# Falsified medicine products: Legal and IT solutions

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- The protection of human health ranks high among non market values that have been pursued through internal market regulation.
- Article 168.TFEU provides that high level of human health protection should be ensured in the definition and implementation of all EU policies and activities.
- Article 9. protection of health among other social objectives like employment, social protection and social exclusion-health as a general EU policy
- According to the CJEU national health measures fall within internal market rules . Medical goods and services doesn't have any special status due to their nature /public interest/ so the free movement must be guaranteed to the same subject as any other goods or services. /V.Kosta p.244/

- http://ec.europa.eu/health/human-use/videos/index_en.htm

- Information and communication technologies have enormous potential to improve the quality, safety and efficiency of healthcare.
- IT solutions - tool for achieving regulatory requirements.

- Falsified medicines (the term 'falsified' is used to distinguish the issue from IP violations, so-called 'counterfeits') are a major threat to public health and safety.
- As falsifications become more sophisticated, the risk that falsified medicines reach patients in the EU increases every year. Falsified medicines represent a serious threat to global health and call for a comprehensive strategy both at European and international level.

# Falsified medicines

- are fake medicines that pass themselves off as real, authorised medicines.
- might contain ingredients, including active ingredients, which are of bad quality or in the wrong dose – either too high or too low.
- They have not been properly evaluated to check their quality, safety and efficacy - as required by strict EU authorisation procedures - this could be detrimental to your health.
- are a major threat to public health
  - *the term 'falsified' refers to all forms of falsification, while the term 'counterfeit' specifically refers to an infringement to intellectual property rights.*
- As falsifications become more sophisticated, the risk that falsified medicines reach patients in the EU increases every year.

# Most falsified

- **Lifestyle products /developed countries/:**

-Erectile disfunction
-Obesity
-Intelectual stimulans
-Hormons,steroids
-Antihistaminic
-Corticosteroids

- **Life threatening diseases /developing countries/**

- Oncological
- Antibiotics
- Cardiovascular
- Pain killers
- Etc.

# Fake medicine distributions channel

- Illegal distribution chain via Internet,
- various forms of advertising,
- door to door sale….
- Legal chain of distribution through wholesalers /cca.2%/

- **MEDICRIME CONVENTION**

/The COUNCIL OF EUROPE-pan European organization 47 states in Europe/ binding int.instrument/

Council of Europe :**Convection of medical products and similar crimes involving threats to public health**

