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

Chair:

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Project coordinator:
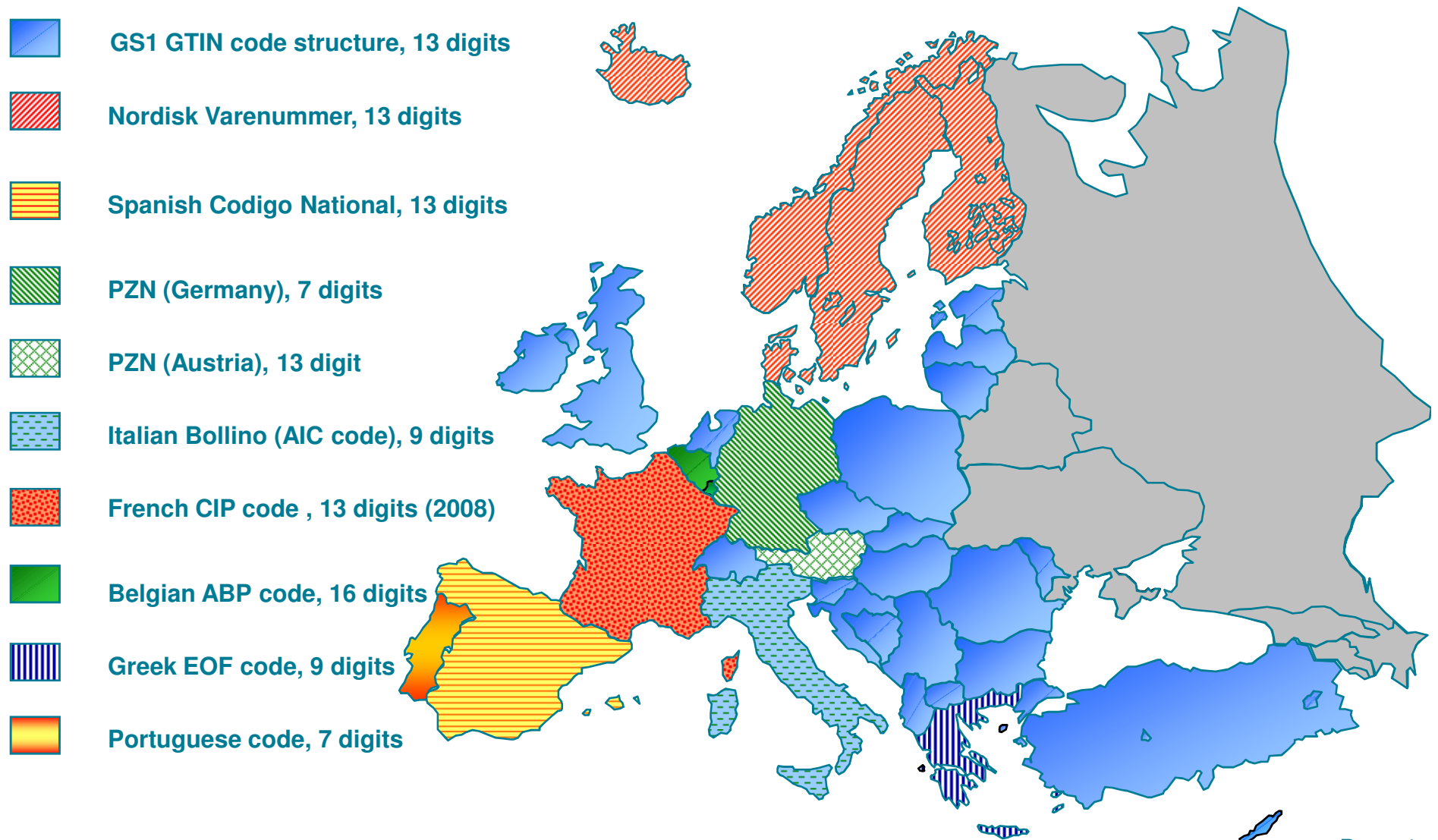
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GS1 Healthcare Conference 2009

Agenda

1. Objectives & European Context

2. The EFPIA concept: Rationale & Benefits

3. Next Steps

4. The Pilot Project

5. Conclusion

Which Traceability Improvements ?

