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European Federation of Pharmaceutical Industries and Associations

Improving patient safety across Europe through serialisation

Speaker : Grant Courtney

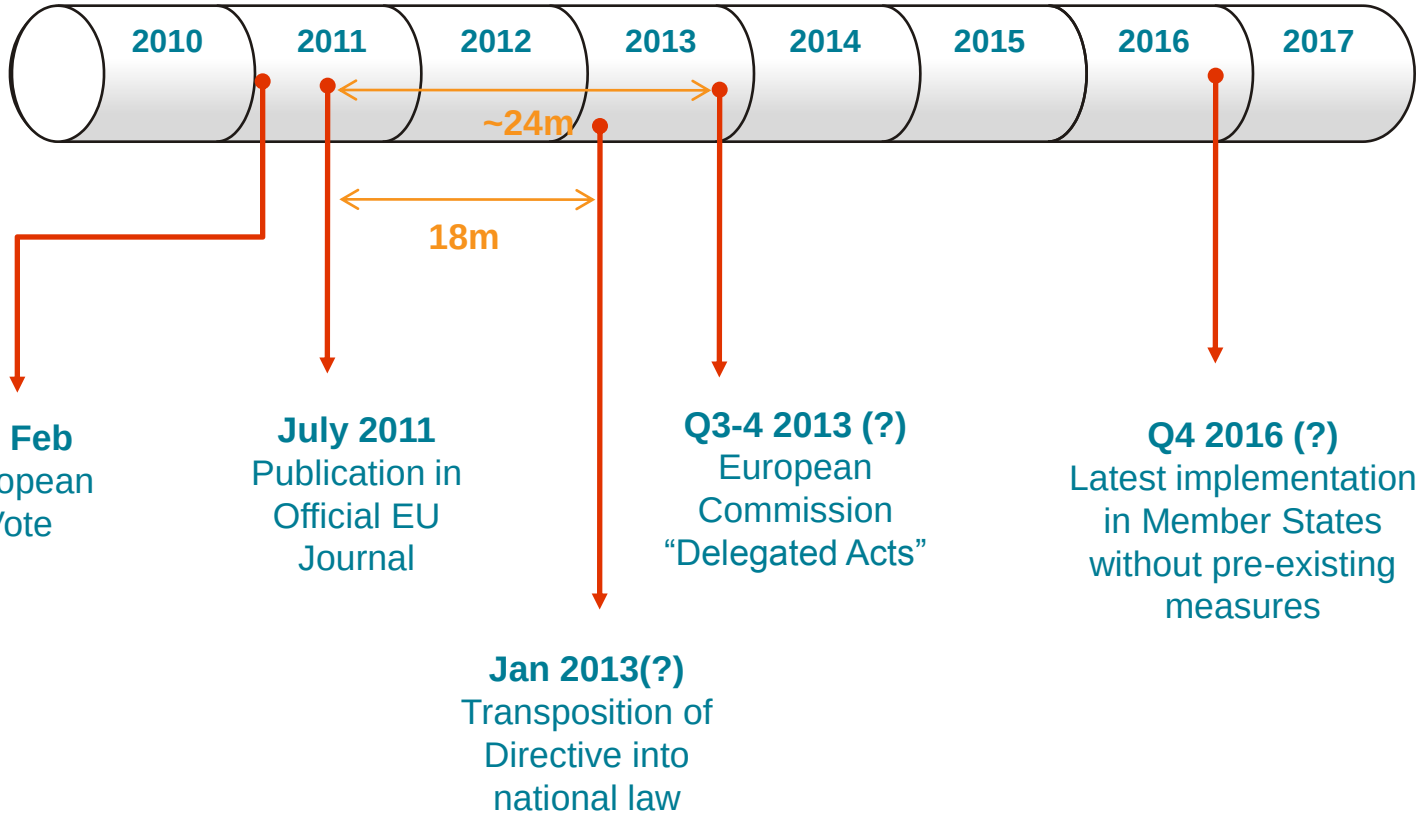
Event: GS1 - Amsterdam

Date: Oct 2011

Who am I ?

