



European Medicines Verification System

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Secretary General PGEU

Delegated Regulation on the Safety Features (I)



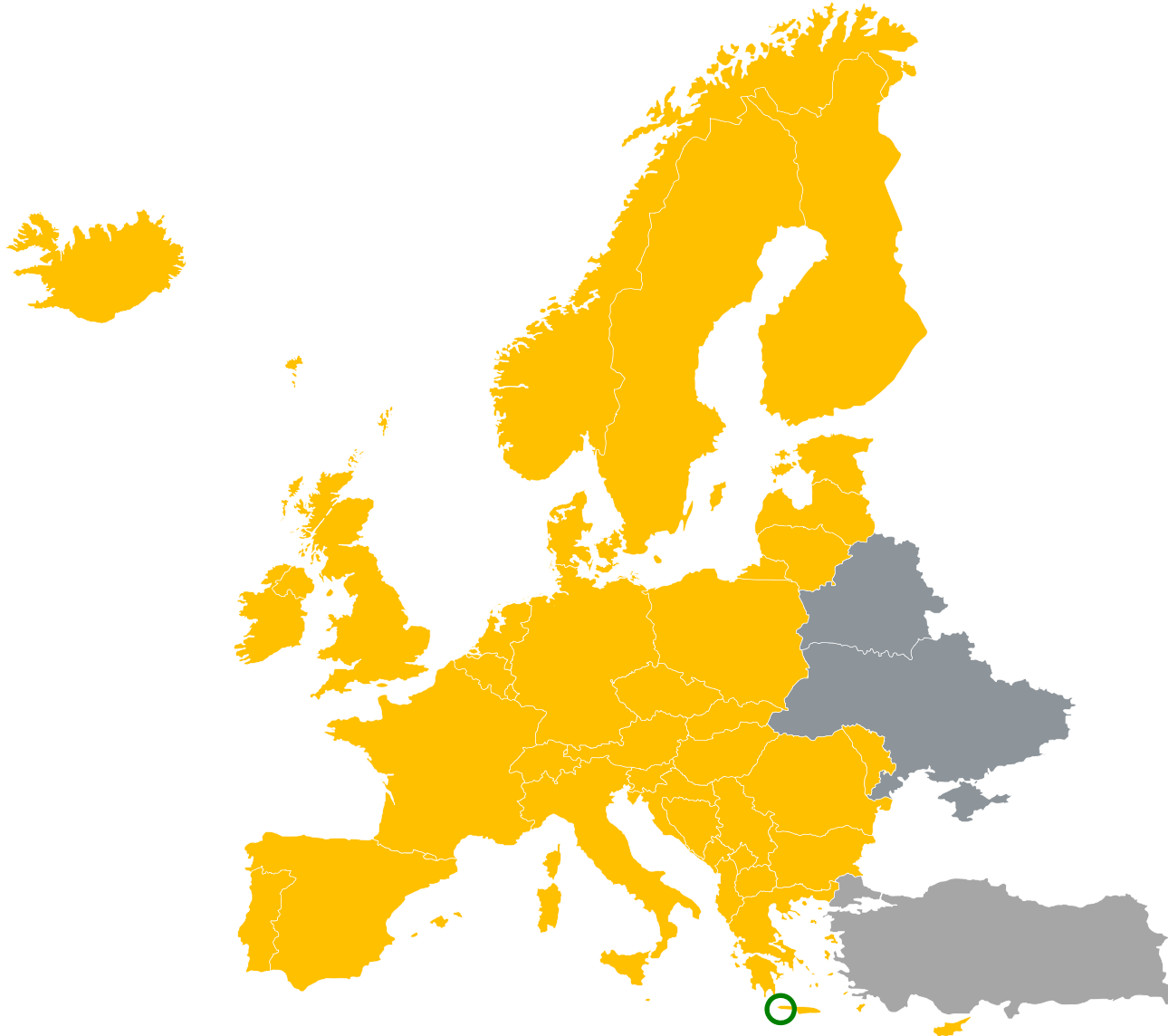
The Delegated Regulation (EU) 2016/161 "*laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use*" was published on 9th February 2016.



