



European Federation of Pharmaceutical
Industries and Associations

Update on EFPIA Project for Coding and Identification of Pharmaceutical Products in Europe - Plans for a pilot trial

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STOP Conference



1. Objectives & European Context
2. The EFPIA concept: Rationale & Benefits
3. Next Steps
4. The Pilot Project
5. Conclusion

- **Traceability today :**

- At batch level

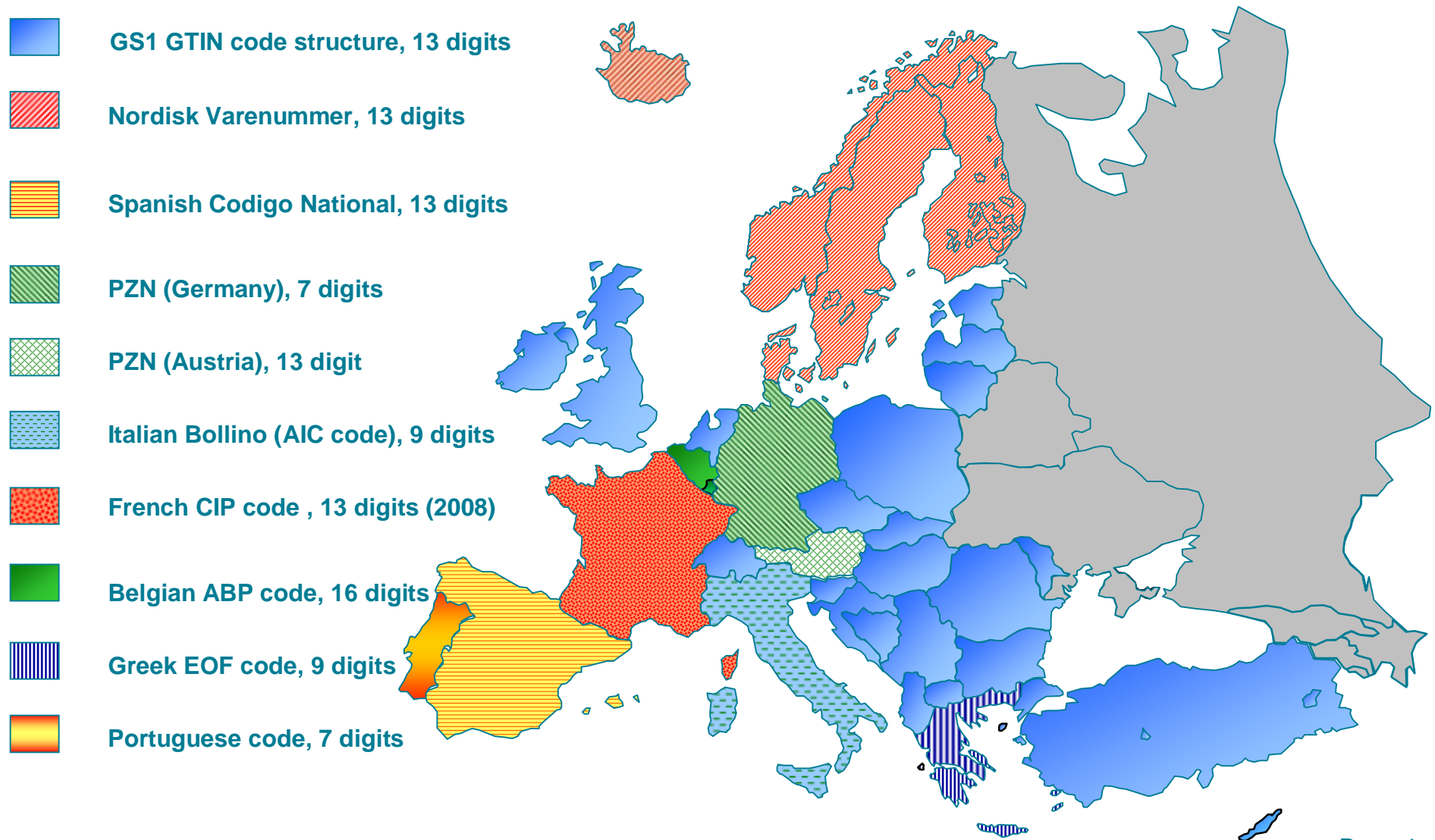
- Linear barcode including product code read automatically with a barcode reader at pharmacy level (best case/not in all countries)
 - Batch number and expiry date (variable mentions) written in clear on the secondary and primary packaging

- **Traceability tomorrow :**

- At unit of sales level (i.e. at box level)

- **Product code, batch number and expiry date will need to be included in the code in order to be read automatically and avoid dispensing errors**
 - Deliver the right product to the patient
 - Automatic detection of expired products
 - **Serialization (1 randomized number per box) would allow to**
 - Prevent counterfeits
 - Fight reimbursement fraud

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



Unique pack identification (mass serialisation)

4 countries (Belgium, Italy, Greece & Turkey) are already requesting for each pack a serial number (in addition to the national product code)