- 15 years supply chain and product design for GlaxoSmithKline
- Member of the GS1 Healthcare Leadership Team and Co-Chair of the Public Policy Team
- Sit on various **efpia** groups addressing product coding

Serialisation Status in Europe



The EU Falsified Medicines Directive

- On 27 May 2011 the EU Council formally adopted Directive, which will be released in the EU Official Journal in July 2011.
- The Directive should be transposed in Member States' national laws by January 2013, in summary:

  - All prescription-only medicines will have to bear safety features (i.e. a unique serial number placed on each pack together with tamper evident packaging). Certain products or product categories of prescription-only medicines might be exempted according to a risk assessment; OTCs are excluded in principle from the scope of the Directive unless there is a risk of falsification

  - The Commission will decide the specifications of the serial number allowing identification/ authentication of individual packs and will set out the provisions for establishment, management and accessibility of databases in the so-called 'Delegated Acts' (implementing rules)

  - The Delegated Acts should be released with the next 12-24 months and companies will have then 3 years to comply with the technical requirements as of the date of publication of the Delegated Acts.

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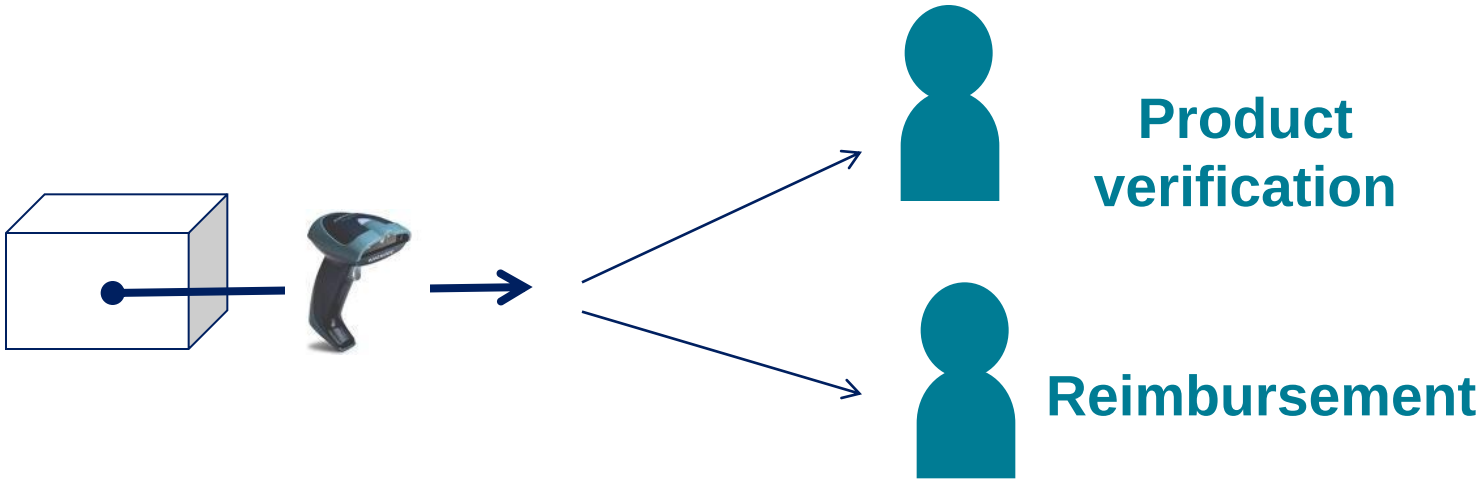
National numbers

