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Medicines Verification at the Point of Dispense

GS1 Global Healthcare Conference, Amsterdam Oct. 5, 2011

A view from the pharma industry:

the efpia model and key benefits

A view from an insider

Speaking in personal capacity

Prof dr Leo NEELS

A view from the industry
- Leo Neels,
  - **HoA pharma.be**
  - **ExCom Member efpia**
- pharma's Objectives:
  - **Patient Safety: counterfeit / expiry / product recalls**
  - **"Dispense the right medicine to the right patient"**

  - **Ex Factory and Point of Dispense**
  - **NOT "tracking & tracing"**

  - **Complexity reduction – Cost effectiveness – Technical suitability**

 - **Stakeholder model**
- Everybody aligned?

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EFPIA Recommendation for Coding of Pharmaceutical Products in Europe

Data Matrix – Coding proposal derived from GS1 standards
(EAN 128 syntax with Application Identifiers; Data matrix ECC200)

Manufacturer Product Code (GTIN or NTIN)	14 digits
Unique Serial Number (randomized)	up to 20 alpha-numeric characters
Expiry Date	6 digits (YYMMDD)
Batch Number	up to 20 alpha-numeric characters

+ minimum requirements on quality of randomisation

Example:

GTIN:	(01) 07046261398572
Batch:	(10) TEST5632
Expiry:	(17) 130331
S/N:	(21) 19067811811
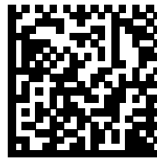
Specifications provided in EFPIA's:
"European Pack Coding Guidelines"

efpia **E.U. … NOT "the United States of Europe"**

- 27 Member States, 33 Health Insurance schemes

efpia

- GS1 GTIN code structure, 13 digits
- NTIN - Nordisk Varenummer, 13 digits
- NTIN - Spanish Codigo National, 13 digits
- PZN (Germany), 7 digits
- NTIN - PZN (Austria), 13 digit
- Italian Bollino (AIC code), 9 digits
- NTIN - French CIP code , 13 digits (2008)
- Belgian ABP code, 16 digits
- NTIN - Greek EOF code, 9 digits
- Portuguese code, 7 digits
- NTIN - Swiss referencecode
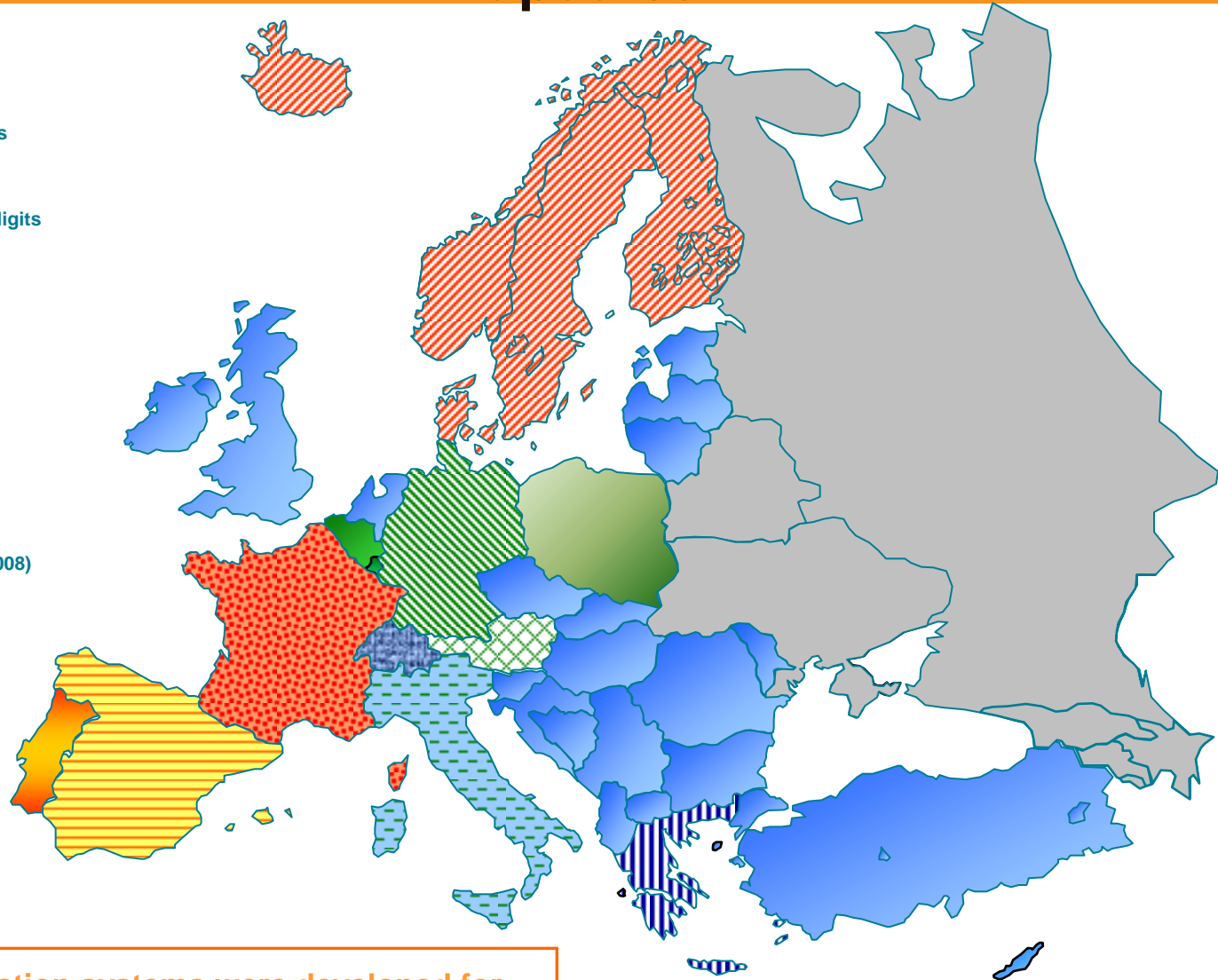
⇒ **Most National Identification systems were developed for reimbursement control**