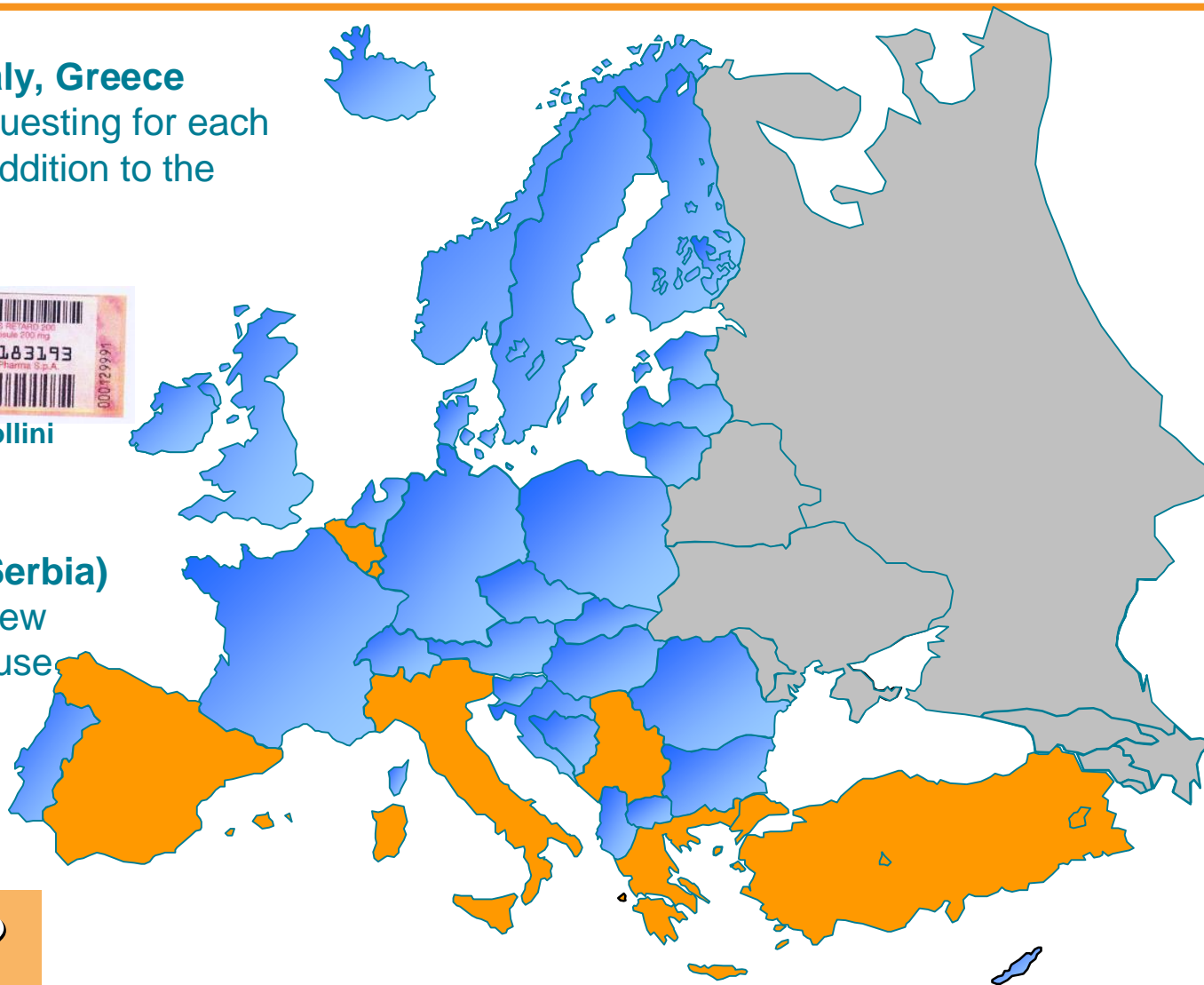


Vignette Royale Belge



Bollini

2 countries (Spain and Serbia) are currently working on new legislation mandating the use of a serial number



Who's next ?

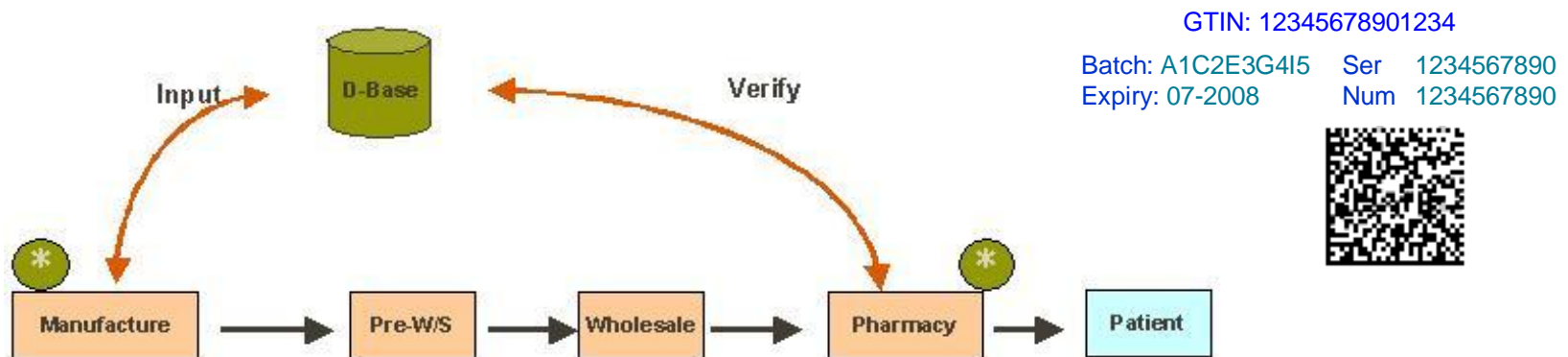
Why Harmonising the different identification systems ? (=> unique standard)

- Need to improve patient safety at a European level and enhance the control of the supply chain
 - Reduce dispensing and dosing errors risk
 - Increase efficiency of batch recall
 - Fight Reimbursement fraud & prevent counterfeits
 - Increase transparency of the supply chain (Repackaging Issues)
- Fragmented supply chain in Europe with different coding schemes implemented or proposed by different Member States (=> Risk of developing 27 different Bollino in Europe)
 - Increase manufacturing complexity, production costs and supply chain differentiation across the European market
 - Individual systems are inefficient to protect European borders

⇒ **EFPIA's proposal for a standardised coding & identification of pharmaceuticals in Europe consistent with existing international standards (GS1 EAN)**

The EFPIA Concept in Europe (end-to-end system)

- The EFPIA concept on coding and identification of pharmaceutical products consists in two parts :
 - The harmonization of pharmaceutical products codification throughout Europe via the implementation of a **serialized Data Matrix** (ECC200) on secondary packaging of all products sold in Europe
 product code + batch number + expiry date + serial number
 - The **verification** of pharmaceutical products at their point of dispensing (serial numbers)



Key Benefits

- **More effective and efficient products recalls**
- **Automatic detection of expired products**
- **Prevention of counterfeit medicines & reimbursement fraud**
- Improved traceability for pharmacy and hospital management systems allowing **reduction of dispensing errors** (in association with e-prescription systems) ⇒ deliver the right product to the right patient
- Harmonized and unique codification & identification system in Europe based on mass serialization and international standards ⇒ **Improved Europe borders protection**



