



The Global Language of Business

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## European Commission

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# EU Falsified Medicines Directive – EU Commission, DG Health and Food Safety

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# ***Identification and authentication of medicines in Europe: What to expect in 2019***

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Health and  
Food Safety

# The European Union (EU) Directive 2011/62/EU - main contents

***Obligatory  
safety features***

*Active substances,  
quality*

*„Online  
pharmacies“*

# Safety Features

*Safety features:* **Unique Identifier (UI)**

- alphanumerical code enabling the identification and authentication of individual packs.

**Anti-tampering Device (ATD)**

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

## Delegated Regulation on the Safety Features (I)

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 **adopted** on 2 October 2015;
- Was **published** in the Official Journal on 9<sup>th</sup> February 2016;
- It **applies as of 9<sup>th</sup> February 2019** in all MS;
- BE, EL and IT may defer the application by up to 6 years.

## Delegated Regulation on the Safety Features (II)

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**

## Delegated Regulation on the Safety Features (III)

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

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

**the choice of the most appropriate device allowing the verification of whether a pack has been opened/tampered with is left to the manufacturer.**



## 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**.
- *But: possible exceptions if justified by assessment of risks of and arising from falsification*
- *Exceptions included in Annex I and II of Regulation (EU) 2016/161.*

## Lists of 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:** reported incidents of falsification

# Technical characteristics of the UI

## The UI - Composition

➤ The UI 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**

➤ UI also ISO-compliant (ISO 15418; ISO 15434).

Product code	Serial number	Batch number	Expiry date
(01)09876543210982	(21)12345AZRQF1234567890	(10)A1C2E3G4I5	(17)180531

*Illustrative example – not binding*

## The UI – Properties

- The UI is carried by a 2D barcode (Data Matrix ECC200);
- Minimum printing quality;
- Human-readable format.

<b>PC:</b>	<b>09876543210982</b>
<b>SN:</b>	<b>12345AZRQF1234567890</b>
<b>NN:</b>	<b>(optional)</b>
<b>Batch:</b>	<b>A1C2E3G4I5</b>
<b>Expiry:</b>	<b>180531</b>



*Illustrative example – not binding*

## The UI – Multiple barcodes allowed?

- The **Data Matrix** = only **2D barcode allowed for authentication** and identification of a medicinal product.
- **QR codes are allowed**, except for identification and authentication.
- Multiple UIs are allowed, e.g. in case of **multi-language packs** intended to be marketed in more than one Member State, where each UI contains the specific national reimbursement/ID number of one of the destination Member States.

# Verification of the Safety Features

## 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.
- The integrity of the ATD is checked.



## Verification of the safety features (II)

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

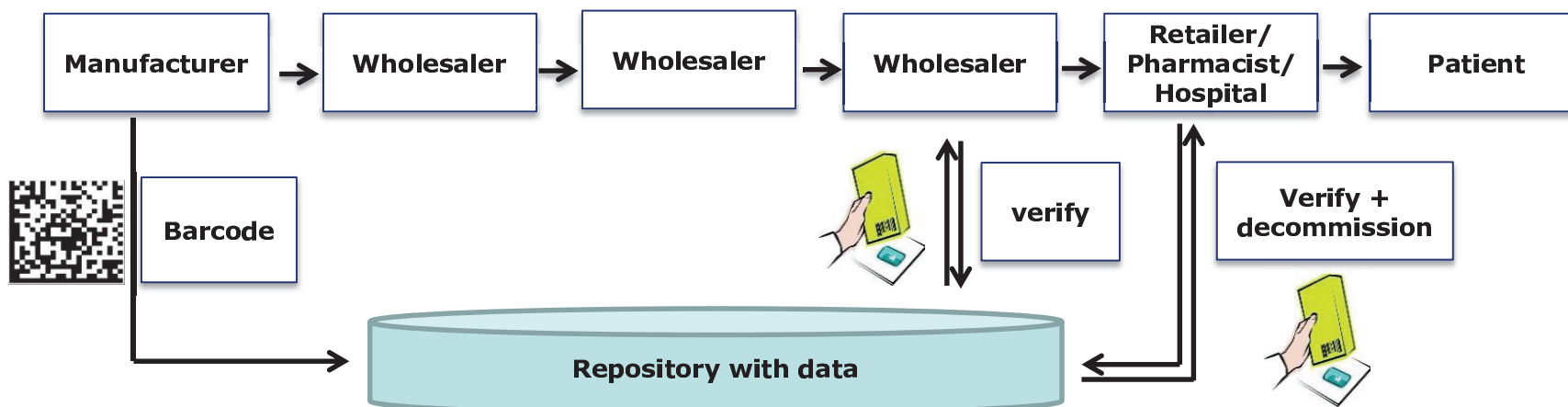
➤ **What happens in the middle of the chain?**