The coding situation in Europe today: Overview of National Codification Systems (II) - **updated**

17 countries have a **full GS1 GTIN** (1) **code structure** (UK, Ireland, Czech Republic, Slovakia, Latvia, Lithuania, Estonia, Malta, Netherlands, Turkey Romania, Bulgaria, Serbia, Albania, Bosnia and Herzegovina, Macedonia)

12 countries use **an NTIN** (2) (EAN 13 compatible code structure) with product identification number allocated by a number bank or an external agency for the coding of pharmaceuticals

Scandinavia (No,Dk,Fi,Ice), France, Spain, Switzerland, Austria, Slovenia,Greece

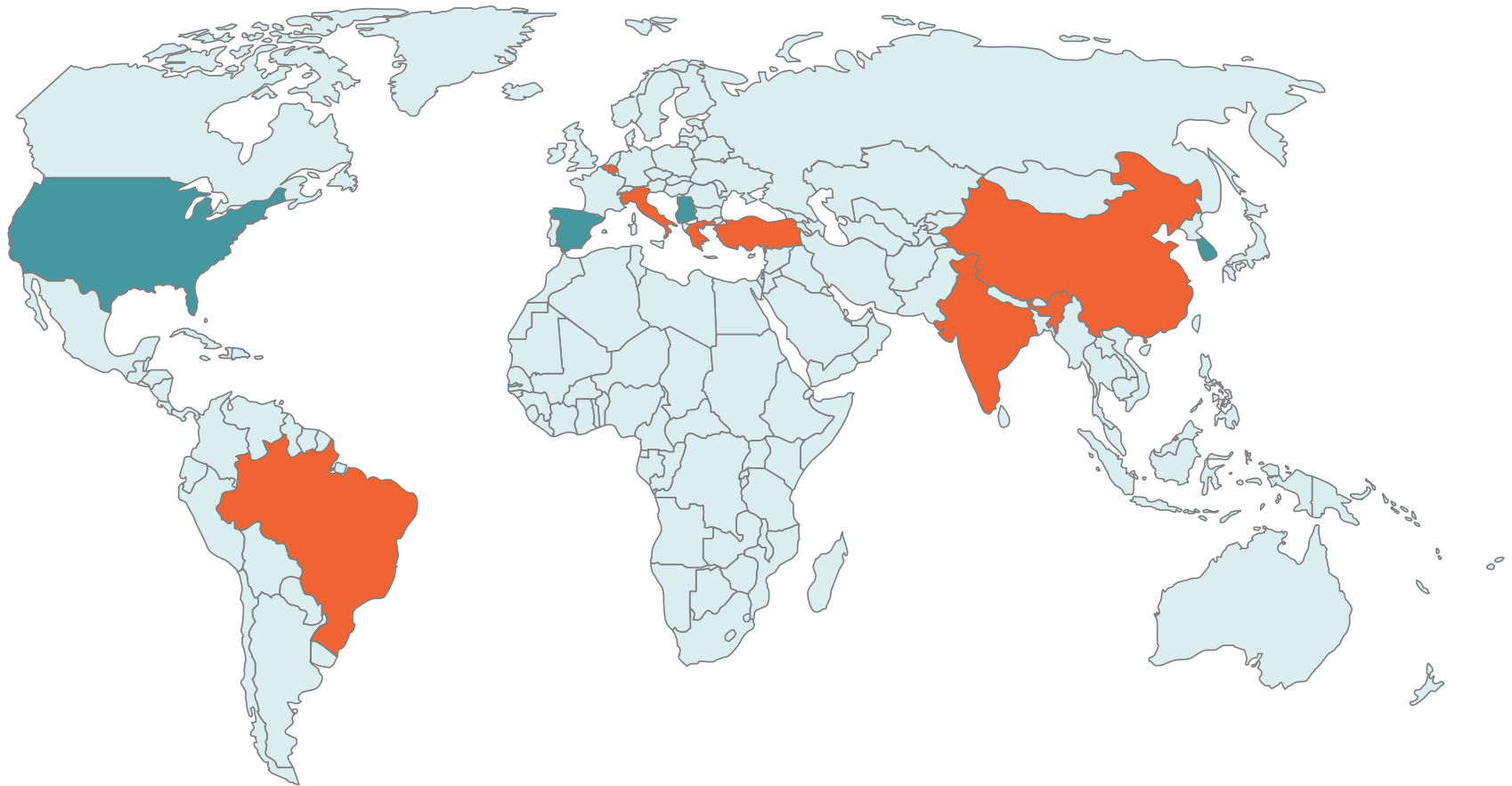2 countries allow NTIN **AND** GTIN (DK, Switzerland)