More efficient and secured medicines supply chain
Reduction in liability risks, meeting better duty of care
Improved patient safety



EFPIA Recommendations 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/EAN14 or pseudo-GTIN]
Unique Serial Number (randomized)
Expiry Date
Batch Number

14 digits
up to 20 alpha-numeric characters
6 digits (yymmdd)
up to 20 alpha-numeric characters

Example:

(01) GTIN:	12345678901234	
Serial Number:	1234567890	
(17) Expiry:	080731	
(10) Batch:	A1C2E3G4I5 A1C2E3G4I5	

Evolution of french national code (pseudo-GTIN)

CIP 7:	3597441
CIP 13:	3400935974419
PseudoGTIN pack:	03400935974419

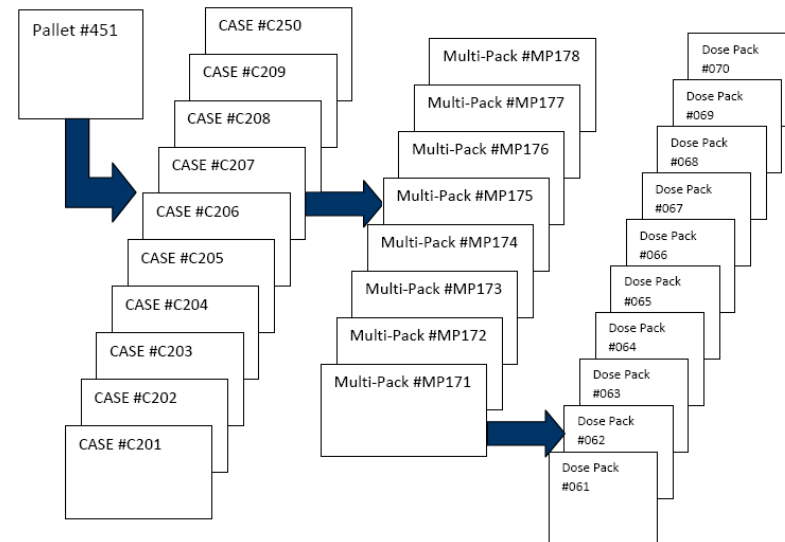




- Data matrix is a EAN.UCC (GS 1) standard since July 2004
- Data matrix is using international syntax EAN.UCC (GS1) 128
- Data matrix is the smallest symbol for a given quantity of information
- Data matrix is robust : the Reed Solomon error correction system allow Data matrix reading even with a high level of code damage (information redundancy)
- Data matrix can be printed with technologies currently used in Pharmacy (Inkjet, laser, Drop on Demand, thermal transfer)
- Data matrix is cost competitive (0.1 to 0.3 cents of €)
- Datamatrix has been used successfully by IFAH for coding all animal health products worldwide
- Data matrix is mandatory in Turkey since 1/01/09 (serialized), will be required in France on 1/01/11 (for each pharmaceutical packaging => product code + batch n° + expiry date)
- Italy, Germany and Spain are also evaluating possibility to use serialized Data Matrix (in future)

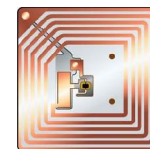
Why an “end to end” process and not an e-pedigree ? - Technological impacts

e-Pedigree requires having a detailed knowledge/record of the content of the packaging hierarchy along the supply chain (i.e. pallet, case, box)



This requires either:

- An aggregation process (inference) by which the manufacturer manages the association of items serialised codes with the code of the container into which they are packed (using datamatrix) => **Much more complex and expensive than the “end to end” efpia concept**
- Or adding RFID tags on every pack (in addition to Data Matrix) to read/analyse which unit packs are contained in the various cases/pallets => **Unreliable and very expensive**



Some issues have been identified with the use of RFID at individual pack level :

- ✓ Interferences with metals and liquids => lack of robustness (read rate < 100%)
- ✓ Compatibility with biologicals (vaccines and biotech) not yet proven
- ✓ Lack of harmonised standards
- ✓ Privacy concerns
- ✓ Requires business processes changes
- ✓ High cost : RFID tag cost = 20 to 40 cents of euro (compared to 0,1 to 0,3 cents of euro for Datamatrix cost)

- Pilot Projects within the pharmaceutical industry have shown that RFID technology is currently not mature enough to be considered as a universal track & trace technology applicable to all pharmaceutical products
- A number of problems remain to be worked out, namely reliability of the technology, readability issue (interference with liquids and metals) but also lack of common standards as well as public concerns due to privacy issues
- However, RFID could have some interest for the future, especially at case and pallet level for logistic applications. Therefore the adoption of Data matrix does not prevent the adoption of RFID at a latter stage (in addition to Barcodes) once the technology has matured and **if it can bring significant benefits in terms of logistics management (ROI)**

-
- **Continue Engagement with national Authorities and the European Commission to establish legal frameworks to enable use of an harmonised coding system at national/EU level**
 - Ensure harmonisation of product codes across Europe (GTIN or pseudo GTIN) - ex : evolution of PZN in Germany
 - Ensure original pack integrity throughout the entire supply chain (including original manufacturer code) , which supposes tamper evidence on all original packs and ban on repackaging activities
 - Promote choice of Data matrix as harmonized standard carrier across Europe as well as systematic control at the dispensing point
 - Ensure companies commitment to implementation of Data matrix and mass serialization on all packs upon an agreed period of time

Efpia project : Next Steps (2)

Conduct a Pilot Project

Objectives of the pilot: Proof of Concept

- **Political:** Conduct a pilot experiment in one European Country in cooperation with pharmacists in order to establish the EFPIA project as a credible alternative to national traceability systems
- **Technical:** Test the technical capabilities of the system (especially response time & data security) and ensure that the system as currently designed can be integrated into existing user operations (manufacturers, full-line wholesalers, pharmacists).

