The Global Language of Business

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EU Falsified Medicine Directive

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European Commission

The EU Falsified Medicines Directive What's New?

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EU Anti-Falsified Medicines Legislation: Directive 2011/62/EU

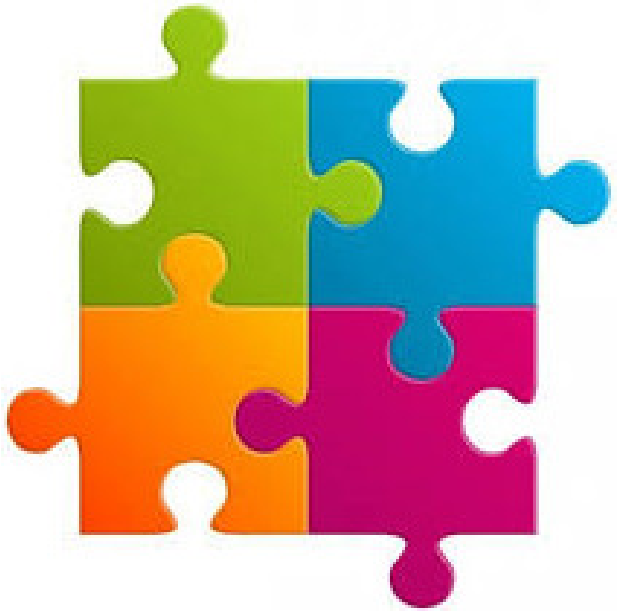
4 Pillars

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.

Reinforcing the Distribution Chain

- New/Updated **GDP guidelines:**
  - for *medicinal products* – Nov 2013;
  - for *APIs* – March 2015;
- EudraGMDP ⇨ **EU database** of medicinal product distributors
- API distributors = mandatory **registration with NCAs**.

Active substances (API)

- As of 2nd July 2013, APIs can only be imported into the EU if:
  - **Written confirmation** on GMP for API; or
  - Exporting country is **"listed"** by the Commission; or
  - **EU GMP** certificate.
- New requirements for API manufacturers:
  - **Registration** of EU API manufacturers and importers;
  - **Audit by manufacturers** of medicinal products;
  - **Inspections by NCAs**;
  - Legally binding **GMP for APIs** (based on ICH Q7)

Internet sales: EU common logo for online pharmacies

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

Patient takes informed decision!

- Clicking the logo securely redirects to **a list of authorised pharmacies** in a given MS;

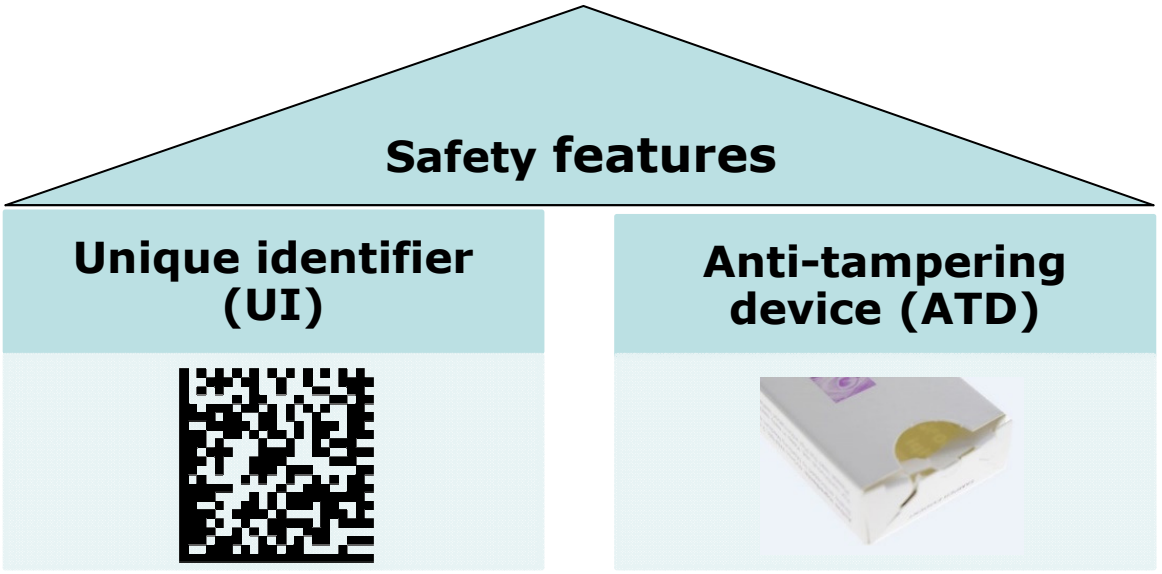
- Awareness campaigns to inform on the **risks of buying from illegal websites**.