4 countries have their own **non- GS1 compatible solution**

Belgium, Germany, Italy, Portugal.
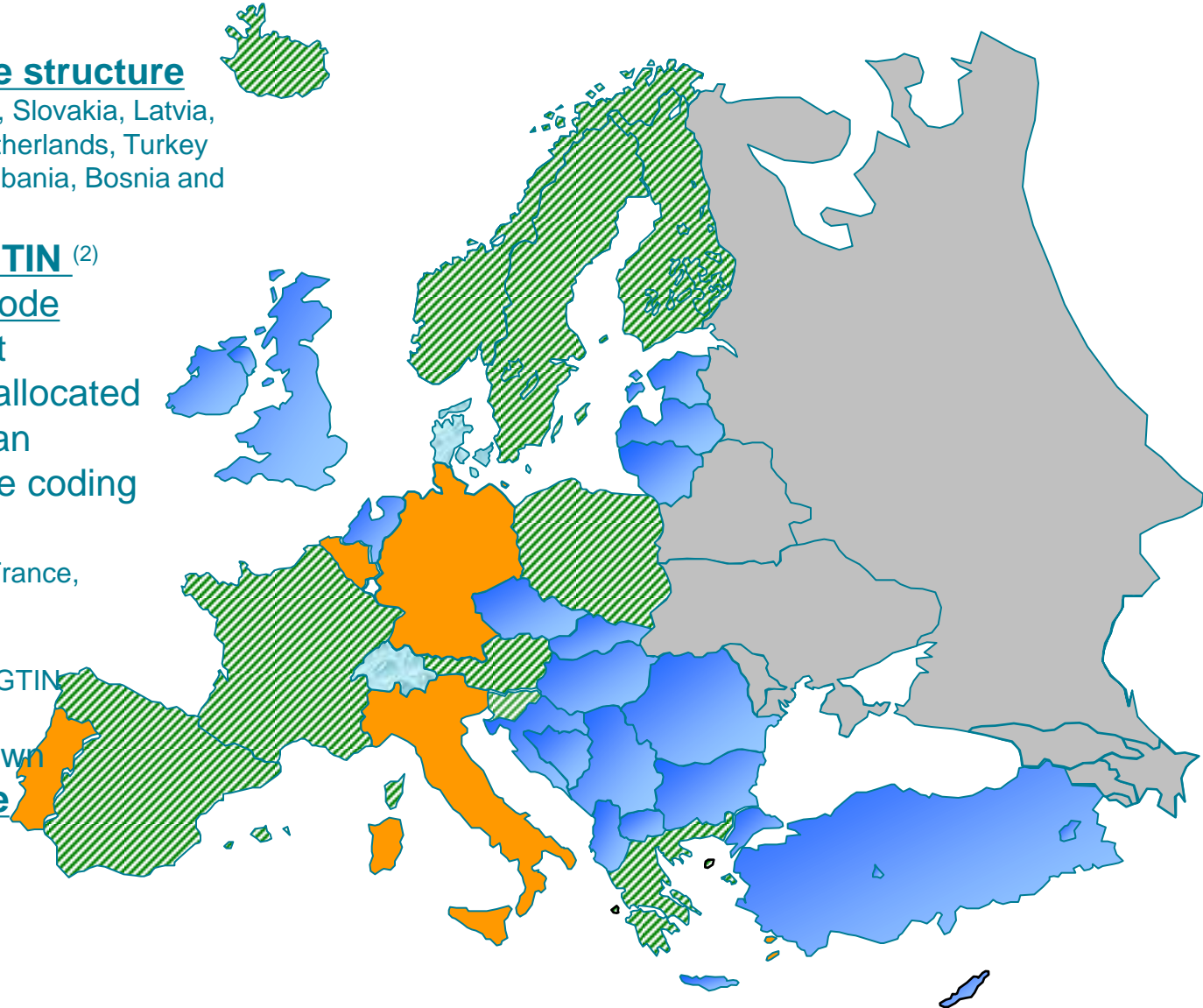
(1) GTIN: Global Trade Item Number
2) NTIN: National Trade Item Number

Identification of pharmaceuticals

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- = country accepts GTIN
- = country requires NTIN
- = country requires national ID #
- = no input available

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Serialisation of pharmaceuticals

![GS1 Healthcare logo]

= country requires serial number

= country developing requirement for serial number

DataMatrix on pharmaceuticals

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Switzerland: SmartLog Pilot

Spain: Pilot

France: AFSSAPS regulation (2011)