- **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

GS1 GTIN code structure, 13 digits

Nordisk Varenummer, 13 digits

Spanish Codigo National, 13 digits

PZN (Germany), 7 digits

PZN (Austria), 13 digit

Italian Bollino (AIC code), 9 digits

French CIP code , 13 digits (2008)

Belgian ABP code, 16 digits

Greek EOF code, 9 digits

Portuguese code, 7 digits

![efpia]

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)
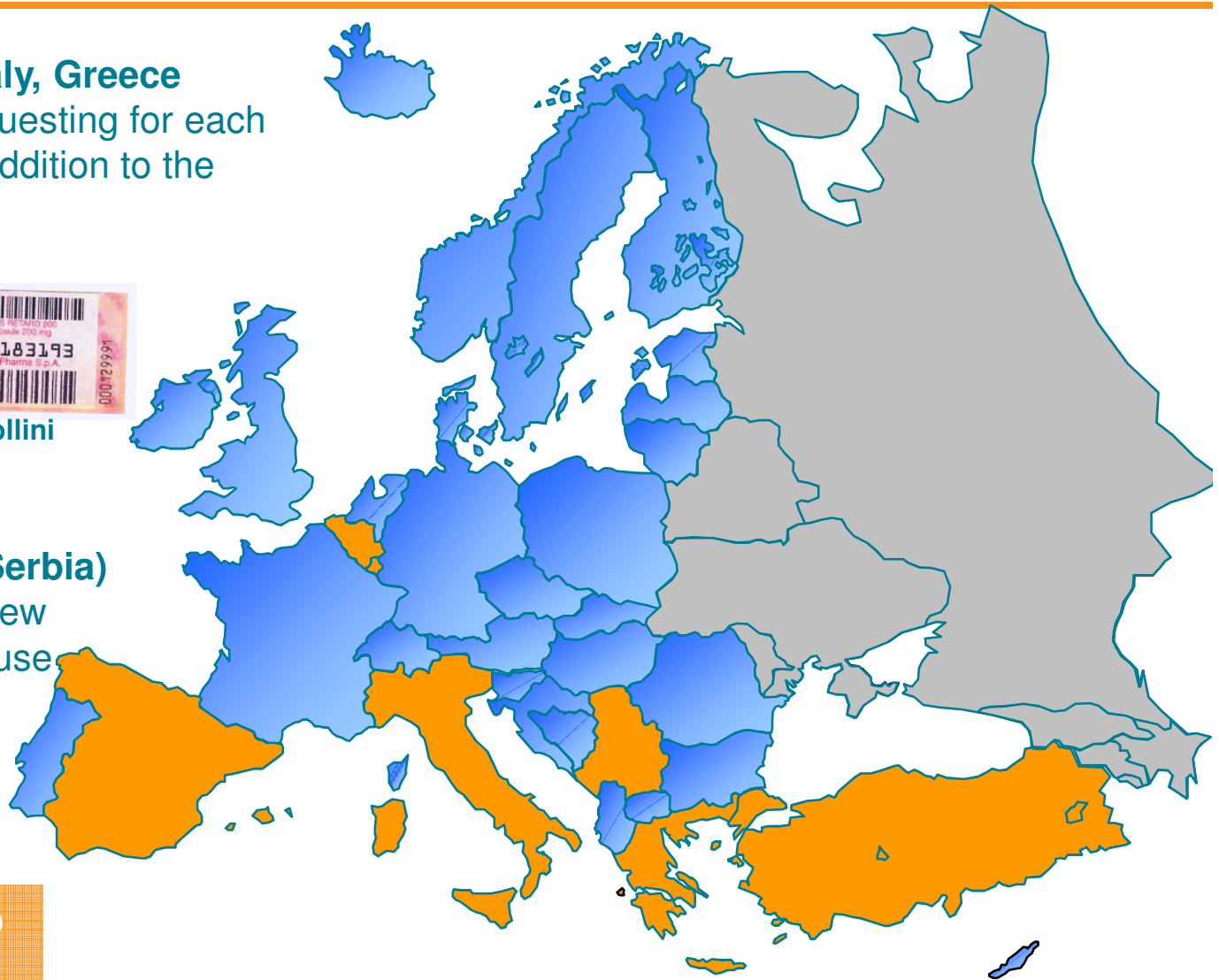