Selected Location: Sweden

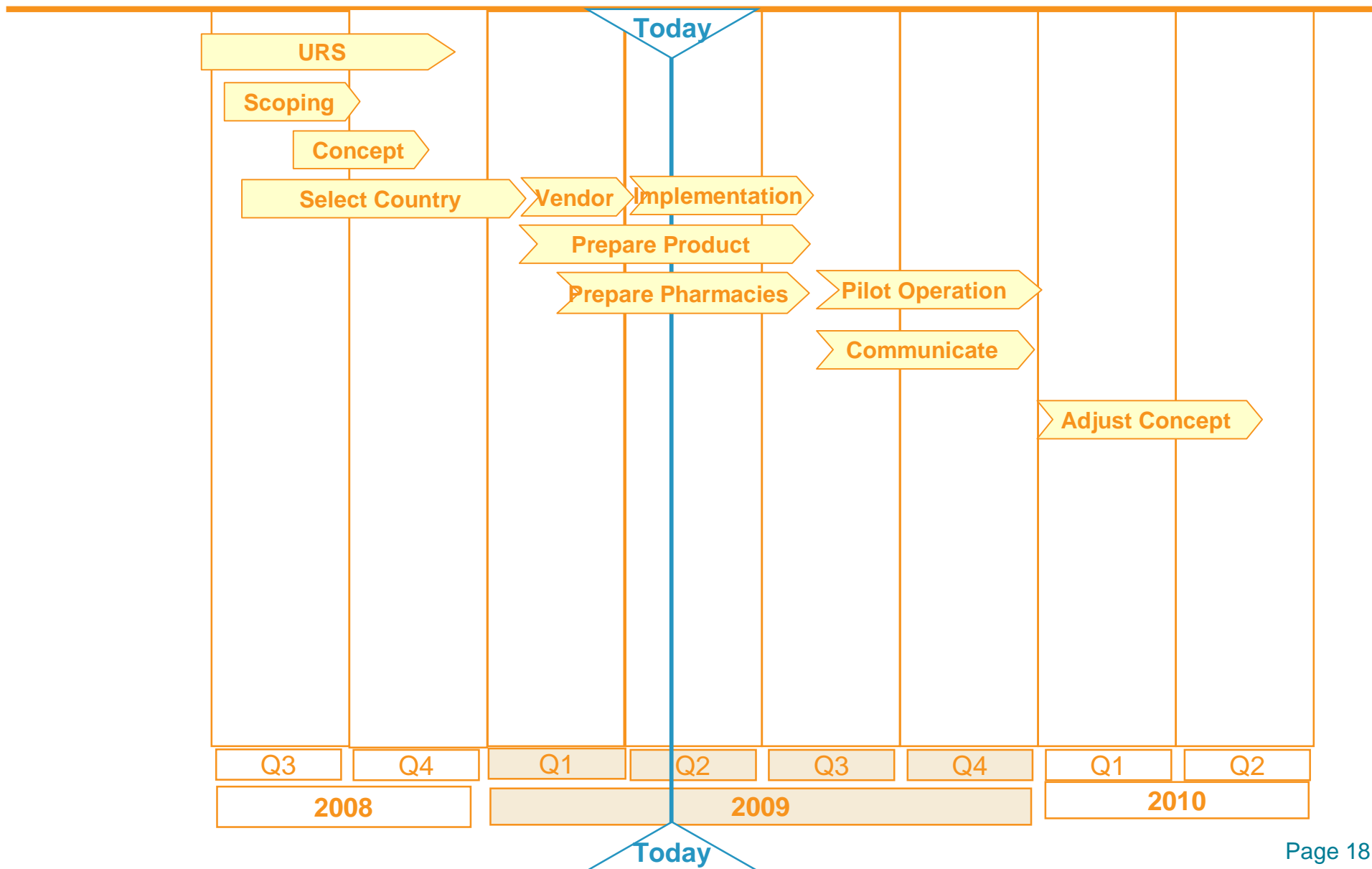
Cost: supported by EFPIA

Pilot to be implemented for a fixed period after which point the equipment will be removed and the results evaluated

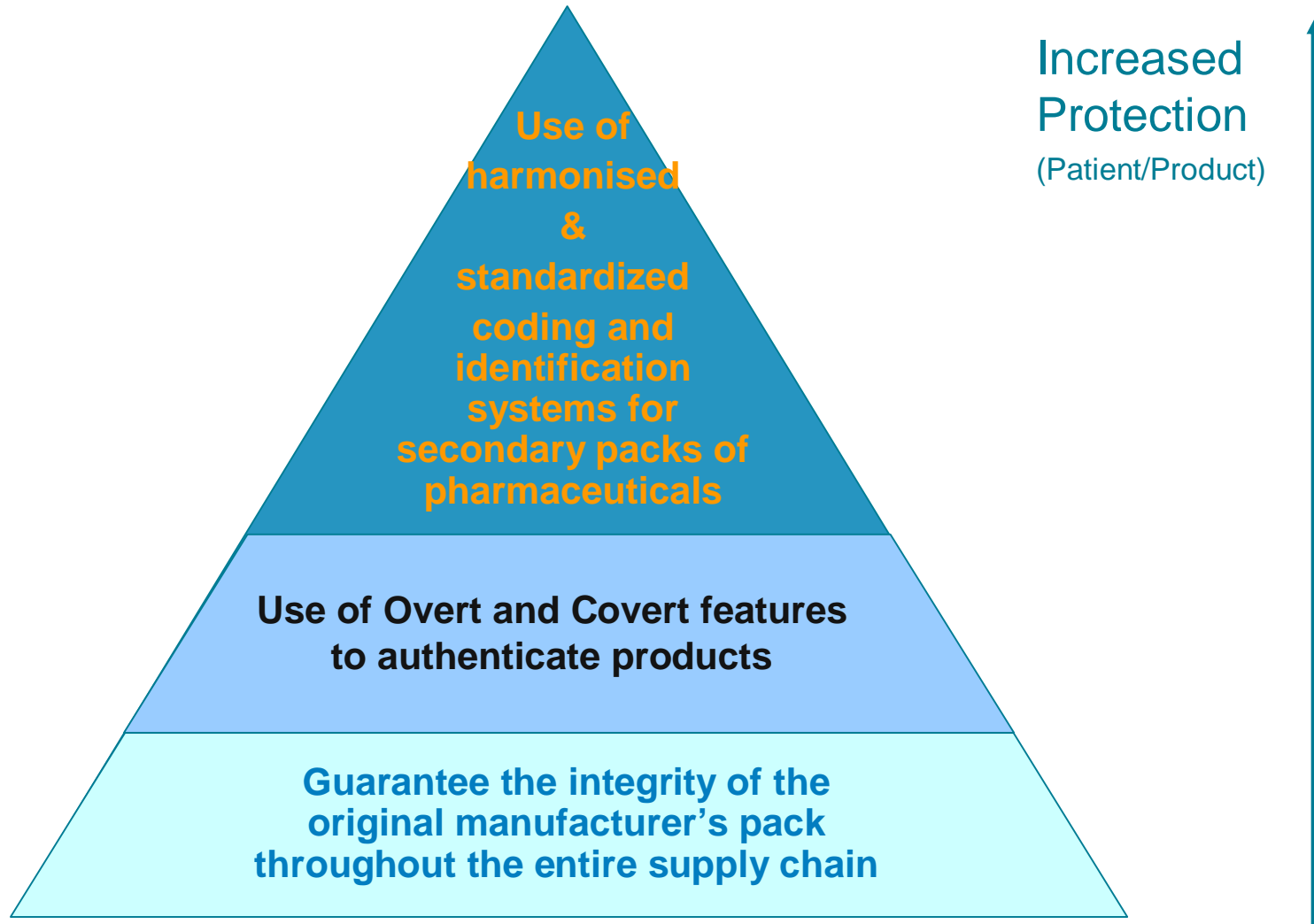
- Planned Pilot size
 - 30 - 50 pharmacies (depending on “throughput” per pharmacy)
 - Duration of operational phase ~ 3 to 4 months (planned to start mid August)
 - Number of coded packs to be dispensed: ~ 100 000
- Coding of packs
 - Codes will be applied to packs using labels
 - Labels should contain Data Matrix as well as serial number in human readable form
- Integration with pharmacy environment
 - All pharmacies use currently 2D barcode readers in Sweden (but not all of them are ECC200 capable)
 - All pharmacies use same software (Apoteket’s unique IS system)



