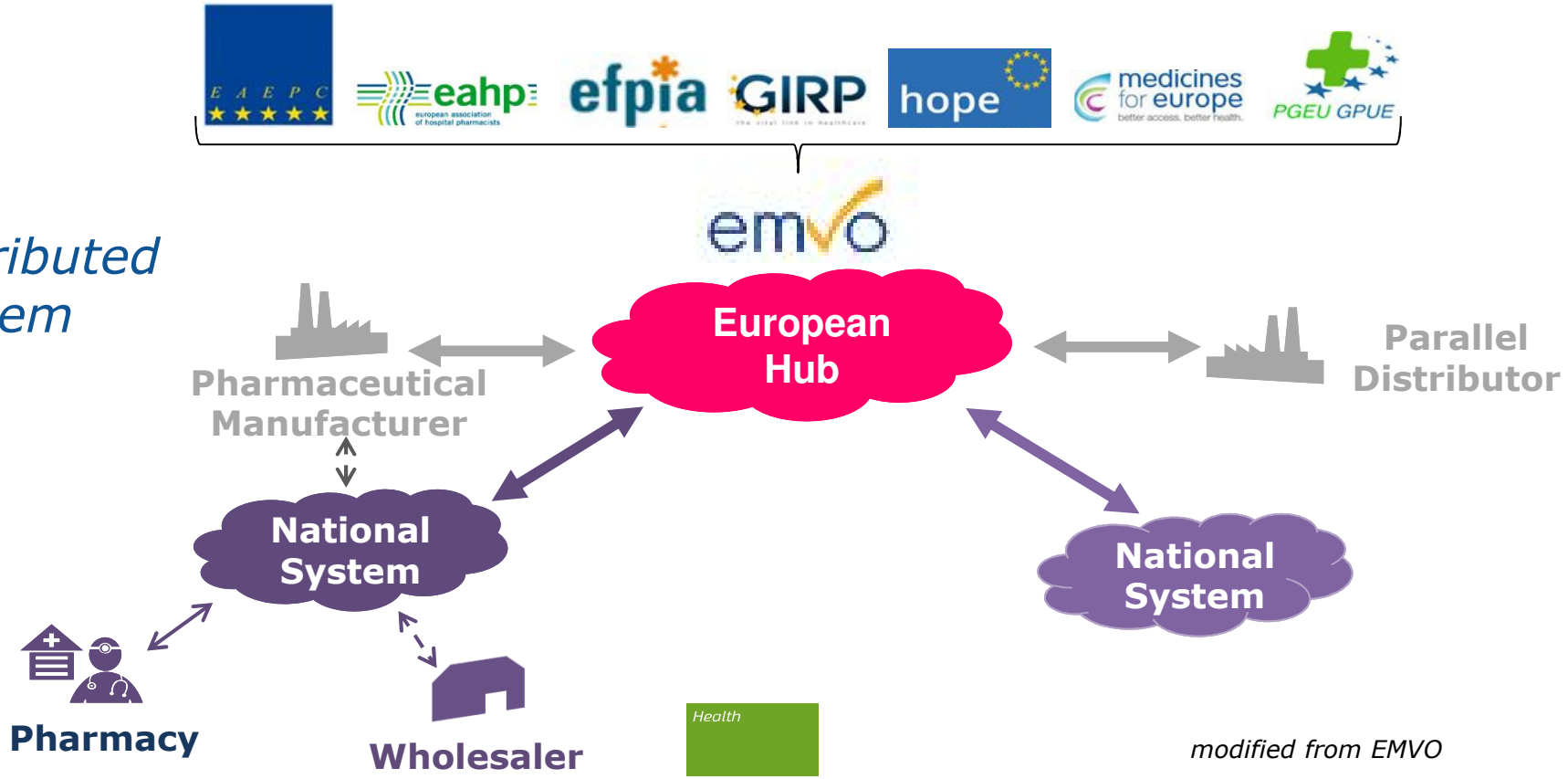
The Repositories System - Architecture

Distributed System



modified from EMVO

The Repositories System – Access by NCAs

National competent authorities (NCAs) can access the repositories system and the information contained therein for:

- **supervising** the functioning of the repositories
- **investigating** potential incidents of falsification;
- **reimbursement**;
- **pharmacovigilance or pharmacoepidemiology**.

Practical Information

- The new rules = 9th February 2019.
- Packs on the market before February 2019 can stay on the market until they expiry date
- Q&A published by the Commission
- Regulatory requirements:
  - Implementation plans for CAPs and NAPs published by EMA and CMDh

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Critical Next Steps

- Setting up NMVOs: *7 still missing*
- Signing IT contracts so databases can be set up: *17 still missing*
- Onboarding verified users so that the system can be pilot-tested – essential for pharmacies and hospitals

Everybody's efforts needed to make the safety features a success!!!

Conclusions

- The FMD = safer and better-quality EU medicines
- EU logo = buyers empowered to chose safe, legal online medicine websites
- Safety features: **in 2019!**

  = no more false/expired/recalled medicines reach patients

  = easier traceability and recalls

Thank you!

Questions?

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