Belgium: Pilot project unit dose marking

Austria: Cytostatics
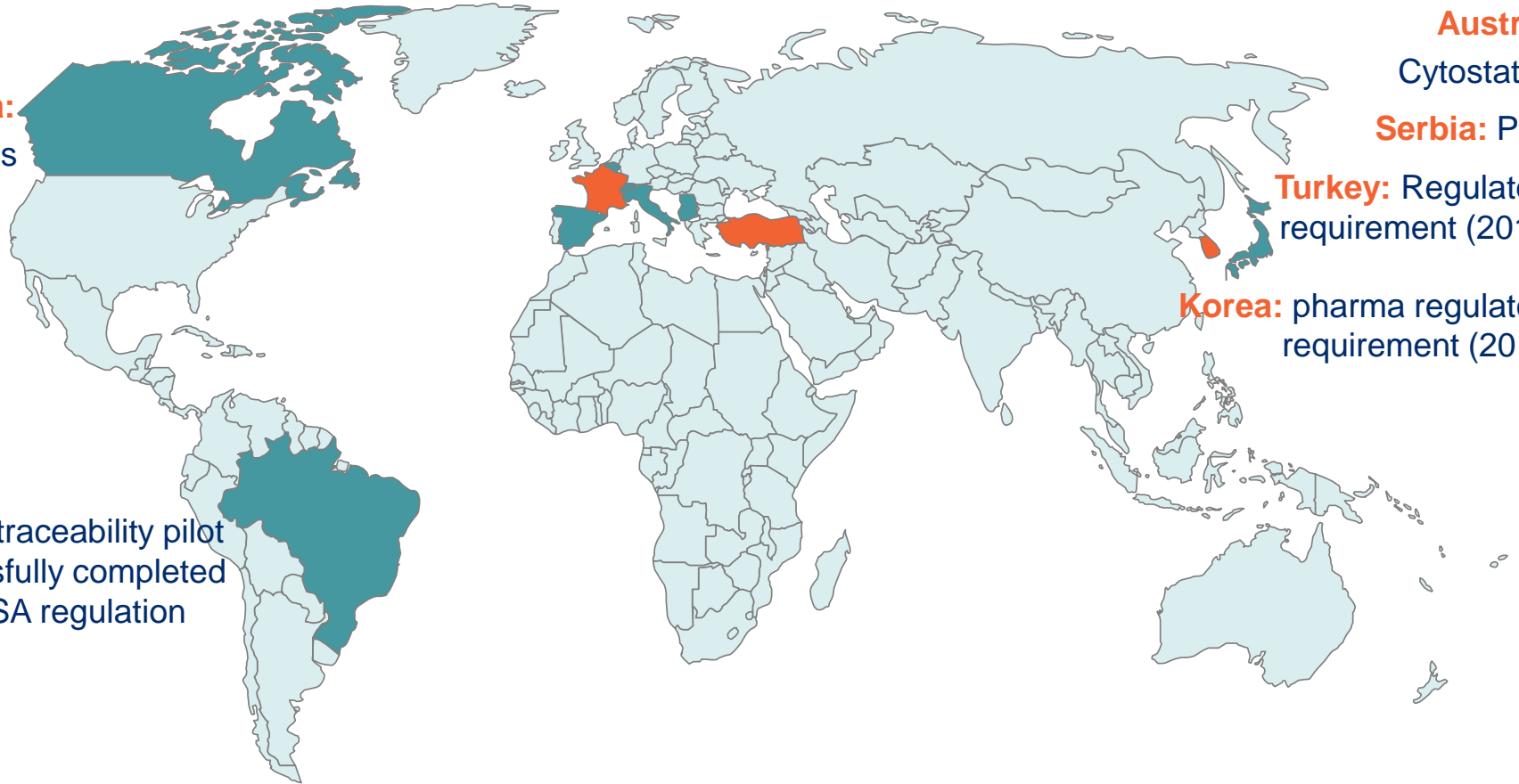
Serbia: Pilot

Turkey: Regulatory requirement (2010)

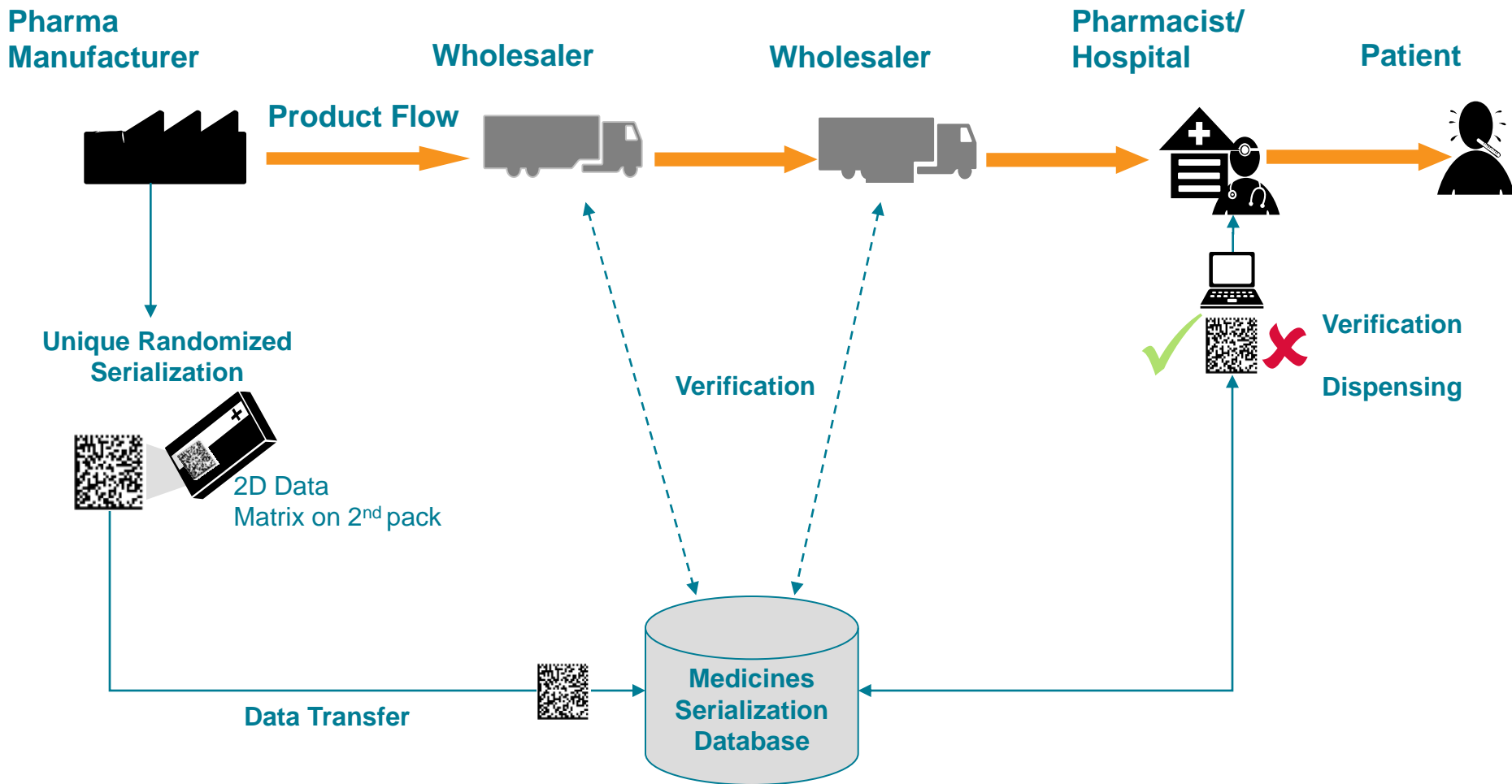**Korea:** pharma regulatory requirement (2011)