Pilot Project schedule (as of Jan 30, 2009)

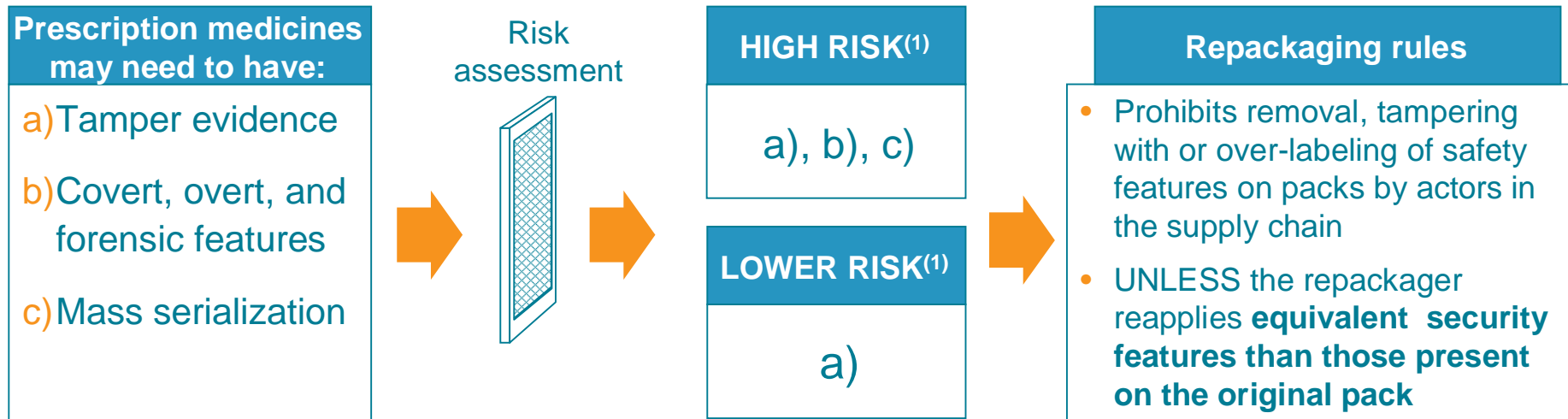


Serialization and control at dispensing point is one of the 3 Key Principles to secure product dispensation and improve patient safety