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Countries in scope of the the FMD



Delegated Regulation on the Safety Features (II)

SAFETY FEATURES

- UI is carried in 2D code and contains: product code, serial number, batch number, expiry date and reimbursement number (optional).
- Anti Tampering Device: choice is left to a manufacturer.

SYSTEM DESIGN

- End to end verification system with risk-based verification at the middle of supply chain.
- As general rule, the decommissioning of the UI takes place at the time the medicinal product is supplied to the public.
- Exceptions: hospitals, number of other actors (vets, dispensing doctors, etc.).



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Delegated Regulation on the Safety Features (III)

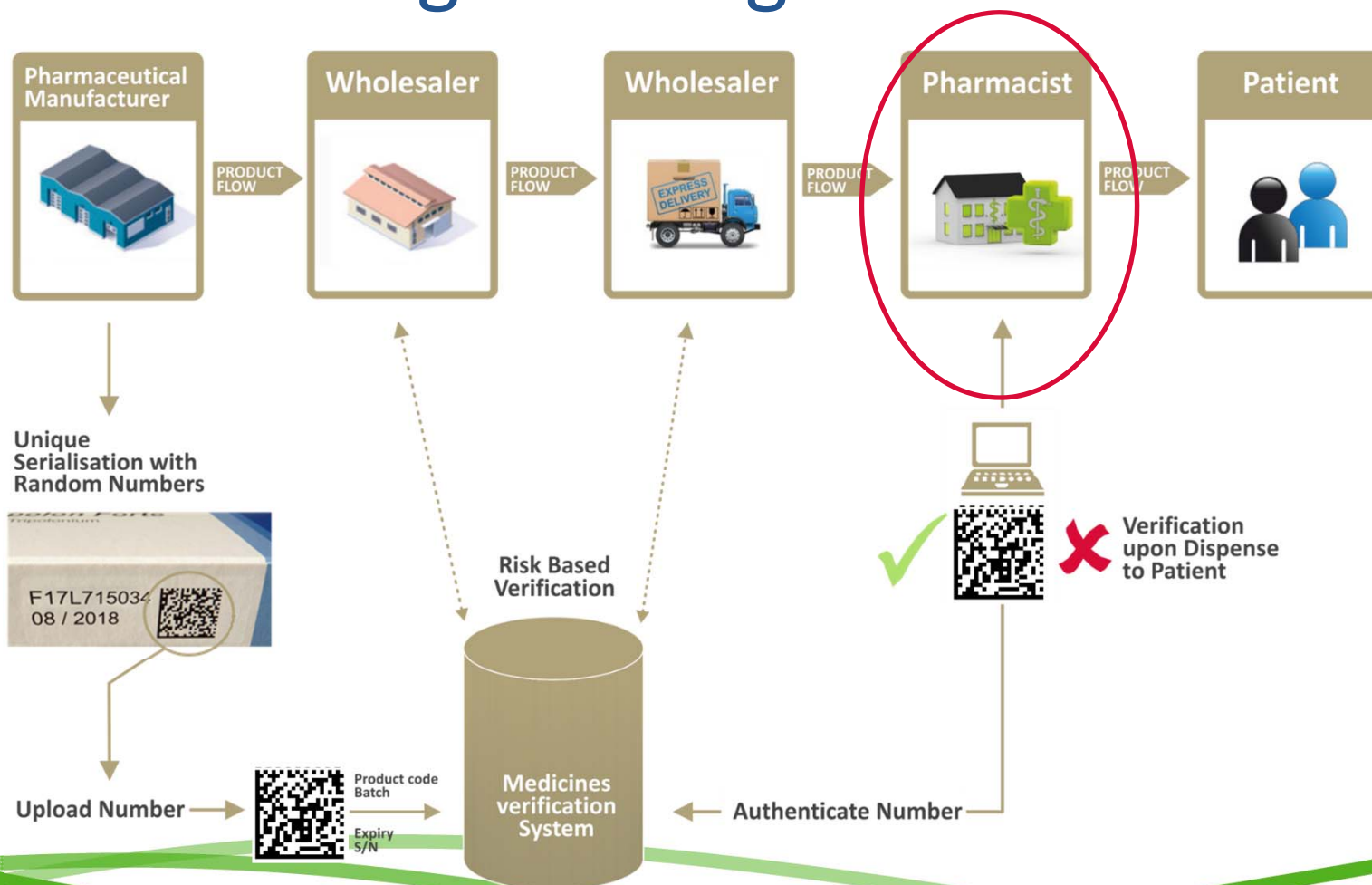
REPOSITORY SYSTEMS

- Number of national and supranational systems.
- Interoperability ensured via Central Hub.
- National systems governed by non-profit legal entities (organisations), established and managed by relevant stakeholders.
- Systems supervised by EU and/or national authorities.

SCOPE

- All medicinal products subject to prescription except listed in the annex.
- Medicinal products not subject to prescription that are listed in Annex.
- Medicinal products to which Member States have extended the scope of application.

Obligations for pharmacies under the Delegated Regulation



Obligations for pharmacies under the Delegated Regulation (I)

- In order to verify the authenticity of a medicinal product and decommission the unique identifier **pharmacies** are required to connect :
 - to **the national repositories system (database)** serving the territory of the Member State in which they are authorized(Art 25);
 - **via application programming interfaces** (Art 32).
 - The repositories system will also include **graphical user interfaces** providing **direct access** to the repositories system (Art 32).



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Obligations for pharmacies under the Delegated Regulation (II)

Obligations of pharmacies (Art. 10; 25; 28):

- **verify the safety features** (*UI and anti-tampering device*) and **decommission the unique identifier** of any medicinal product bearing the safety features they supply to the public **at the time of supplying it to the public**;
- **where only part of a pack of a medicinal product is supplied**, they shall verify the safety features and decommission that unique identifier **when the pack is opened for the first time**.