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046124

Vignette Royale Belge

CRUDIS RETARD 200
30 capsule 200 mg
A023183193
Aventis Pharma S.p.A.

00012999

Bollini

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

Who's next ?

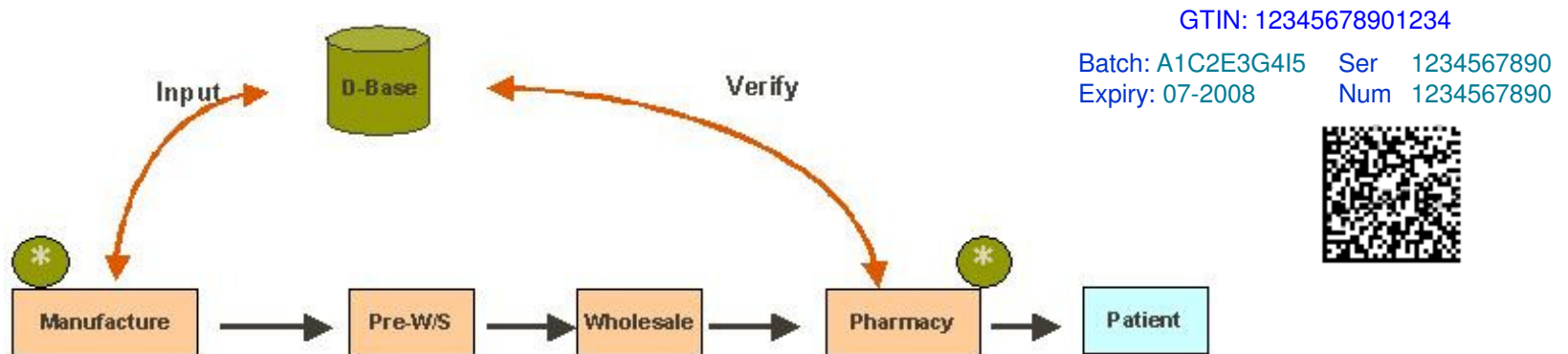# Why Harmonising the different identification systems ? (=> unique standard)

- 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 ($\Rightarrow$ 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

$\Rightarrow$ **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 :

  1. 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

  2. The **verification** of pharmaceutical products at their point of dispensing (serial numbers)

GTIN: 12345678901234

Batch: A1C2E3G4I5   Ser   1234567890
Expiry: 07-2008   Num   1234567890

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]   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

Example:

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

Evolution of french national code (pseudo-GTIN) CIP 7:   3597441

CIP 13:   3400935974419

PseudoGTIN pack: 03400935974419

Why Data Matrix ECC200 ?