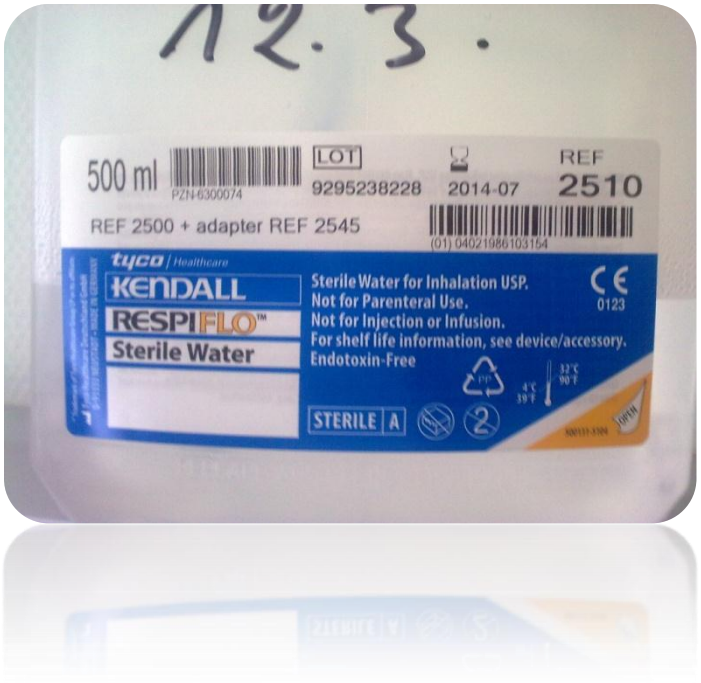
Challenges – national numbers

- Multiple processes need to be accommodated by the barcode information on the pack e.g. verification, reimbursement, product identification etc
- In some countries these processes can be achieved through the use of the GTIN alone
- Other countries use national numbers to operate some of these processes



Challenges – national numbers

- We need to ensure that we don't have a proliferation of barcodes on the pack
- Pharmacists want a single barcode to scan and a minimum impact on their working practices when product verification is introduced
- There are challenges to move to GTIN to facilitate all processes (current systems, processes, legislation etc)



So what is EFPIA and GS1 doing ?

Challenges – national numbers

- A vision is being developed where the end point should be a GTIN on the pack and other numbers looked up using the GTIN
- To allow a transition towards this vision GS1 in looking at introducing a new AI to carry the national reimbursement number in the same barcode as an attribute on the GTIN
- This approach will only be required in a very few number of cases and should be viewed as a stepping stone towards the vision of using the GTIN

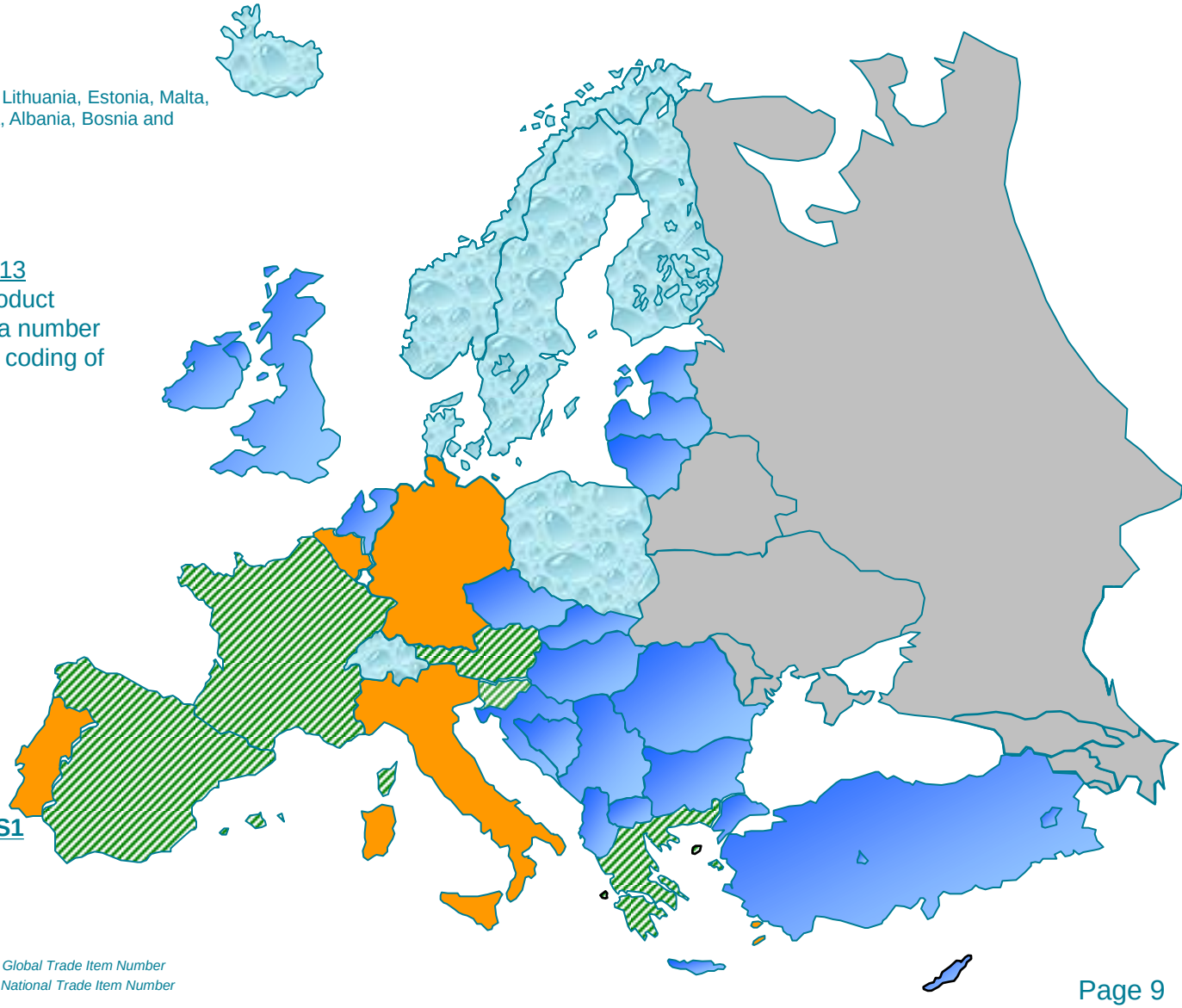
The coding situation in Europe today: Overview of National Codification Systems - **updated**