Obligations for pharmacies under the Delegated Regulation (III)

We will also have to verify the safety features and decommission the unique identifier of the following **medicinal products bearing the safety features**: (Art. 25):

- Products in our physical possession that **cannot be returned to wholesalers or manufacturers**;
- Products that are **requested as samples** by competent authorities;
- Products that we supply for use in **clinical trials** (*authorised investigational medicinal products or authorised auxiliary medicinal products*).

Derogation:

Medicinal products provided as **free samples** are exempted from the obligation to verify and decommission.



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Obligations for pharmacies under the Delegated Regulation (IV)

Obligations in case of inability to verify the authenticity and decommission the unique identifier (Art 29):

- **where technical problems prevent** verifying the authenticity of and decommissioning a unique identifier at the time the medicinal product bearing that unique identifier is supplied to the public, pharmacies shall **record the unique identifier** and, **as soon as the technical problems are solved, verify the authenticity of and decommission the unique identifier.**



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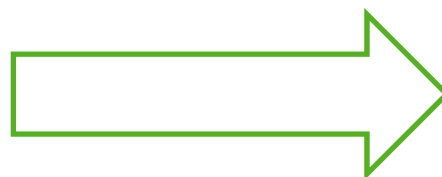
Obligations for pharmacies under the Delegated Regulation (V)

Actions to be taken by a pharmacy in case of suspected falsification (Art 30):

**Package has
been tampered**

OR

**Verification of
the UI indicated
that the product
may not be
authentic**



SUPPLY

AND



**INFORM
RELEVANT
COMPETENT
AUTHORITY**

Rights of Pharmacies under the Delegated Regulation

- Pharmacies can **revert the status of a decommissioned** unique identifier to an active status if number of conditions are fulfilled (Art 13).
- Pharmacies have a **right to participate in the legal entity or entities** governing national verification system, on a voluntary basis, at no cost (Art 31).
- Pharmacies are **not required to be members of a specific organisation** or organisations in order to **use the repository system** (Art 31);
- Pharmacies are **responsible for any data generated** when they interact with the repositories system. They **own and can access data** they have generated, with the exception of the status of a unique identifier (Art 38).