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*



## Timing of the decommissioning of the UI

- As general rule, the decommissioning of the UI takes place **at the time the medicinal product is supplied to the public.**
- Exceptions:
  - **Hospitals** can decommission the UI at any time the medicinal product is in their physical possession (for example, when they receive the product).
  - When only **part of a pack** is supplied, the UI should be verified and decommissioned when the pack is opened for the first time.

## Exceptions to the end-to-end system

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

## Reversing a decommissioned UI

### ➤ Can the decommissioning operation be undone?

Yes, it is possible to reverse the status of a decommissioned UI and bring it back to active status, provided that certain conditions are met:

- Same authorised legal person and in the same premises as the initial decommissioning;
- No more than 10 days after the initial decommissioning;
- the pack bearing the UI has not expired nor has been recalled/withdrawn/marked for destruction/identified as stolen/supplied to the public.

## Suspected falsification

- **What to do if there is reason to believe that the packaging of the medicinal product has been tampered with, or the product may not be authentic?**
  - manufacturers shall not release the product for sale or distribution;
  - wholesalers shall not distribute, supply or export the product;
  - Pharmacies, hospitals and other persons authorised or entitled to supply medicinal products to the public shall not supply the product to the public;
  - The person suspecting the falsification or tampering shall immediately inform the relevant competent authorities.

# The Repositories System

## The Repositories system (I)

- 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** with supervision by competent authorities.
- It consists of:
  - a central information and data router ('**hub**');
  - **national or supranational repositories** connected to the hub.



## The Repositories System (II)

### ➤ Hub:

- **routes queries/information in case of cross-border verification/decommissioning of UI**
- **Links old and new batch numbers/UIs of parallel traded products.**