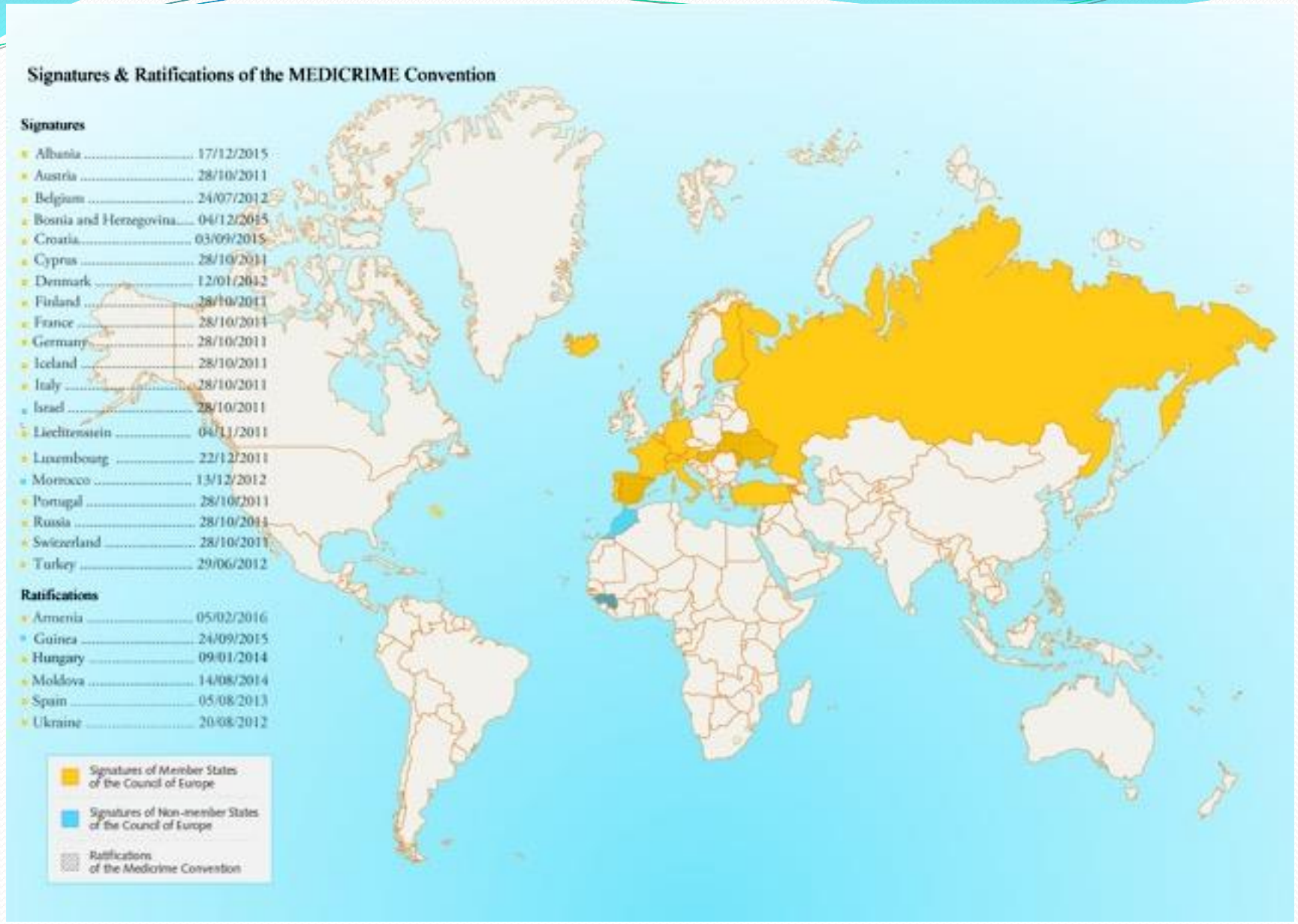
Adopted Strasbourg, /09/02/2010/

Opening of the Treaty Moscow,28/10/2011/

Entry into force, 01/01/2016

- Counterfeiting medical products and similar crimes threaten the right to life enshrined in the European Convention on Human rights and Fundamental Freedoms

- The "Medicrime Convention" is the first international criminal law instrument to oblige States Parties to criminalize:
- the manufacturing of counterfeit medical products;
- supplying, offering to supply and trafficking in counterfeit medical products;
- the falsification of documents;
- the unauthorized manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements.
- The Convention provides a framework for national and international co-operation across the different sectors of the public administration, measures for coordination at national level, preventive measures for use by public and private sectors and protection of victims and witnesses. Furthermore, it foresees the establishment of a monitoring body to oversee the implementation of the Convention by the States Parties.


Signatures & Ratifications of the MEDICRIME Convention
Signatures
Albania 17/12/2015
Austria 28/10/2011
Belgium 24/07/2012
Bosnia and Herzegovina 04/12/2015
Croatia 03/09/2015
Cyprus 28/10/2011
Denmark 12/01/2012
Finland 28/10/2011
France 28/10/2011
Germany 28/10/2011
Iceland 28/10/2011
Italy 28/10/2011
Israel 28/10/2011
Liechtenstein 04/11/2011
Luxembourg 22/12/2011
Morocco 13/12/2012
Portugal 28/10/2011
Russia 28/10/2011
Switzerland 28/10/2011
Turkey 29/06/2012
Ratifications
Armenia 05/02/2016
Guinea 24/09/2015
Hungary 09/01/2014
Moldova 14/08/2014
Spain 05/08/2013
Ukraine 20/08/2012
Signatures of Member States of the Council of Europe
Signatures of Non-member States of the Council of Europe
Ratifications of the Medicrime Convention

# EU Regulatory framework

- Following adoption by the Council and the European Parliament, the Falsified Medicines Directive (Directive 2011/62/EU)

The Falsified Medicines Directive applies since 2 January 2013.