Counterfeiting - European Directive (10/12/08) EFPIA interpretation

Visual summary of Draft EC pharma package

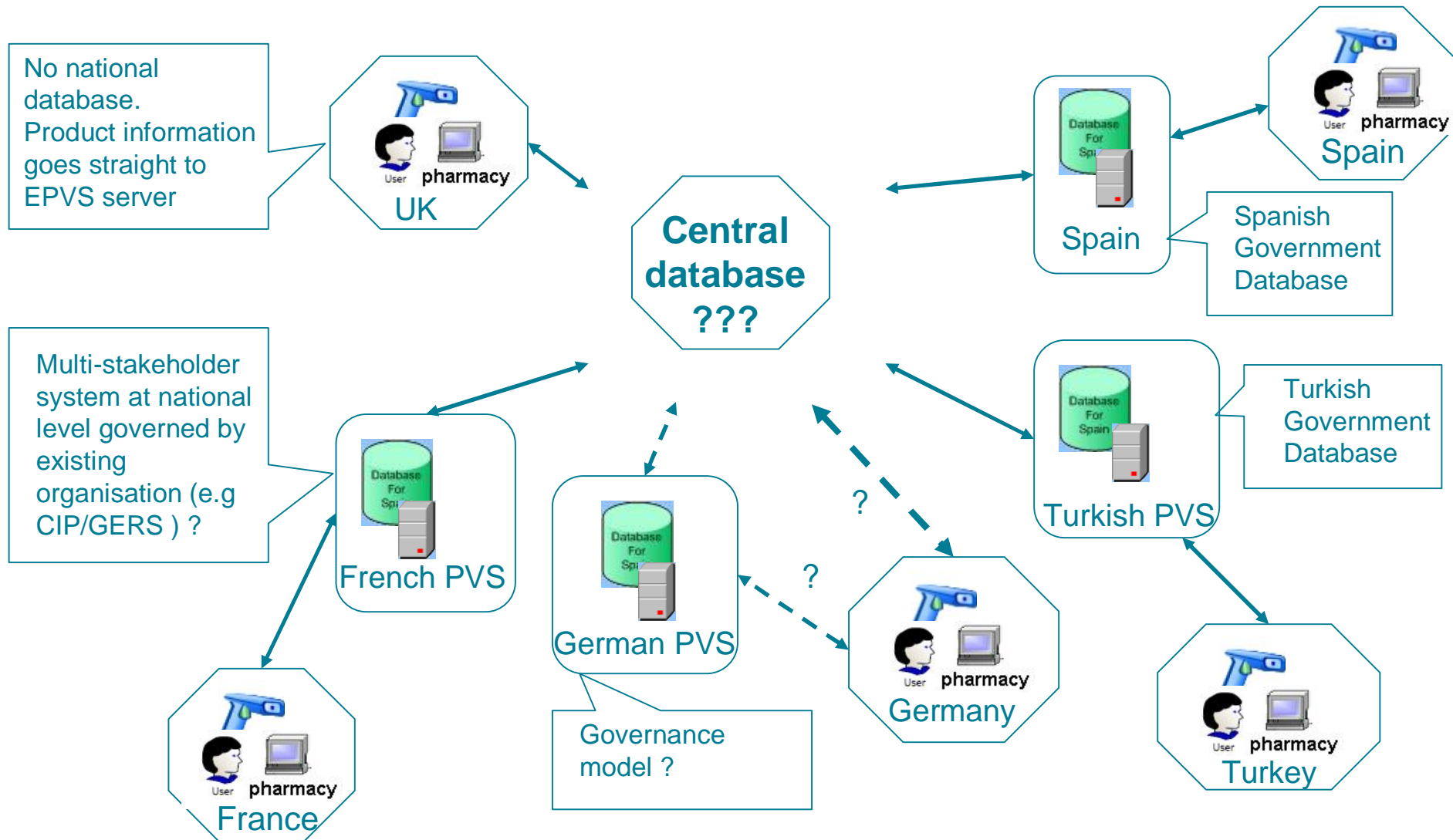


What does it mean for efpia ?

- **Mass serialization in Europe should be a reality over the next 4-5 years**
- Reinforces the need for EFPIA to propose a unique standard for adoption in Europe in order to ensure the introduction of an efficient and cost effective system (serialized Data Matrix)

1) Risk can be based on products, markets or prevalence of counterfeits. What falls into each risk category has not yet been defined Source: Draft EC pharma package

In future, not all countries could fit the same governance model (flexibility is required) but interoperability and common standards are essential



- This is an **ambitious and long term** project which will improve supply chain security and patient safety
- It requires **commitment and important resources from industry** for the long term (three to five years) to deliver all the elements
- “Wait and see” is not an option
- It provides an opportunity to build new, long term strategic relationships with key stakeholders, particularly pharmacists, to **improve patient safety and supply chain management**
- It **involves costs for all parties** and requires definition of **governance structures** between key stakeholders
- Governments and European Commission support is critical to deliver requirements for **pack integrity in the supply chain and verification at point of dispense** (ref European Directive proposal)
- **Serialized Data matrix** is currently the only identification technology that could be implemented on **all products** within 3 to 5 years

Thank you for your attention

Any Question ?

Back up slides

In Europe :

- All medicines reach the patient in its original pack (except for re-imported repackaged products)
- ⇒ EFPIA recommends a control of the serial number of each product at the dispensing point (Pharmacy or hospital)
 - Through access to a global manufacturer's database
 - Using a web service

In the US :

- Drugs are most often not dispensed by the pharmacist in their original pack
- ⇒ Control at dispensing point is more difficult to implement
- ⇒ A pedigree concept has been proposed to allow traceability of medicines all along the supply chain (History of the commercial transactions of medicines)
 - Pedigree at batch level: (relative to the corresponding prescription drug)
 - Or at individual pack level (i.e unit of sales based on mass serialisation)


- GTIN = Global Trade Item Number (= EAN.UCC14) = unit of sales
- The product code contains **14 digits = Indicator (1digit) + EAN 13**
- **This product code is unique in the world (GS1 codification standard)**

Indicator	Company code (owner of the Market Autorisation)							Product number (1 à 99999)					Check digit
I	N	N	N	N	N	N	N	0	0	0	0	1	C


Product information is coded in the Datamatrix using EAN-UCC 128 syntax

- Standard harmonized Application Identifiers (AI) are used to announce the type of information provided:
 - AI (01) : identify the product code of the commercial unit
(GTIN = 14 numeric digits)
 - AI (10): identify the batch number (10 alphanumeric digits)
 - AI (17): identify the expiry date (6 numeric digits YYMMDD)
 - AI (21): identify the serial number (20 numeric digits)