Canada: Vaccines

Brazil: traceability pilot successfully completed – ANVISA regulation

■ = country requires DataMatrix

■ = country using DataMatrix in pilots and/or developing requirement for DataMatrix

Medicines verification at the point of dispense

Pharma Manufacturer

Wholesaler

Wholesaler

Pharmacist/ Hospital

Patient

Product Flow

Unique Randomized Serialization

2D Data Matrix on 2nd pack

Verification

Verification

Dispensing

Data Transfer

Medicines Serialization Database

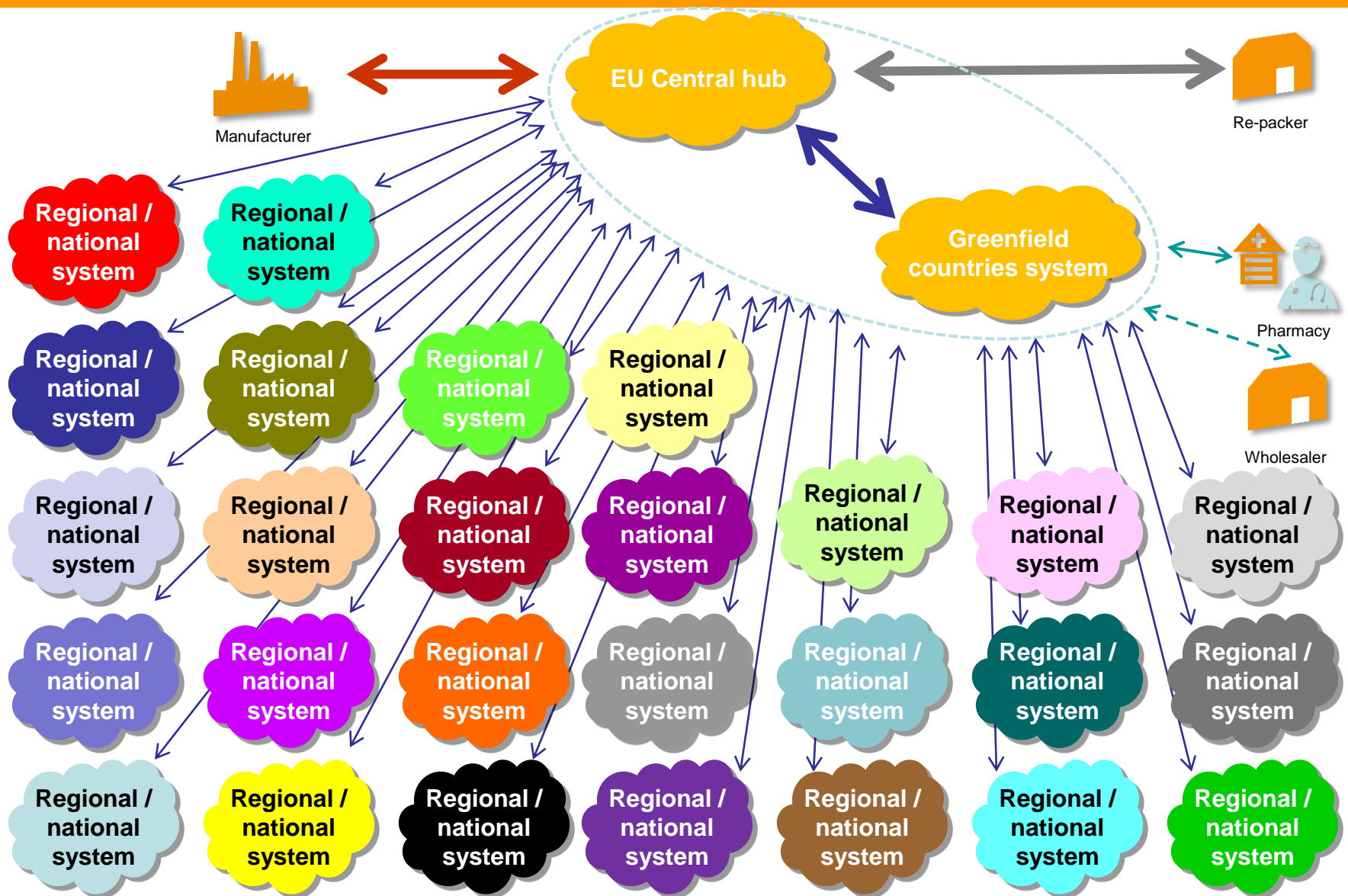## Point-of Dispense Verification Model

Stakeholder Governed Pan European System must

- Ensure product and patient safety