- The Directive introduces tougher rules to improve the protection of public health with new harmonised, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled.
  To this end, these new measures include:
- Obligatory safety features on the outer packaging of the medicines, to be detailed via a delegated act;
- A common, EU-wide logo to identify legal online pharmacies. This would make it easier to distinguish between legal and illegal online pharmacies throughout the European Union;
- Tougher rules on the controls and inspections of producers of active pharmaceutical ingredients; and
- Strengthened record-keeping requirements for wholesale distributors

# Transposition

- Member States had to transpose Directive 2011/62/EU into national law by 2 January 2013. The transposition process is now complete

- 1/prescription medicines will need to bear, on their outer packaging, a pack-specific number and an anti-tampering device that will allow the pharmacist to verify that the medicine is authentic and unopened before dispensing it. This will prevent falsified medicines from reaching the patients.
- 2/the active ingredients of medicines are to be manufactured according to appropriate quality standards (“good manufacturing practice for active substances”) regardless of whether they are manufactured in the EU or imported. If imported, the country of origin has to certify that the active ingredient has been manufactured according to standards equivalent to those of the Union. These provisions ensure that only safe, high quality ingredients are used in medicines in the EU.
- 3/legitimate online pharmacies will be identified by the same logo across the EU. The logo, when clicked, will allow the verification of the legitimacy of the pharmacy. This will allow EU citizens to make an informed choice when buying medicines over the internet.

# Safety features for medicinal products for human use

- The delegated act (Commission Delegated Regulation (EU) 2016/161(547 KB) ) detailing the characteristics of the safety features, how medicine authenticity should be verified, and by whom, was adopted on 2nd October 2015 and published, after scrutiny by the European Parliament and the Council, on 9th February 2016.
- The delegated Regulation, and the new medicine verification system it lays down, will apply as of 9th February 2019.

# Delegated Regulation on the Safety Features (II)

- Regulation (EU) 2016/161 mainly provides for:

-Technical characteristics of the unique identifier (UI)

-Verification of the Safety Features

-Repositories system for the UI

- 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 the choice of the most appropriate device allowing the verification .
- Medicinal products subject to prescription - unless included in Annex I to the Regulation;
- Medicinal products not subject to prescription which are included in Annex II to the Regulation;
- Medicinal products to which Member States have extended the scope of application of the UI or of the ATD in accordance with Article 54a(5) of Directive 2001/83/EC.pened/tampered with is left to the manufacturer.

# Regulatory requirements

- to be followed to notify the EMA of the placing of the unique identifier and/or the anti-tampering device on centrally authorised products are detailed in an implementation plan developed by the EMA and the European Commission and published in the "product information templates" section of the EMA website.

# Implementation plan

- “Implementation plan for the introduction of the safety features on the packaging of nationally authorised medicinal products for human use “ /Doc. Ref: Co-ordination Group for Mutual recognition and Decentralised procedures-human/345/2016 February 2016/
- The CMDh has prepared this implementation plan to guide applicants and Marketing Authorisation Holders (MAHs) through the regulatory changes necessary to accommodate the new legislative requirements for nationally authorised products, including those approved in mutual recognition and decentralised procedures.
- This plan is in line with the plan prepared by the European Medicines Agency (EMA) and the European Commission (EC) with respect to centrally authorised products.

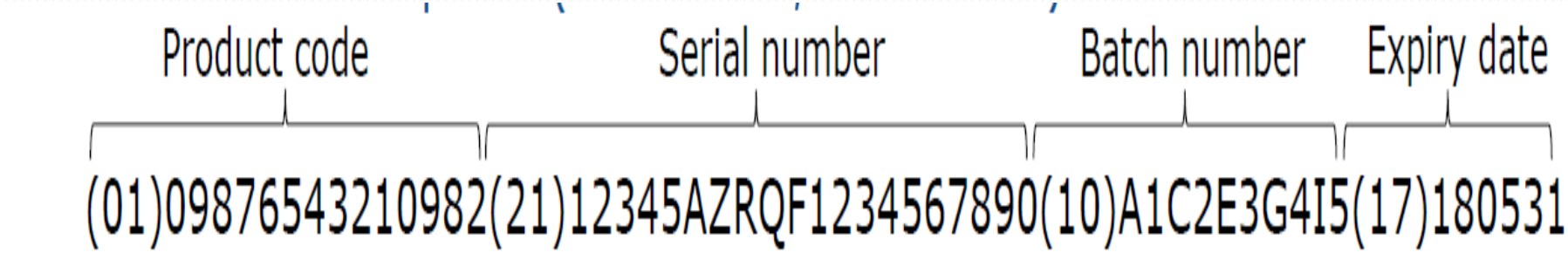
# Good manufacturing practice ('GMP') for active substances