Identification across Europe : Overview National Codification Systems

 17 countries have a **full GS1 EAN 13 code structure**

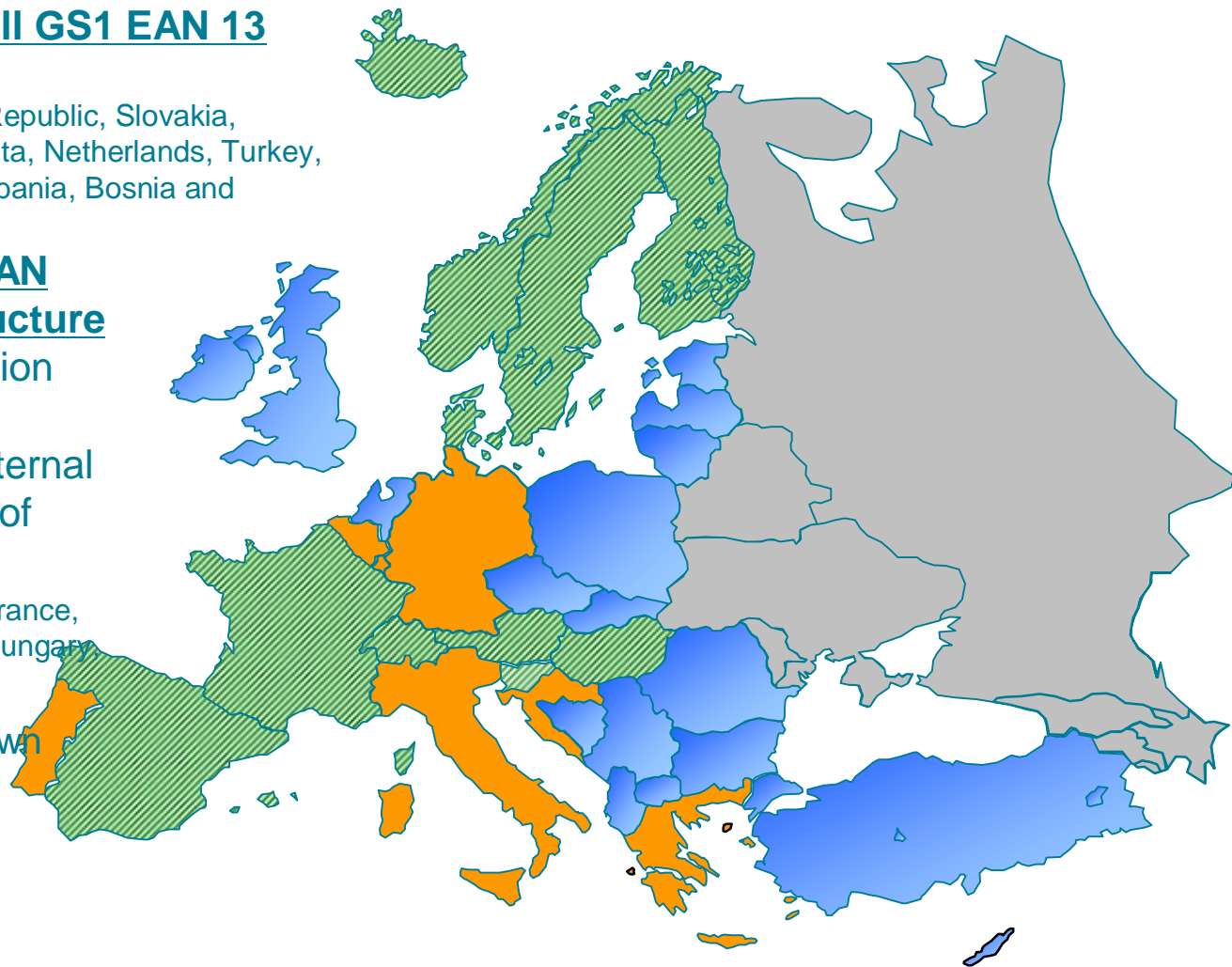
(UK, Ireland, Poland, Czech Republic, Slovakia, Latvia, Lithuania, Estonia, Malta, Netherlands, Turkey, Romania, Bulgaria, Serbia, Albania, Bosnia and Herzegovina, Macedonia)

 10 countries use an **EAN 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, Hungary, Slovenia,

 6 countries have their own **non-EAN compatible solution**

Belgium, Germany, Italy, Greece, Portugal, Croatia

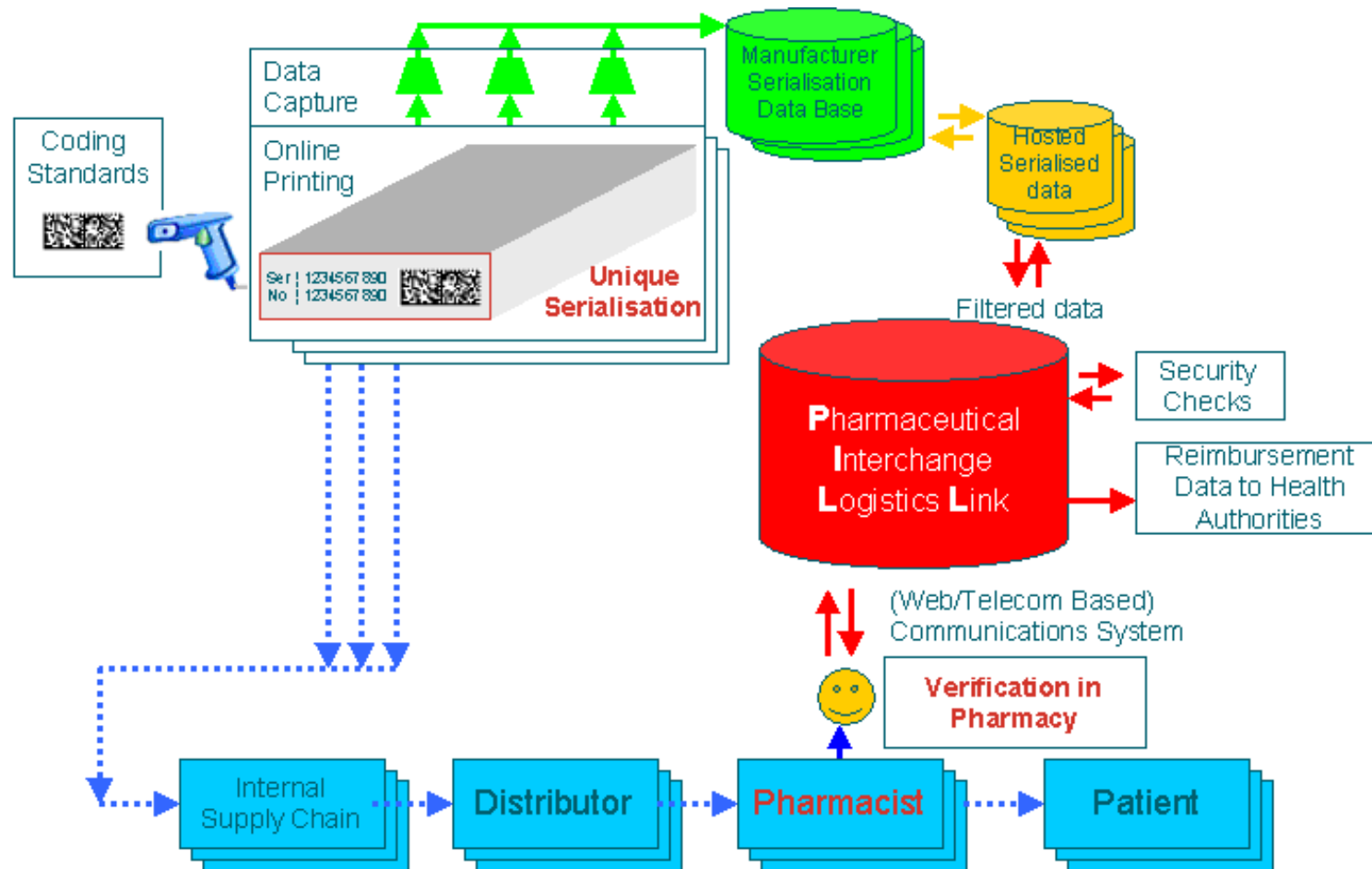


Why 2D Barcode and not RFID ? (at individual pack level)