- Be accepted and supported by many stakeholder organisations
- Accommodate different needs in different regions
  - Example: distributed data base model as planned in Germany
- Be based on same principles in different regions
  - Mandatory coding and verification
  - Harmonised coding system
  - Same basic procedures to be followed in case of exceptional events
- Provide interoperability between regional systems
- Be scalable to be extended over time
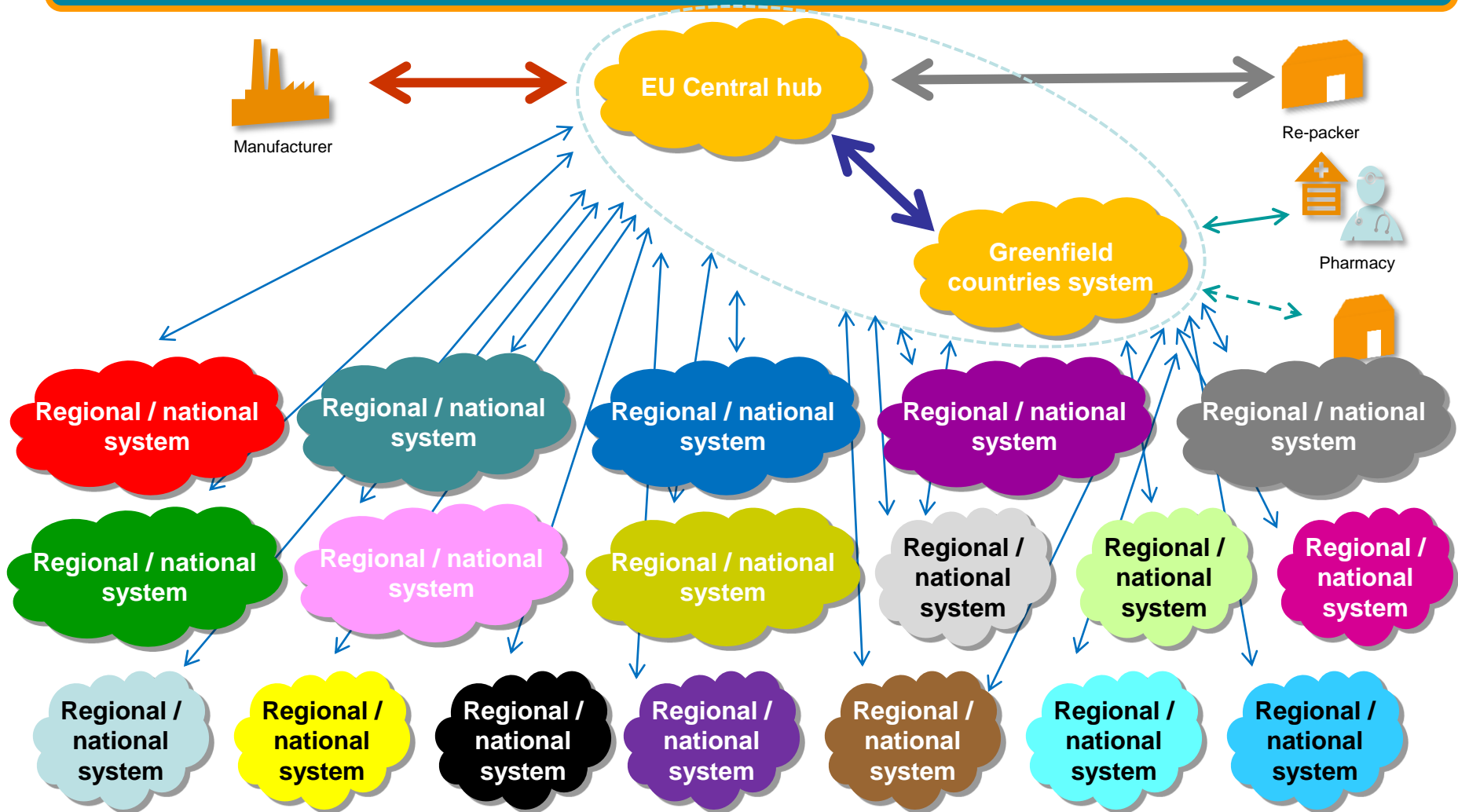- Be cost effective
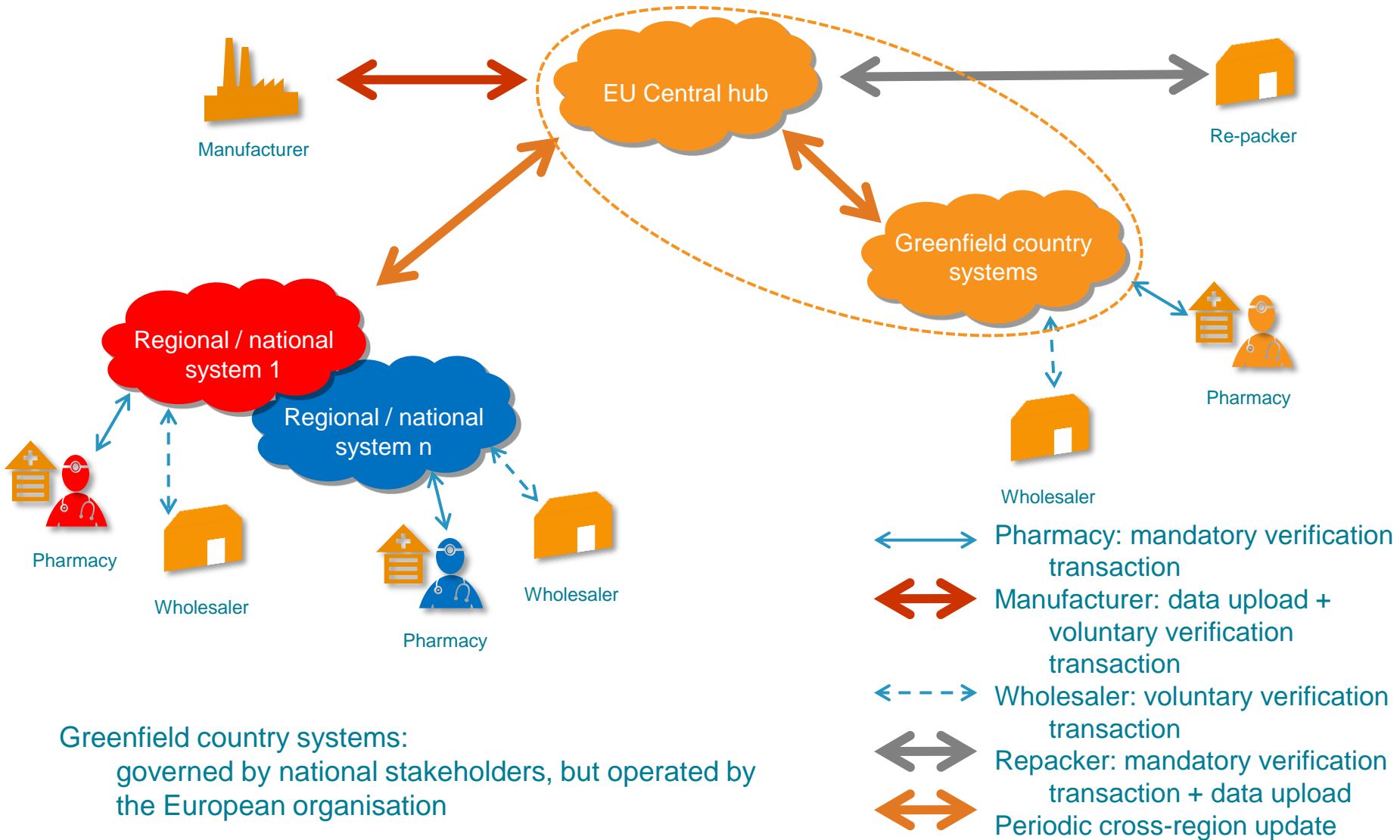
Greenfield country systems:
 governed by national stakeholders, but operated by
  the European organisation