Safety Features: Delegated Regulation 2016/161

The **delegated Regulation (EU) 2016/161** "*laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use*":

- Was **published** in the Official Journal on 9th February 2016;
- It **applies as of 9th February 2019** in all MS;
- BE, EL and IT may defer the application by up to 6 years.

Safety Features



Unique Identifier

Code enabling the identification and authentication of a given pack.

Anti-tampering Device

Device allowing the verification of whether a pack has been opened/tampered with.

Delegated Regulation 2015/161 - Content

Regulation (EU) 2016/161 mainly provides for:

a. **Technical characteristics of the UI**
b. **Verification of the Safety Features**
c. **Repositories system for the UI**
d. **Lists of exceptions from bearing/not bearing the safety features**

Regulation (EU) 2016/161 **does NOT provide** for:

- **Technical options for the anti-tampering device.**

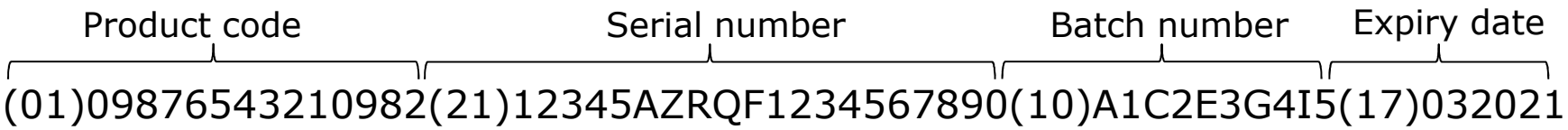
Delegated Regulation 2016/161 - Scope

Which medicinal products have to bear the safety features?

- *The rule:*
  - **Prescription** medicines **shall bear** the safety features while **non-prescription** medicines **shall not.**
- *Exceptions:*
  - **Prescription medicines exempted from the SF:** *Homeopathics, radiopharmaceuticals, ATMPs, medical gases, certain solutions, contrast media, allergy tests and allergens.*
  - **Non-prescription medicines requested to bear the SF** *Omeprazole 20 or 40 mg* (reported incidents of falsification)

The UI - Composition

- The UI is ISO-compliant (ISO 15418; ISO 15434) and will contain:
  - **Product code:** ISO-compliant (ISO 15459); < 50 characters; globally unique; issued by ISO-compliant coding agencies;
  - **Serial number** (max 20 characters; randomised)
  - A **national reimbursement or identification number** (optional)
  - **Batch number**
  - **Expiry date**



Illustrative example – not binding

The UI – Properties

- The UI is 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

Verification of the safety features (I)

End-to-end verification system – *not a full track & trace system*

- **One end - Manufacturers/MAH:**
  - UIs are printed on packs and uploaded in a secure repositories system.
  - ATDs are applied on packs.
- **Other end – Pharmacies/hospitals:**
  - UIs are systematically verified for authenticity and decommissioned at the time of supply to the public.
  - The integrity of the ATD is checked.