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)

5 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
Austria , France, Greece, Slovenia, Spain,

7 countries allow NTIN **AND** GTIN
(DK, Finland, Iceland, Norway, Poland, Sweden, 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

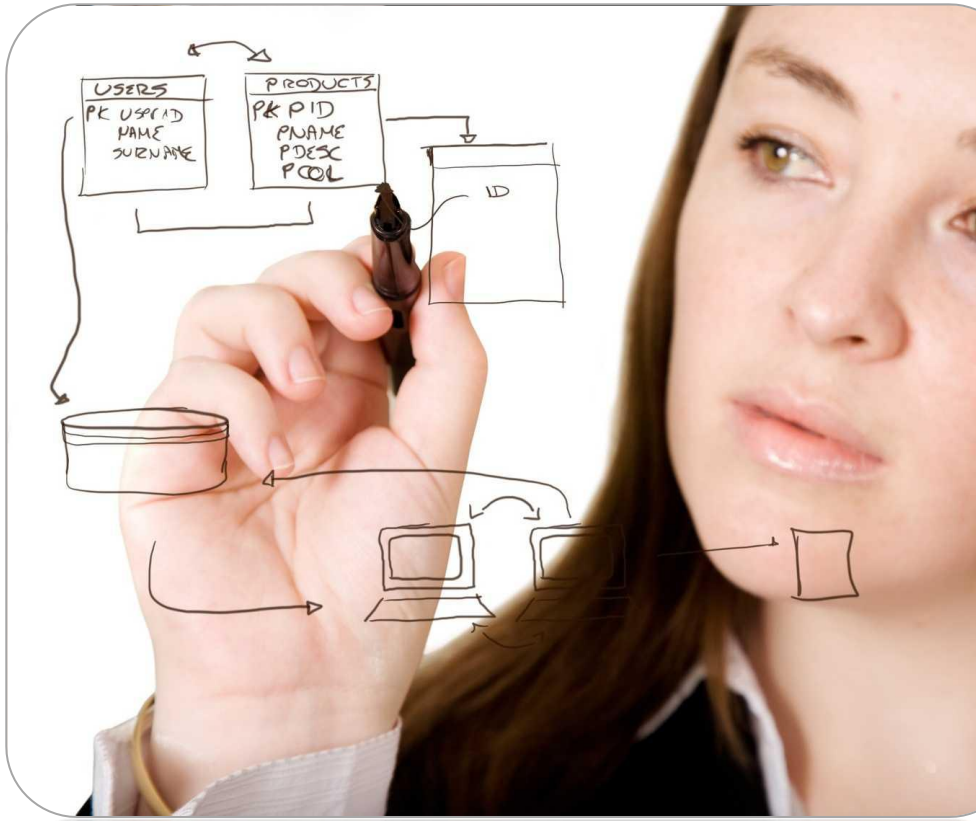
Thank you

Grant Courtney

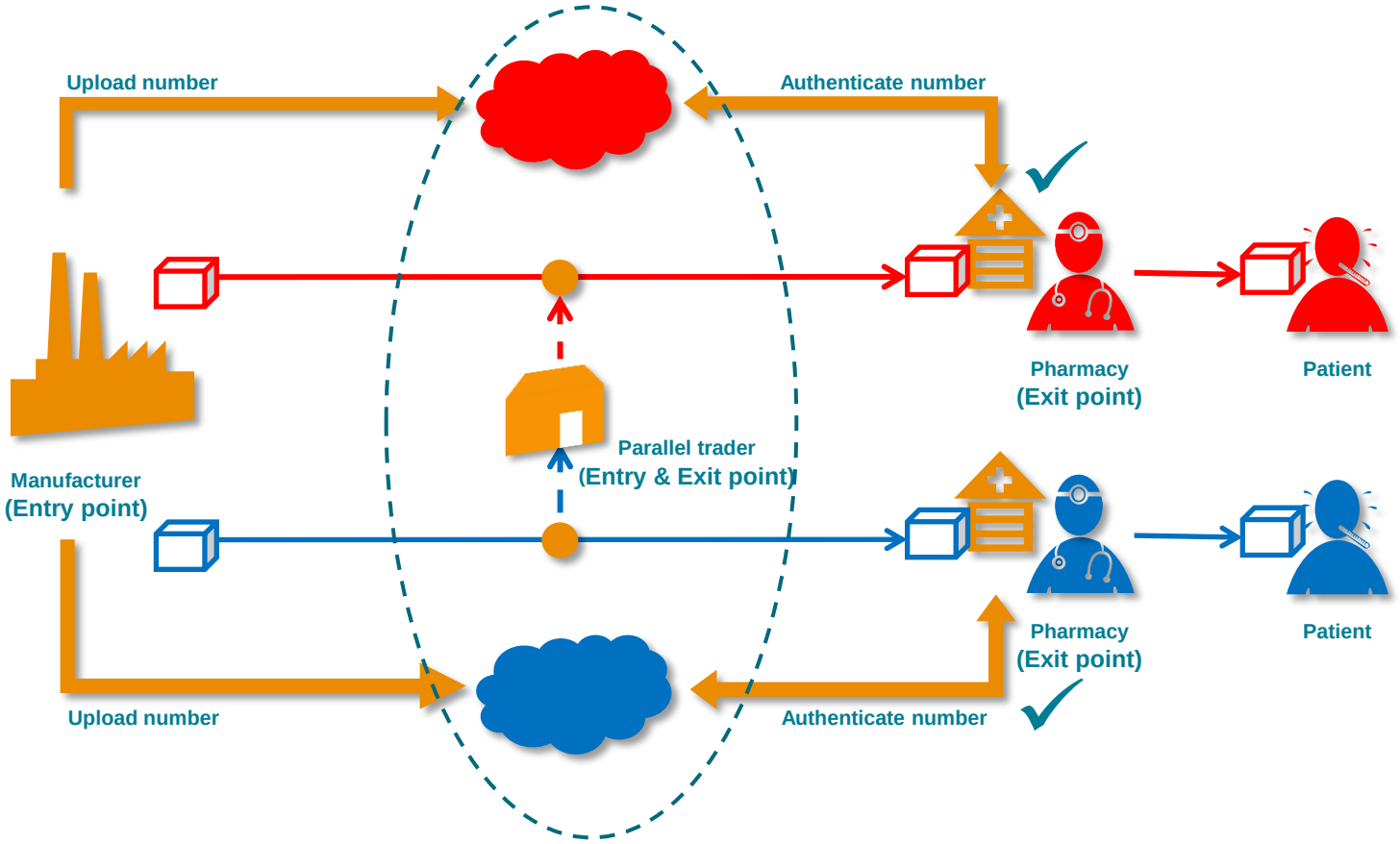
www.efpia.org