-Directive 2011/62/EU places an obligation on Member States to take appropriate measures to ensure that manufacturers of active substances on their territory comply with good manufacturing practice ('GMP') for active substances. It also places an obligation on the Commission to adopt, by means of delegated acts, the principles and guidelines of good manufacturing practice for active substances. /This concept paper was released for public consultation in 2012 with a view to preparing the delegated act on principles and guidelines of good manufacturing practice for active substances in medicinal products for human use/

-The Commission delegated Regulation (EU) No 1252/2014 on "principles and guidelines of good manufacturing practice for active substance for medicinal products for human use"(342 KB) was published in the Official Journal (OJ L337, 25.11.2014, p.1). It applies as of 25 May 2015

# 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).



# 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: | 180531 |

# 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)

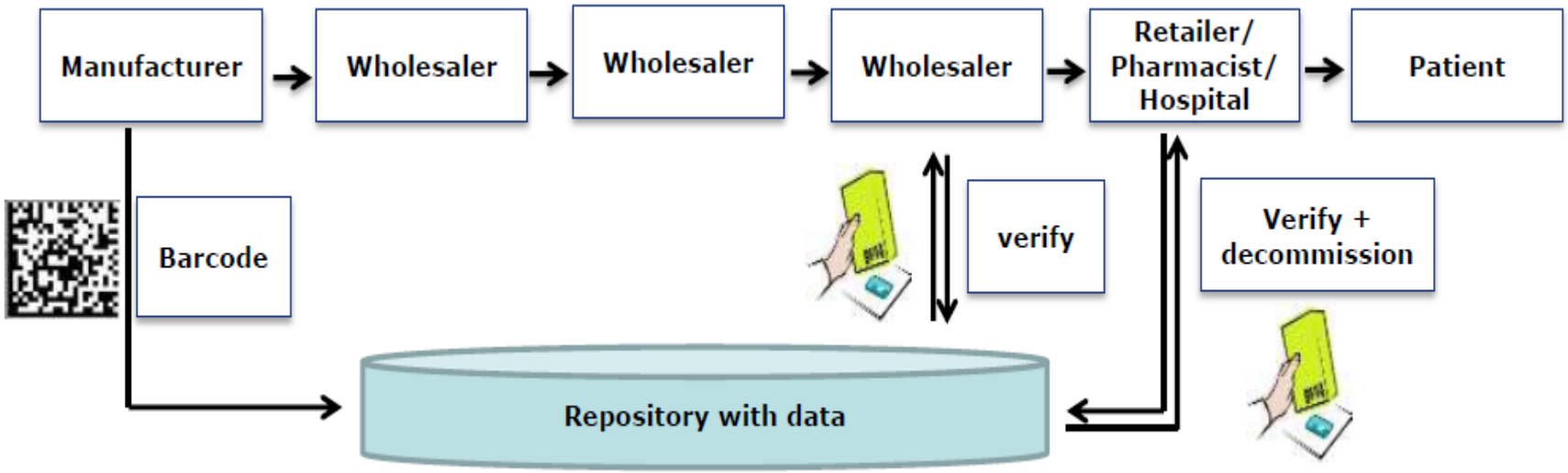
***End-to-end verification system*** *– not a full track & trace system*

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

- The product is **not directly supplied from a manufacturing or marketing authorization 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

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 authorized/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.