- 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 succesfully 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 on1/01/11 (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)
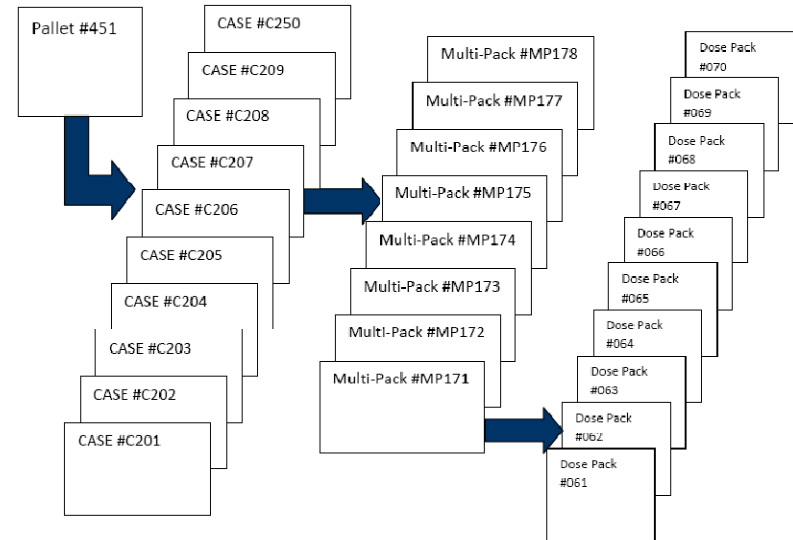
This requires either:

– **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**

The pedigree concept / **Issues with RFID**
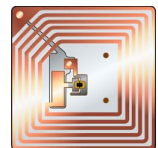
Some issues have been identitifed with the use of RFID at <u>individual pack level</u> :

- ✓ 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)

# Current Assessment of RFID for pharmaceutical applications (Units of sales)

- 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)**

Efpia project : Next Steps (1)

- **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 <u>product codes</u> across Europe (GTIN or pseudo GTIN) - ex : evolution of PZN in Germany**