Verification of the safety features (II)

End-to-end verification system – *not a full track & trace system*

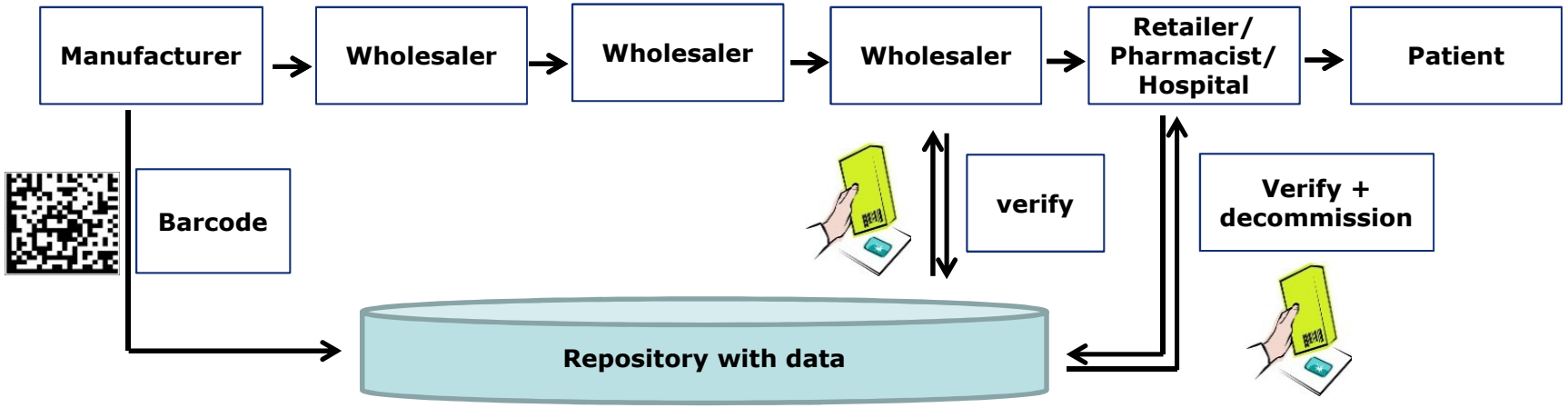
- **What happens in the middle of the chain?**

  Risk-based verification by wholesalers, who verify the safety features when:

  - The product is **not directly supplied from a manufacturing or marketing authorisation holder (or a person supplying on their behalf)**;
  - The product is **returned** by another wholesale distributor or a pharmacy.

Verification of the safety features (III)