# 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)

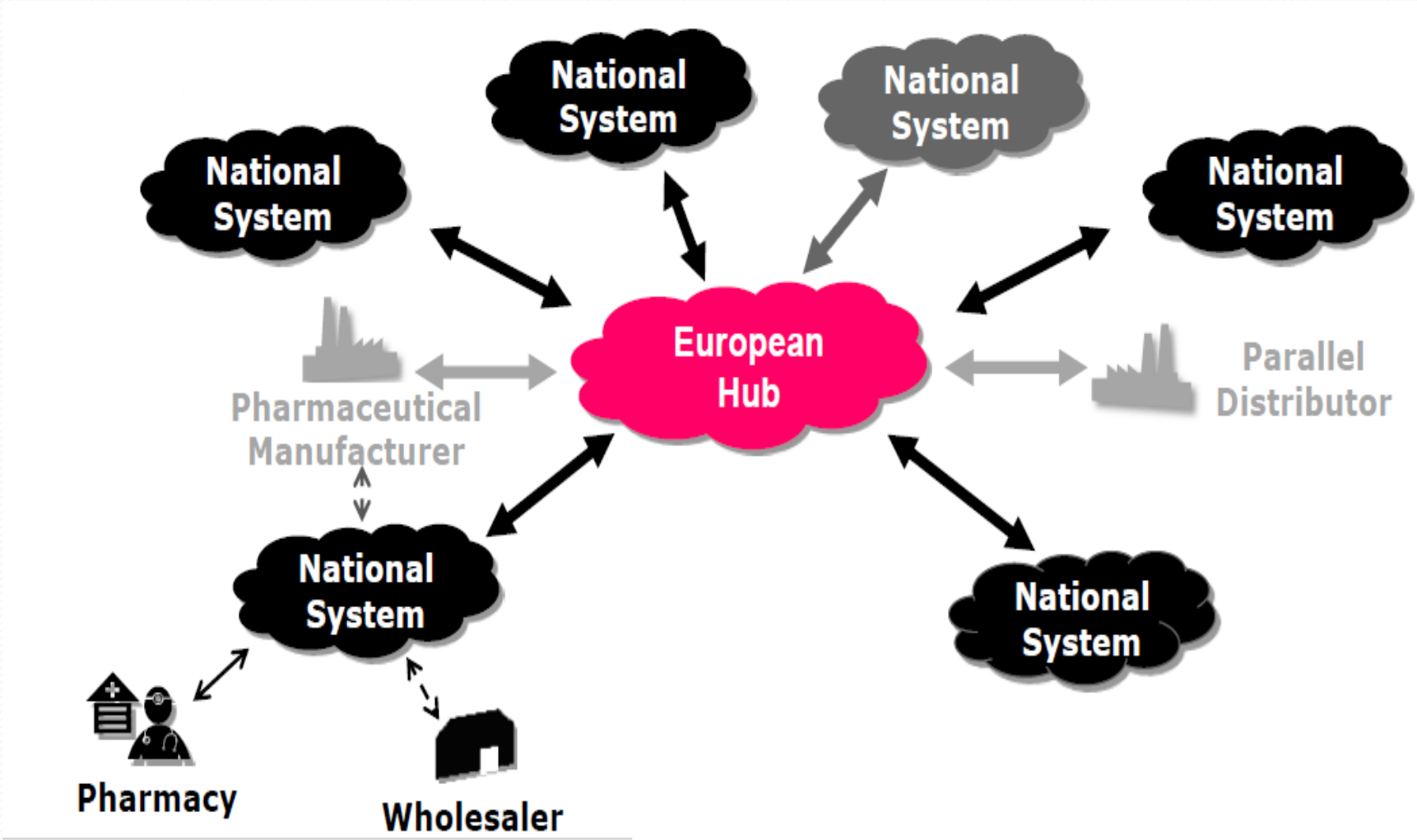
Hub:

- **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



# Conclusion

- ICT technologies - key tool for :
  - achieving regulatory requirements
  - integration - improve the quality, safety and efficiency of large systems like EU healthcare system.
- Project requires to support :
  - Legislative framework and product labeling standards
  - strong protection procedures
  - number of participating parties, different relations between them
  - Becomes base for further integration project development not only on EU level

# Questions?