    - **Ensure <u>original pack integrity throughout the entire supply chain</u> (including original manufacturer code) , which supposes tamper evidence on all original packs and ban on repackaging activities**

    - **Promote choice of <u>Data matrix</u> as harmonized standard carrier across Europe as well as <u>systematic control at the dispensing point</u>**

    - **Ensure companies commitment to implementation of Data matrix and <u>mass serialization</u> on all packs <u>upon an agreed period of time</u>**

Adoption of Data Matrix in Europe

Current status:

- **Already adopted the Data Matrix (in legislation)**
- **Considering adopting the Data Matrix**
- **No reform of bar code use**
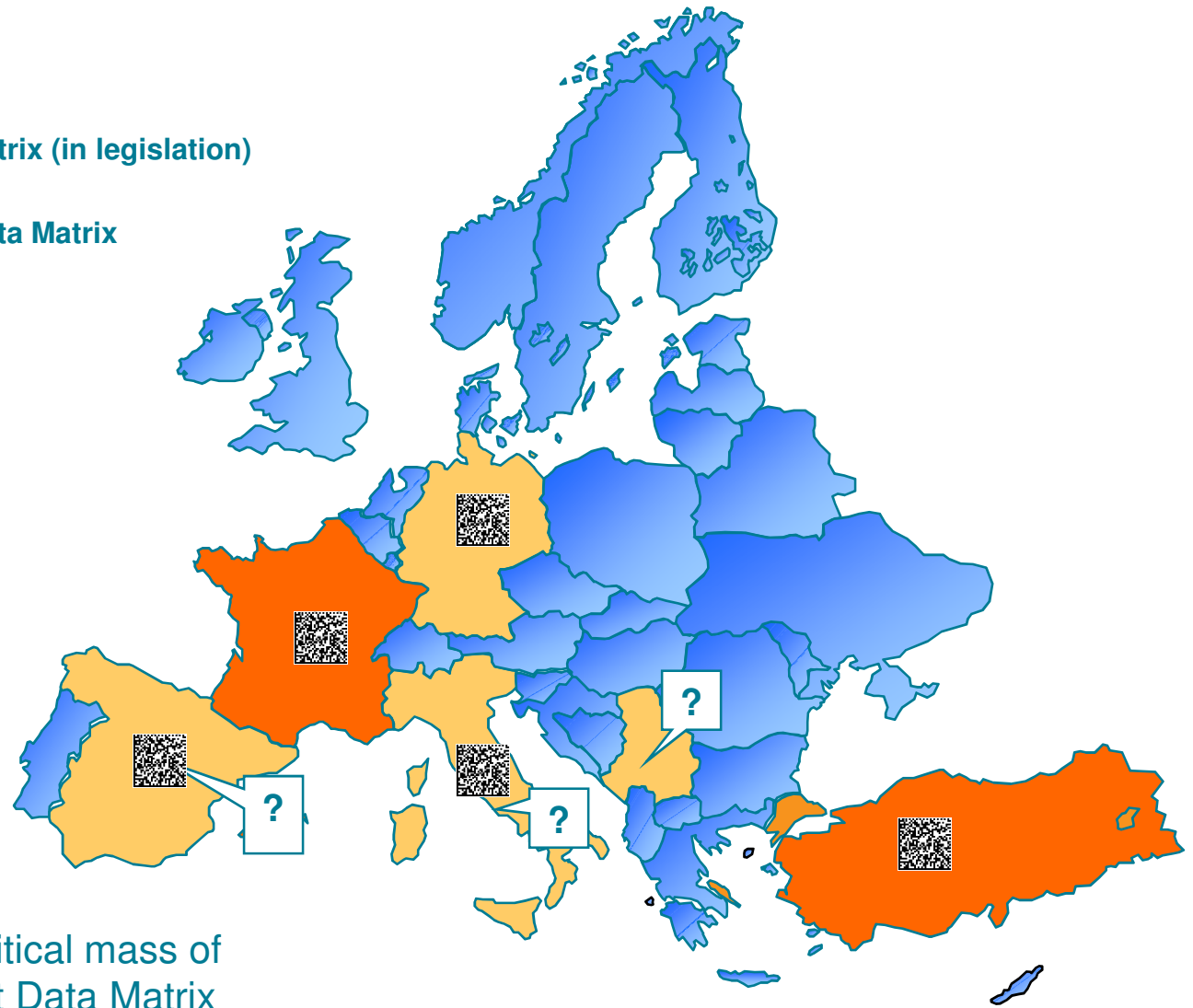
EFPIA Objective: Build a critical mass of countries prepared to adopt Data Matrix