Pharmacy: mandatory verification transaction

Manufacturer: data upload + voluntary verification transaction

Wholesaler: voluntary verification transaction

Repacker: mandatory verification transaction + data upload

Periodic cross-region update

Key Goal – Reduce the Number of National Systems

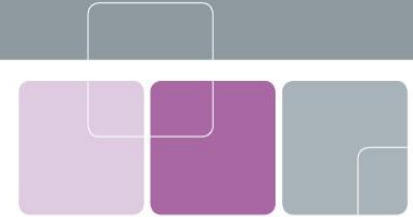# Key Strategies

## Greenfield System Replaces Regional / National Systems
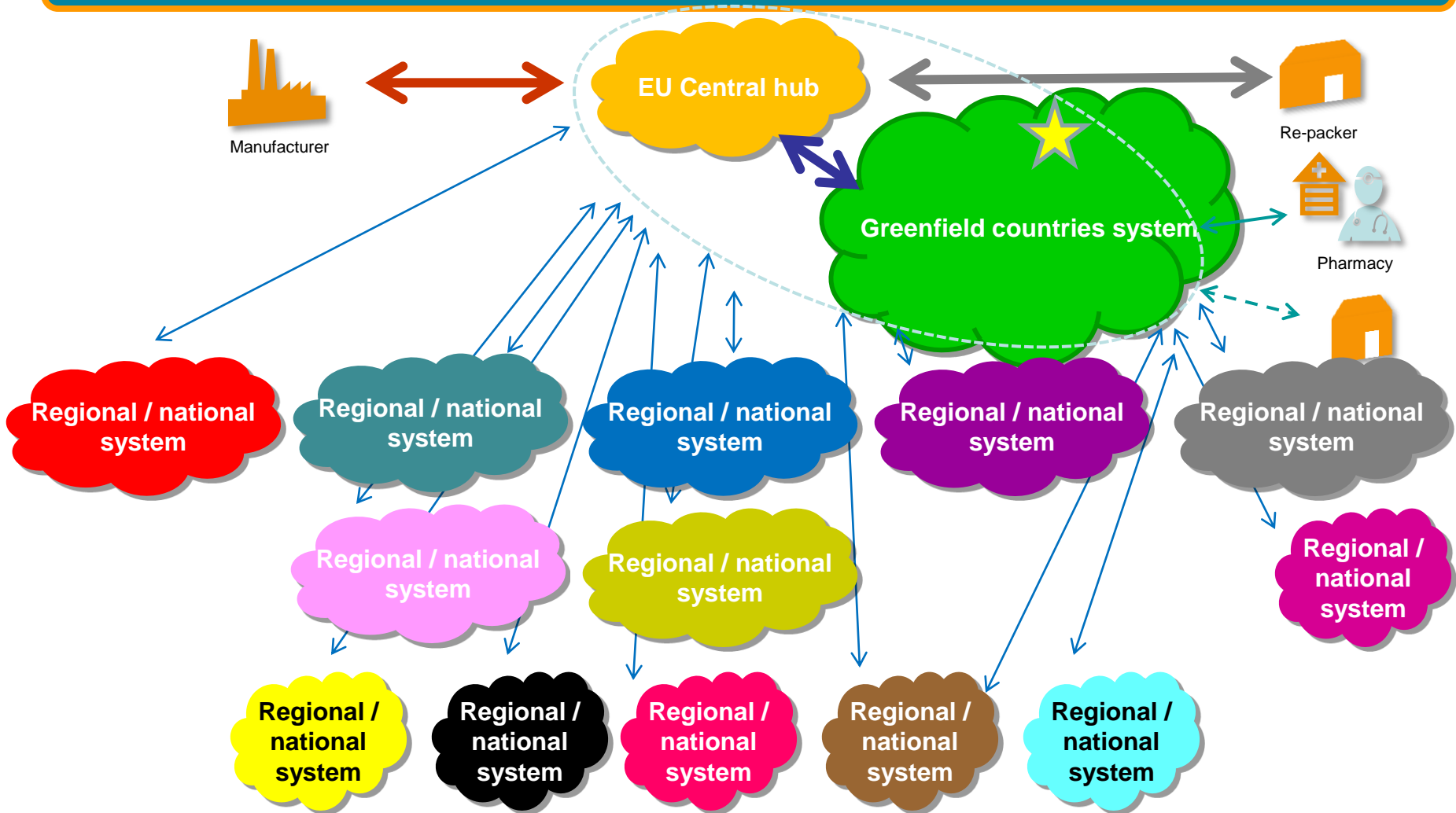
"You'll never walk alone"-approach (1)

