



Implementing the Falsified Medicines Directive: Safer Medicines for Europe

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"Patient Safety through
Medicine Safety"

9 February 2018

Bucharest

Health



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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.

3. Active substances

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

2. Reinforcing the distribution chain

Strengthened GDP and requirements for wholesale distributors

4. Internet sales

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





GDP

Reinforced Distribution Chain



- Improved **GDP guidelines** for medicinal products and their ingredients
- EU database of distributors ⇒ **EudraGMDP**
- Mandatory **registration of** active ingredient distributors

Safer Active Ingredients



"NO WONDER THIS MEDICATION DOESN'T WORK—
ALL THE INGREDIENTS ARE INACTIVE."

- 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)



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;



**Buyer takes
informed decision!**



Click to verify
if the website
is operating
legally

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



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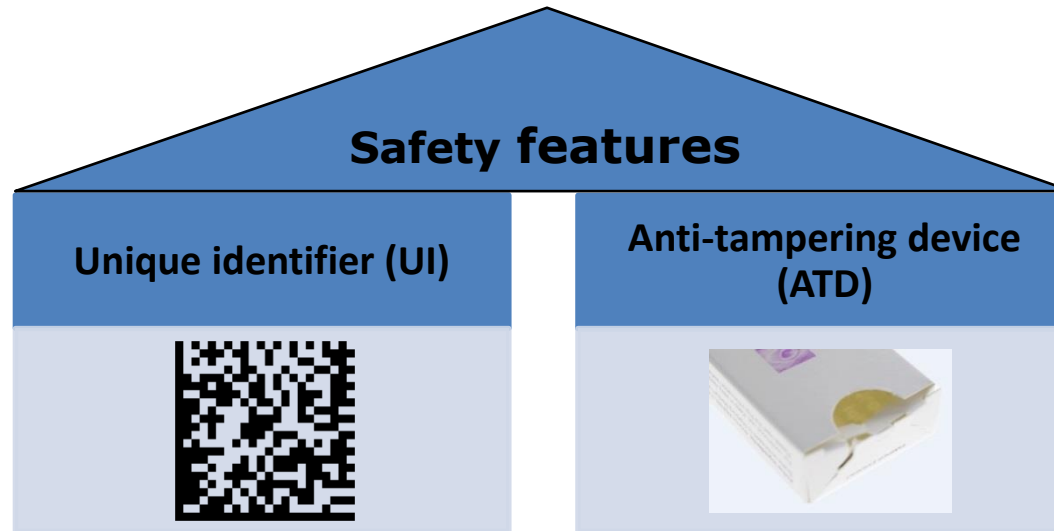
Safer Medicines

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



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

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



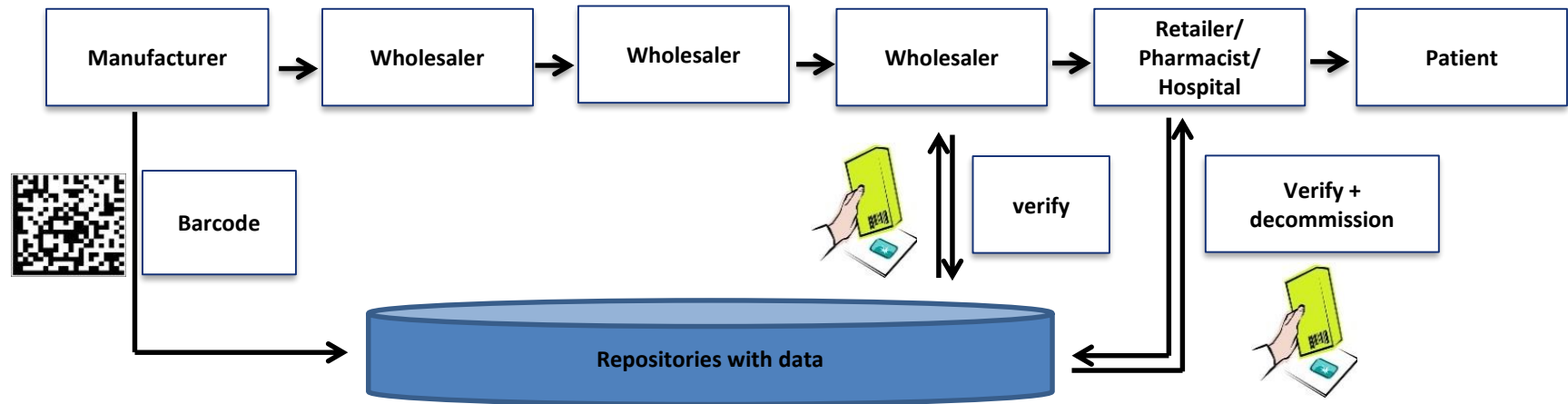
Illustrative example – not binding



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Verification of the safety features

End-to-end verification system + risk based verifications



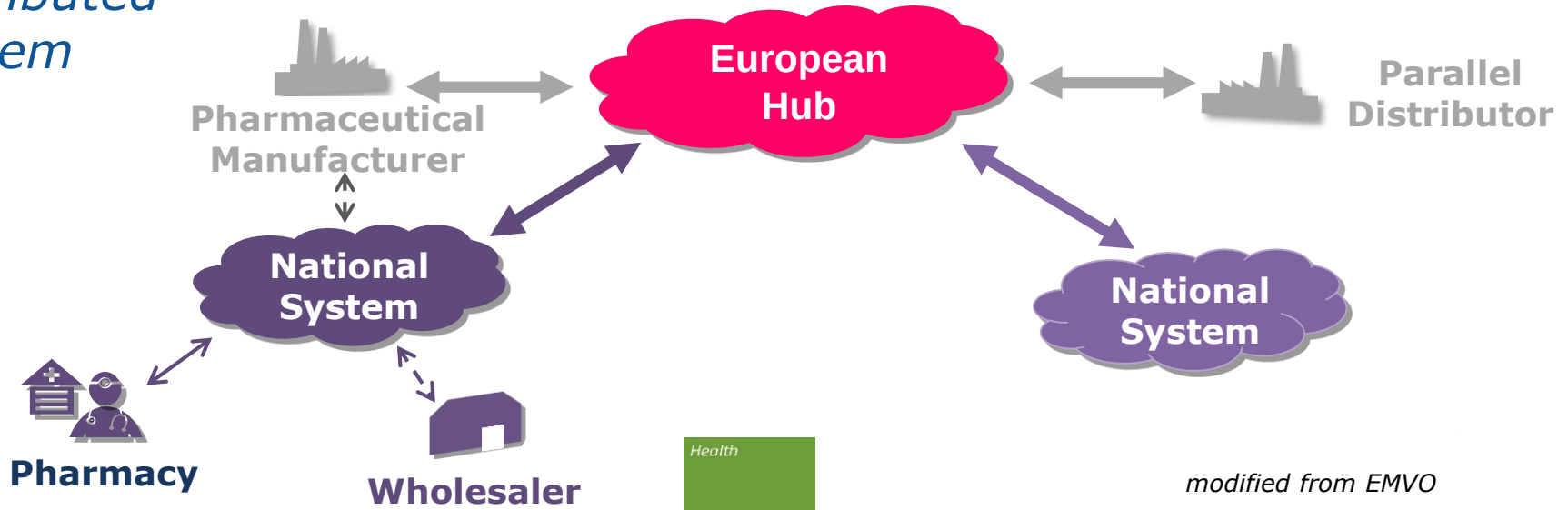


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The Repositories System - Architecture



*Distributed
System*



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 and 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



Critical Next Steps



- NMVOs to sign IT contracts so databases can be set up
- 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 choose 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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