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 and ensure that the system as currently designed can be integrated into existing user operations (manufacturers, full-line wholesalers, pharmacists).
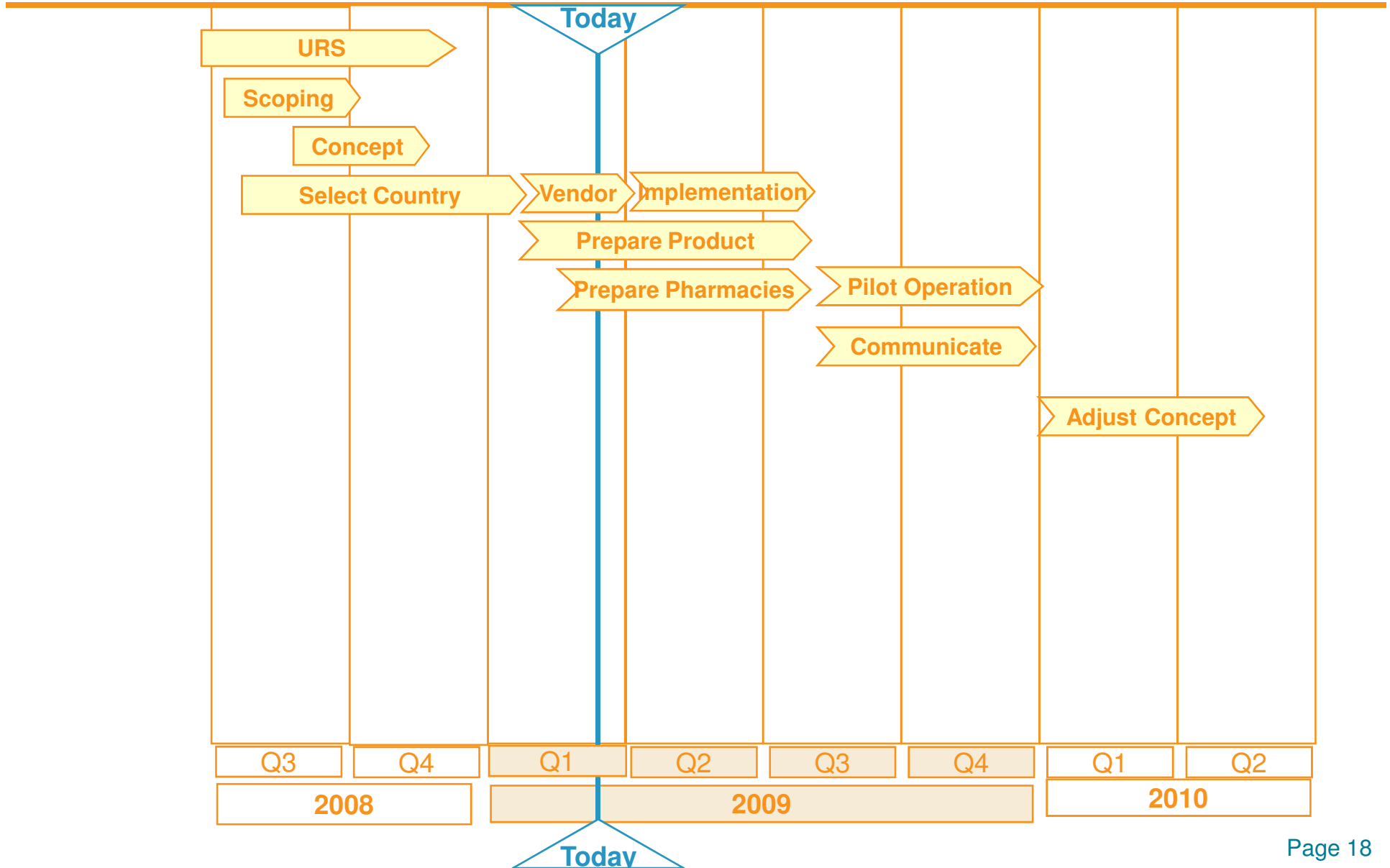
Selected Location: Sweden (tbc)