http://www.youtube.com/watch?feature=player_detailpage&v=JMDohjIkMsg

Current work



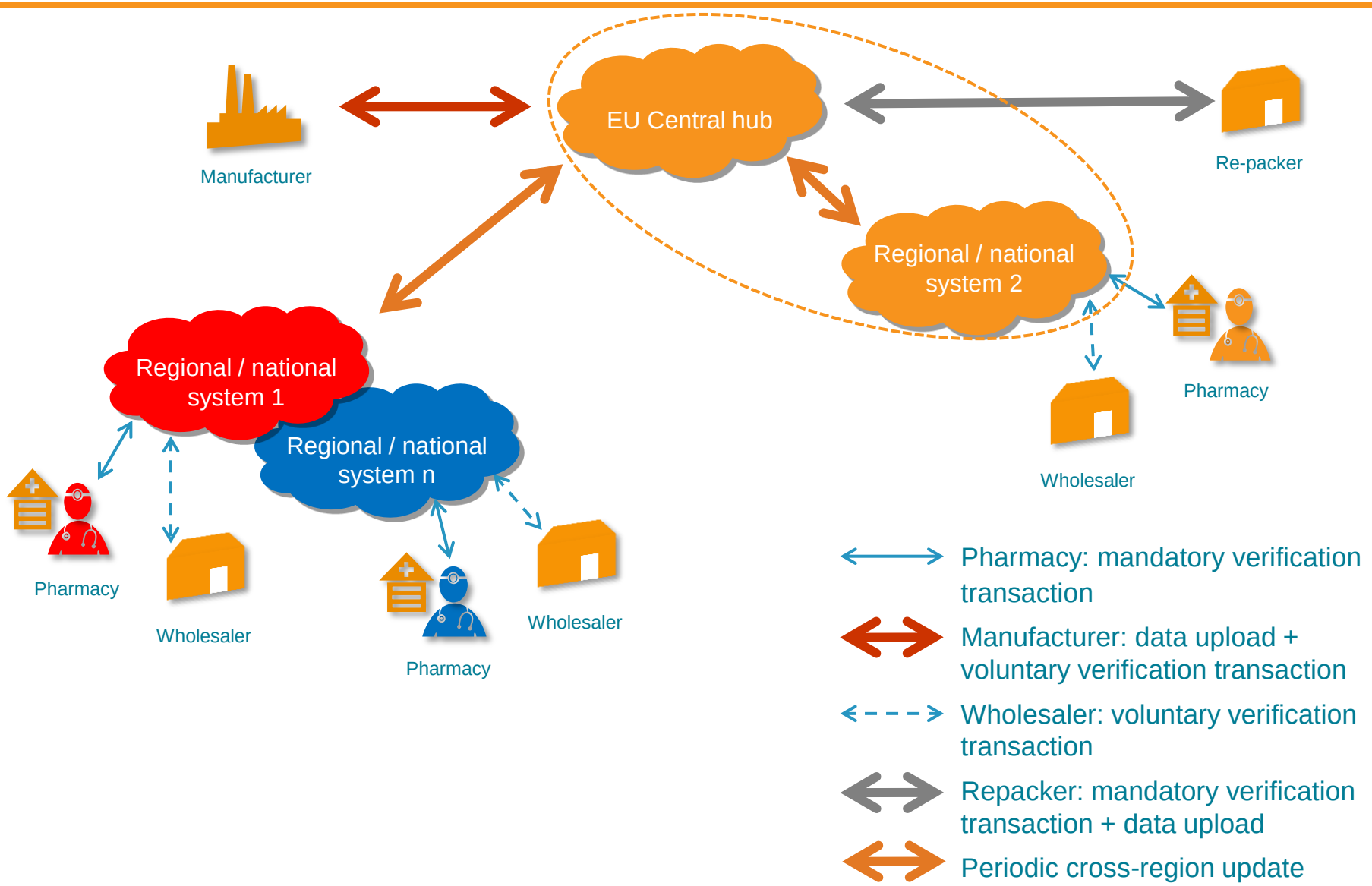
Cross boarder movement



- Criminals will exploit gaps between these systems to introduce counterfeit product