End-to-end verification system + risk based verifications



Exceptions to the end-to-end system

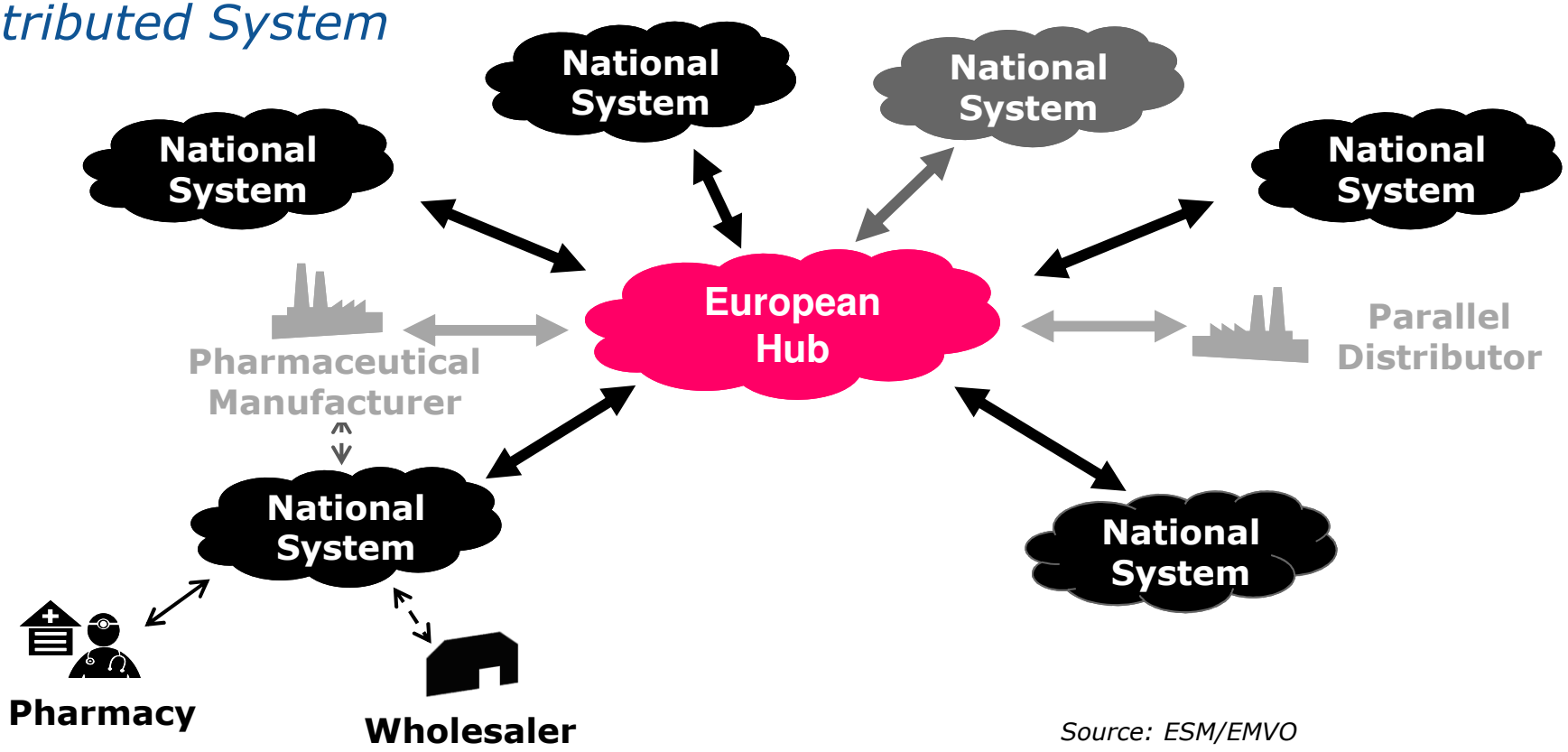
- Member States can **exempt** certain persons from the obligations to verify/decommission:
  - Veterinarians, dentists, opticians, paramedics, nursing homes, etc. (full list in Article 23 of the DR)
- Member States **cannot exempt pharmacies nor healthcare institutions**.
- In this case the verification/decommissioning of the UI is performed by **the wholesaler** supplying those persons.

The Repositories system

- Main task: store the information on the legitimate UIs and **allow the verification/decommissioning of UIs** at any point of the supply chain;
- Established and **managed by stakeholders**;
- **Supervised by Member States**;
- It consists of:
  - a central information and data router (‘**hub**’);
  - **national or supranational repositories** connected to the hub;
- Physically **located in the Union.**

Repositories System Architecture

Distributed System



Source: ESM/EMVO

The Repositories System - Access

The repositories system can be queried by:

- **verified users**, i.e. users whose identity, role and legitimacy has been verified.

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

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

Application of Regulation (EU) 2016/161

- The new rules will apply as of **9th February 2019**.
- **Transitional measures**:
  - *Medicinal products that have been **released for sale or distribution** without the safety features in a Member State before the date in which Regulation (EU) 2016/161 becomes applicable in that Member State, **and are not repackaged or relabelled thereafter**, may be placed on the market, distributed and supplied to the public in that Member State until their expiry date.*

Implementation of Regulation (EU) 2016/161

- Q&A published by the Commission:
  - http://ec.europa.eu/health/files/falsified_medicines/qa_safetyfeature.pdf
- Regulatory requirements: *Implementation plans published by EMA and CMDh*
  - CAPs: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/02/WC500201413.pdf
  - NAPs: http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Falsified_Medicines/CMDh_345_2016_Rev00_02_2016_1.pdf

Conclusions

- In summary, the EU medicine authentication system will start operating in 2019 and will comprise:
  - A EU-harmonised UI carried by a 2D barcode (Data Matrix)
  - Systematic verification of the safety features at the dispensing point and risk-based verification by wholesale distributors
  - Legitimate UIs stored in a system of interconnected and interoperable repositories established and managed by stakeholders under the supervision by competent authorities

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Questions?

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