Cost: supported by EFPIA

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

Pilot Update

- ## 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, likely that EPVS pharmacy client will be developed by Apoteket's SW provider

Pilot Project schedule (as of Jan 30, 2009)

Today

- URS
- Scoping
- Concept
- Select Country
- Vendor
- Implementation
- Prepare Product
- Prepare Pharmacies
- Pilot Operation
- Communicate
- Adjust Concept

Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
2008		2009				2010	

Today

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

Increased Protection
(Patient/Product)

Use of harmonised & standardized coding and identification systems for secondary packs of pharmaceuticals

Use of Overt and Covert features to authenticate products

Guarantee the integrity of the original manufacturer's pack throughout the entire supply chain
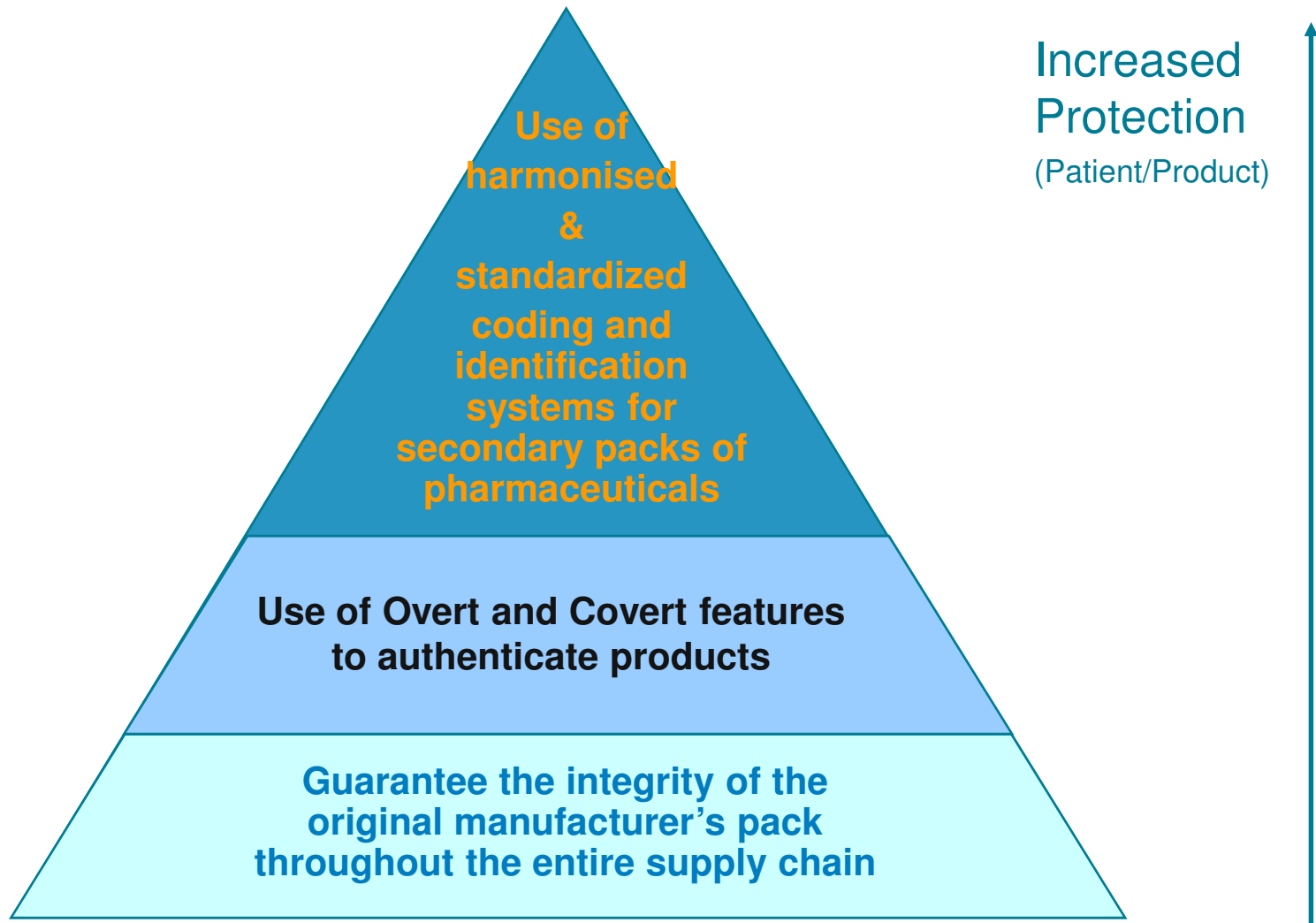
Counterfeiting - European Directive (10/12/08) EFPIA interpretation