Systems will have to be interoperable to ensure patient safety

Pan European Verification System



5 lines of coding

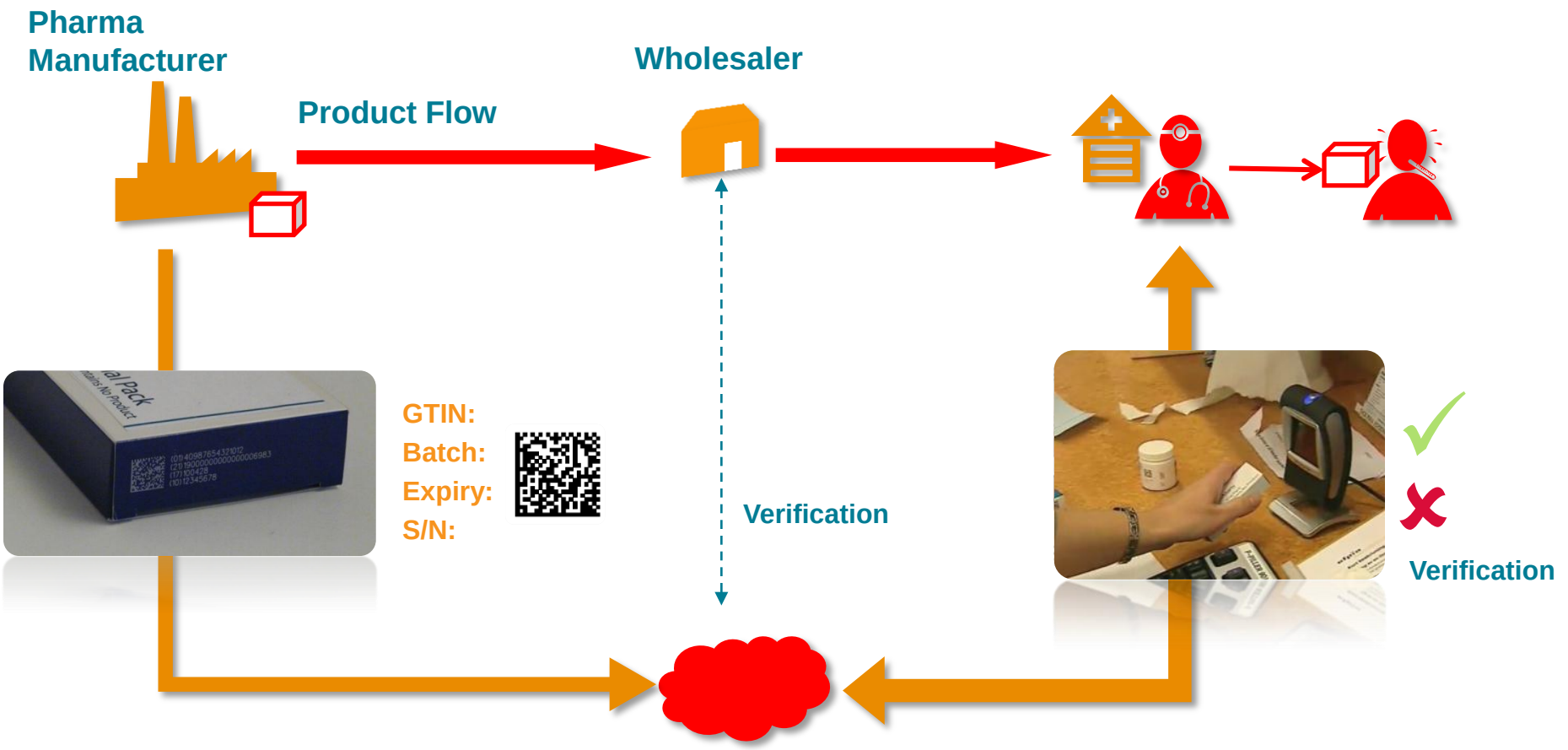
- Propose 5 lines of code in the data carrier
  - NHRN - see below
  - GTIN - AI (01)
  - Expiration date - AI (17)
  - Lot Number - AI (10)
  - Serial Number - AI (21)

The need for standards

- Multiple codes
  - Confusing and time consuming, especially if several are required during dispensing
  - Risk to patient safety if the incorrect code is scanned
  - Issue caused for multi-market packs

The barcode must be unique and allow all requirements to be covered in a single scan

We advocate securing **all** entry and exit points of a country's supply chain through a point of dispense authentication model



Point-of Dispense Verification Model

Pan European Model - Principles

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
  - Link with reimbursement or e-prescription systems
- 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**

Summary Key benefits of model

- Use of Datamatrix code **reduces required space** on pack & provides higher robustness compared to linear barcode
- “Point of dispense verification” is **far less complex** than Track & Trace
- Including batch number and expiry date in the code allows **for logistic and Patient Safety advantages**
- Stakeholder governance focuses on patient safety and **avoids expensive solutions** that may potentially be required by authorities or other parties
- European hub provides a **single point of data entry** for manufacturers
- European hub **facilitates multi market packs**
- Model provides Pan European interoperability connectivity at **lower costs**