### ➤ (Supra)national repositories:

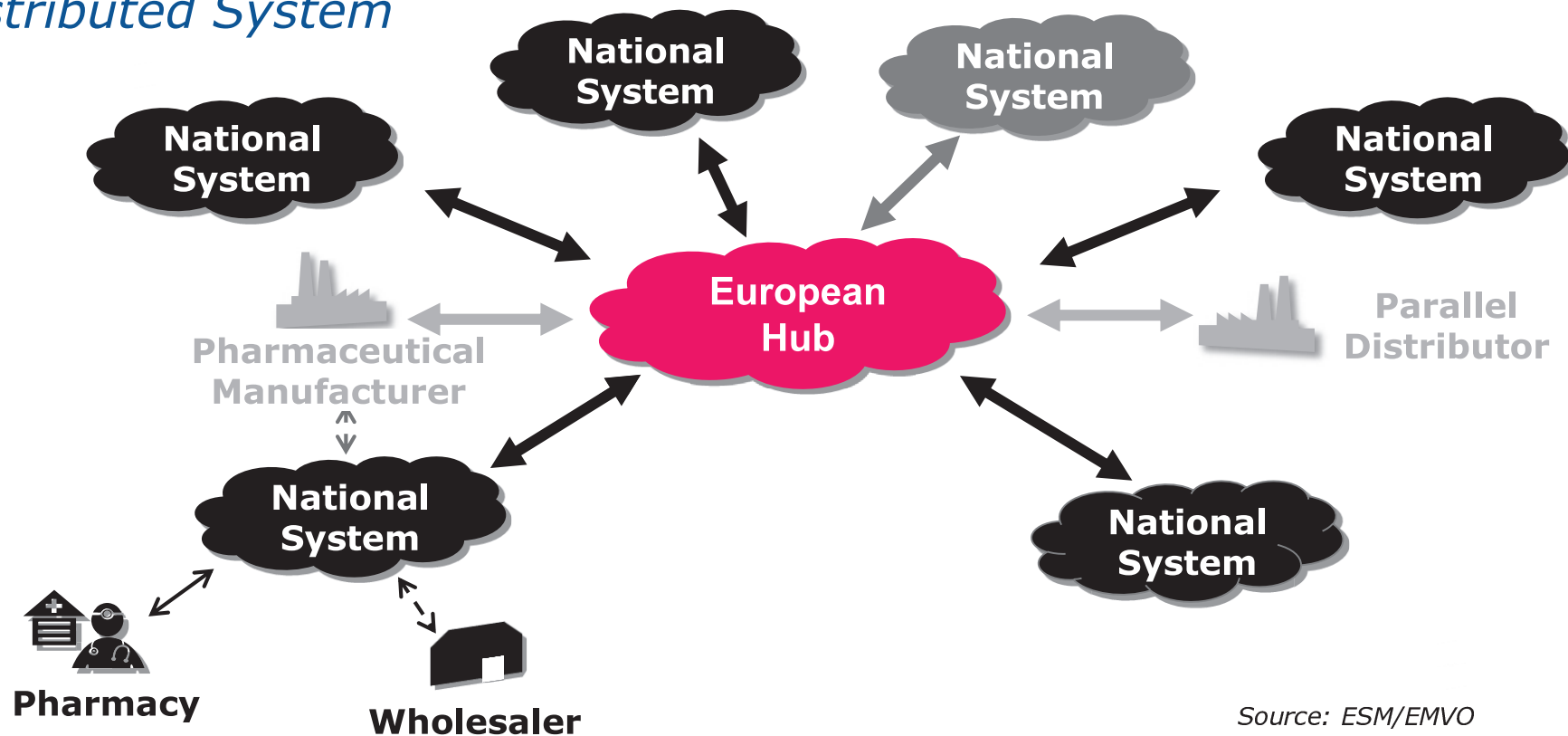
- **Store key data, including serial numbers and UI status.**
- **Query point for pharmacies/hospitals and most wholesalers**

### ➤ Data upload = both hub and (supra)national repositories

### ➤ Physically located in the Union

# Repositories System Architecture

## *Distributed System*



Source: ESM/EMVO

## The Repositories System - Characteristics

The repositories system has to ensure, inter alia:

- **Verification of authenticity and decommissioning** of UIs;
- The **detection** of potential incidents of falsification;
- **Interoperability** among repositories;
- Commercial, confidential and personal **data protection**;
- Virtually **instantaneous** response: 300 ms system response time;
- Records of all operations concerning a UI (**'audit trail'**);

*Member States will be in charge of **supervising** the repositories system and **enforcing** the requirements of the delegated Regulation*

## 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**.

## The Repositories System - Supervision

- Member States are required to supervise the functioning of any repository physically located in their territory, if necessary by means of inspections;
- Member States may contribute to the management and participate to the management board of any repository used on their territory
- Reports of supervision activities are shared with the other national competent authorities, EMA and the Commission.

# **Application of Regulation (EU) 2016/161**

## Application of Regulation (EU) 2016/161

- The new rules will apply as of **9<sup>th</sup> February 2019**.
- BE, EL and IT may defer the application of Articles 1-48 by up to 6 years
- **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.*

## 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





**Thank you!**

**Questions?**

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