Visual summary of Draft EC pharma package

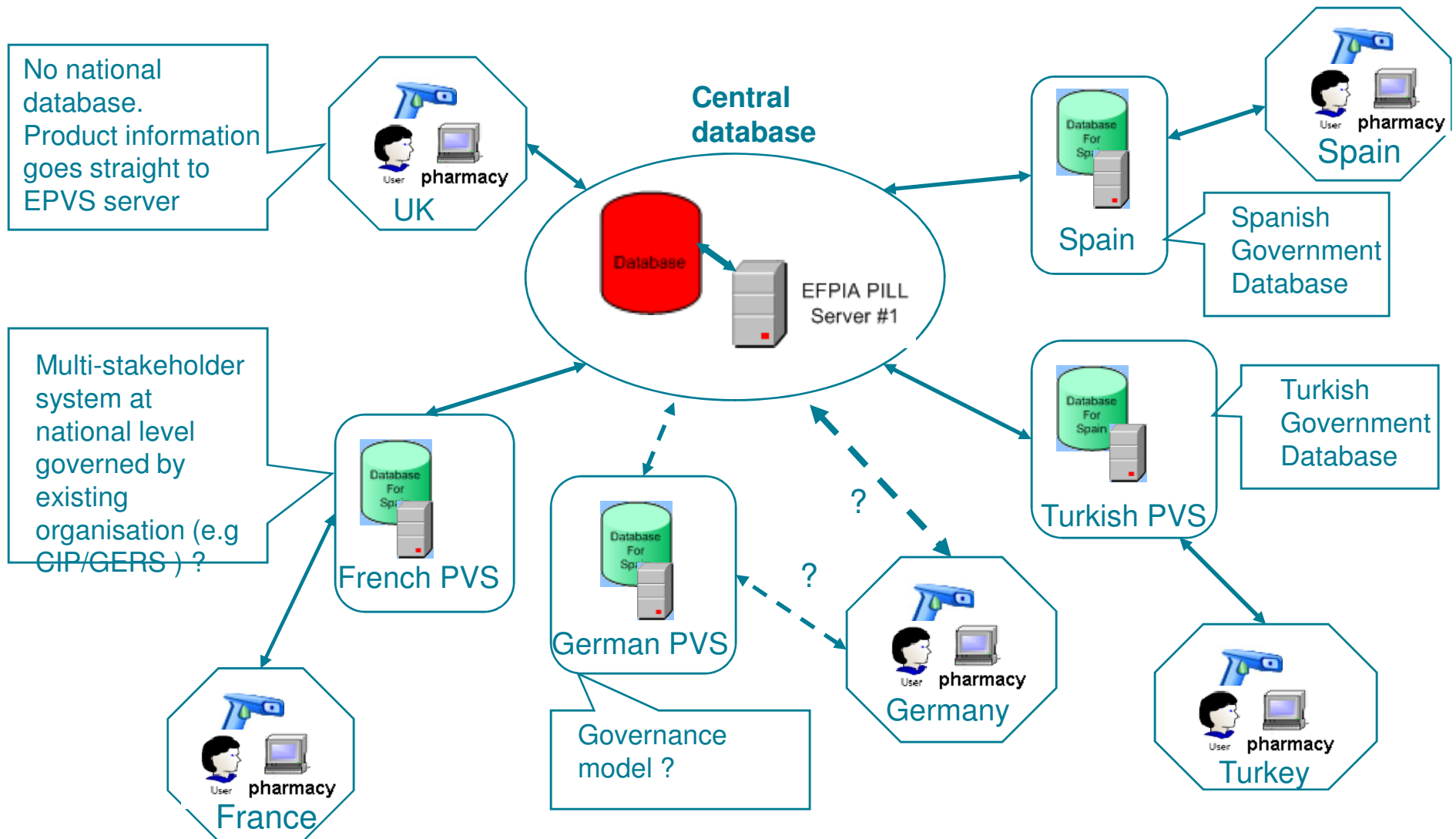| Prescription medicines may need to have:	Risk assessment	HIGH RISK[1]	Repackaging rules
a) Tamper evidence b) Covert, overt, and forensic features c) Mass serialization		a), b), c) **LOWER RISK[1]** a)	• Prohibits removal, tampering with or over-labeling of safety features on packs by actors in the supply chain • UNLESS the repackager reapplies **equivalent security features than those present on the original pack**

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

No national database. Product information goes straight to EPVS server

UK

Central database

Database

EFPIA PILL Server #1

Database For Spain

Spain

Spanish Government Database

User pharmacy

Spain

Multi-stakeholder system at national level governed by existing organisation (e.g CIP/GERS) ?

Database For Spain

French PVS

Database For Spain

German PVS

Governance model ?

?

?

User pharmacy

Germany

Database For Spain

Turkish PVS

Turkish Government Database

User pharmacy

France

User pharmacy

Turkey

Conclusion

- 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 Questions ?

Back up slides

GTIN Definition & Datamatrix Information Content

- 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)**

Indi-cator	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