1. Not a romantic view, but efficacy

2. Focus on the essentials:
   A. Is this medicine the one that it is meant to be
   B. Are you dispensing the right medicine to the right patient?

3. This is about verification, not about tracking & tracing
4. And about genuine partnerships that share the objectives
5. It needs to be agreed upon on a global/European basis

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"You'll never walk alone"-approach, (2)
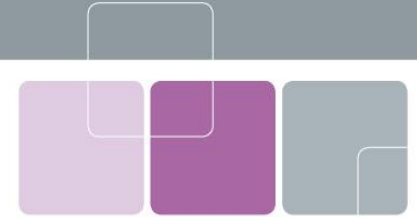
- … And what about "packs" ?
  - Packs issues risk to be on the horseback of the coding issue
  - ➤ "Pack" = treatment?: week / 2 weeks / month / … year?
  - ➤ "Pack" = patient? "Individual Medication Preparation"?
  - ➤ "Pack" = bulk?
  - ➤ "Pack" = unidose? With codes per unidose?
- ➤ And what about the initial objectives?
- ➤ What about breaches of the safety chain?
- ➤ What about product liability?
- ➤ Liabilities of third parties that may be willing to intervene?

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"You'll never walk alone"-approach (3)
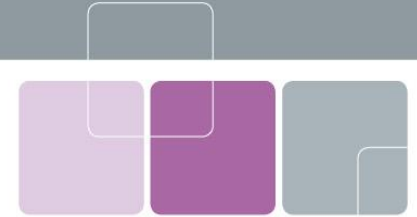
Base actions an true partnership

– NOT per country
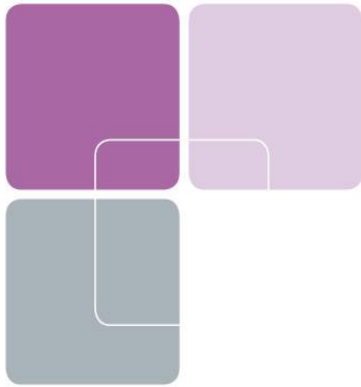– NOT per hospital

Do not walk alone
Or you might

- this needs one European approach
- If not a global one

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1. Combining tamper-evident packaging with a unique serial number

   – Unique serial number on each pack and check it against a central database at the point of dispensing

   – Tamper-evident packaging

   – All prescription medicines

2. Guaranteeing continuity of protection throughout the entire supply chain

   – Repackager to check out the originator's serial number, to provide a new serial number and to link both numbers in the database

3. Ensuring a single coding and identification system on each pack across the EU

   – 2D code containing the unique serial number, product identification code, expiry date, batch number

4. Ensuring product verification database systems can work together across the EU

   – All national database systems to work together and exchange information (interoperability)

   – National database systems to meet equivalent quality assurance requirements

5. Verifying every serialised pack at pharmacy level

   – Systematic verification of every individualised pack at the point of dispensing

   – Stakeholders to define standard procedures for exceptional events such as verification failure, system failure, etc

6. Maximising all the potential benefits of mass serialisation

   – Additional benefits beyond improved counterfeiting prevention such as improved product recall procedures, facilitation of product recall, automatic detection of expired product s, etc

7. Focusing on securing patient safety and protection patient privacy

    – Manufacturers do not seek and will not have access to individual pharmacy data or individual patient/ prescribing profile information

    – Transactional data belongs to the pharmacist

8. Using safety features are simple, robust and cost-effective

9. Working together in the interests of patient safety

    – Establishment and management of product verification systems to be undertaken by stakeholders (setting up of independent non-profit organisations to be jointly managed by relevant stakeholders)

10. Involving other stakeholders

    – Enlarged discussion platform to AESGP (OTCs), EAEPC (parallel traders), EGA (generics) and HOPE (hospitals)

- Many thanks for your attention

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