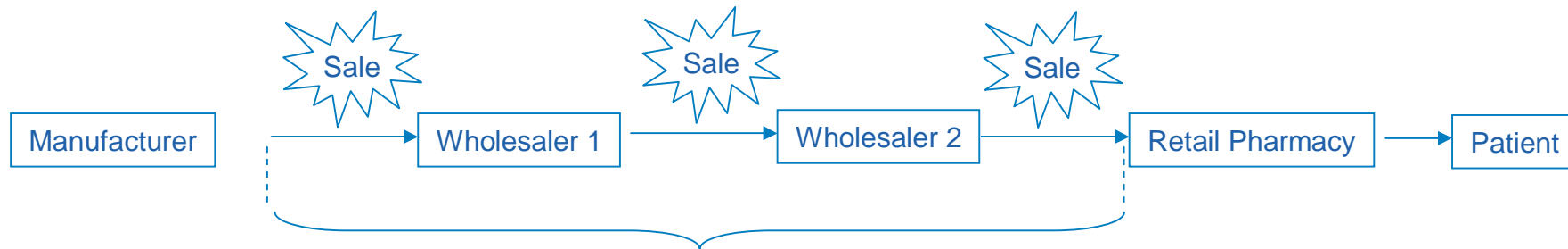
	Datamatrix	RFID
Ability to read at distance/No direct line of sight required?		
Difficulty to modify / alter / copy the code content ?		
Readability robustness? (Interferences with metals/liquids) Efficiency of reading rates ? (100% required)		
Business processes changes ? High speed/High volumes ?		
Compatibility with Biologics (vaccines, biotech products)		
Volume of data to manage? Network complexity (EPC Global) - Harmonized Standards available (EU/US/Asia) ?		
Privacy issues/objections/public concerns ?		
RFID Tag cost ~ 20 to 40 cents € Datamatrix cost ~ 0.1 to 0.3 cents €		

The EFPIA Verification System

The system proposed by EFPIA is intended to be an end-to-end product verification process at the point of dispense



- Certified chain of custody

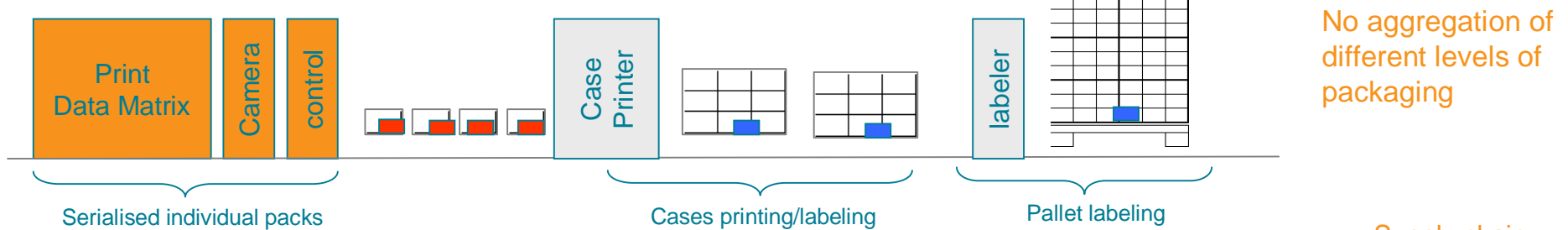


- A pedigree would record these financial transactions and physical movements either at batch level or at pack level (Unit of sales)

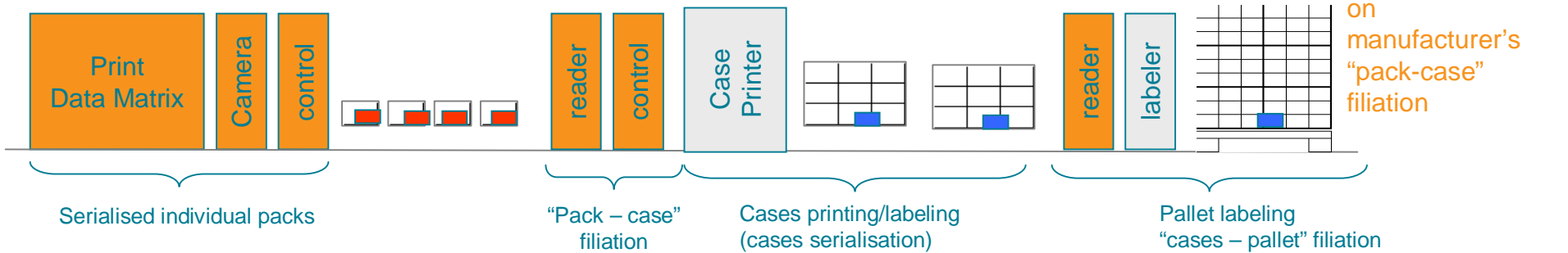
“Pedigree = a document or electronic form containing information that records each distribution of a prescription drug, from sale by manufacturer, through acquisition and sale by any wholesaler or re-packager, until final sale to a pharmacy or other person administering or dispensing the drug”

Comparative impact of different traceability concepts on packaging lines

EFPIA end to end system - Mass serialisation of individual packs with control at dispensing point



Pedigree Concept - mass serialisation based on Data matrix + aggregation/ filiation



Pedigree Concept - mass serialisation based on Data Matrix + RFID (California)