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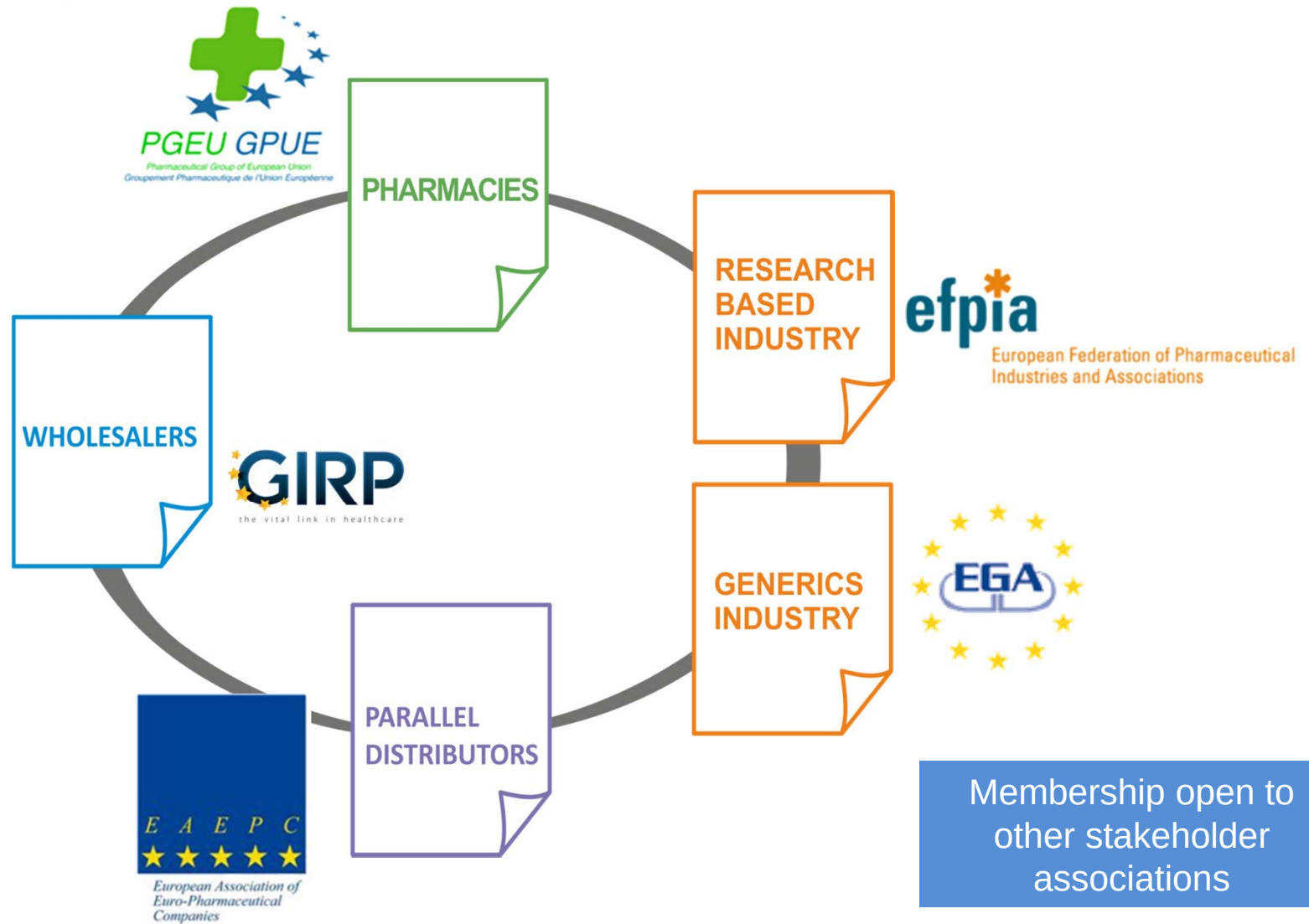


What is next?



TIME IS NOW!

Stakeholders involved



Pan-European Structure

