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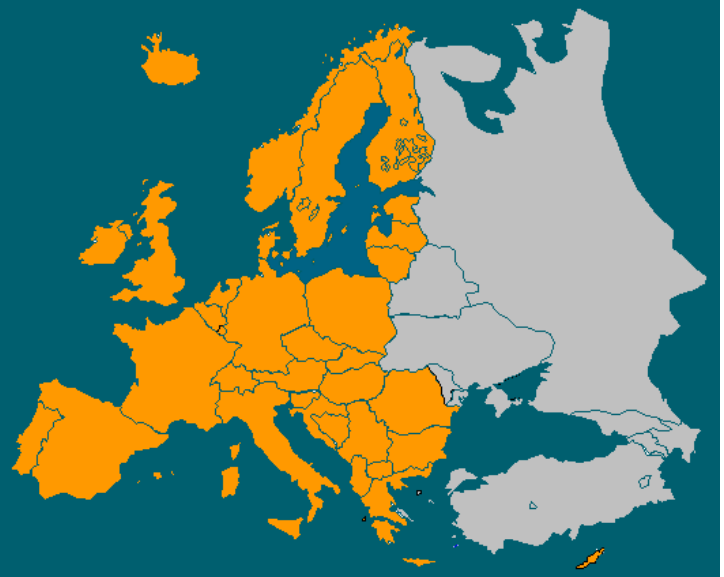
European Federation of Pharmaceutical Industries and Associations

EFPIA's Proposal for Coding and Identification of Pharmaceutical Products in Europe

From Vision to implementation



Jean-Marc Bobée – Sanofi Aventis
Chair Steering Committee

GS1 Healthcare Conference – 31 October 2007

The coding situation in Europe today

- Codification has evolved on a national basis, either voluntarily to facilitate product distribution, or compulsorily in response to some legal requirements.
- Only a handful of European countries use the internationally accepted EAN system managed by GS1; other countries have adopted their own product identification code.
- Bar Code symbology varies greatly from one country to another (the EAN 13 being the most widely used)
- National legal requirements governing codification are a growing trend throughout Europe aiming towards greater traceability requirements

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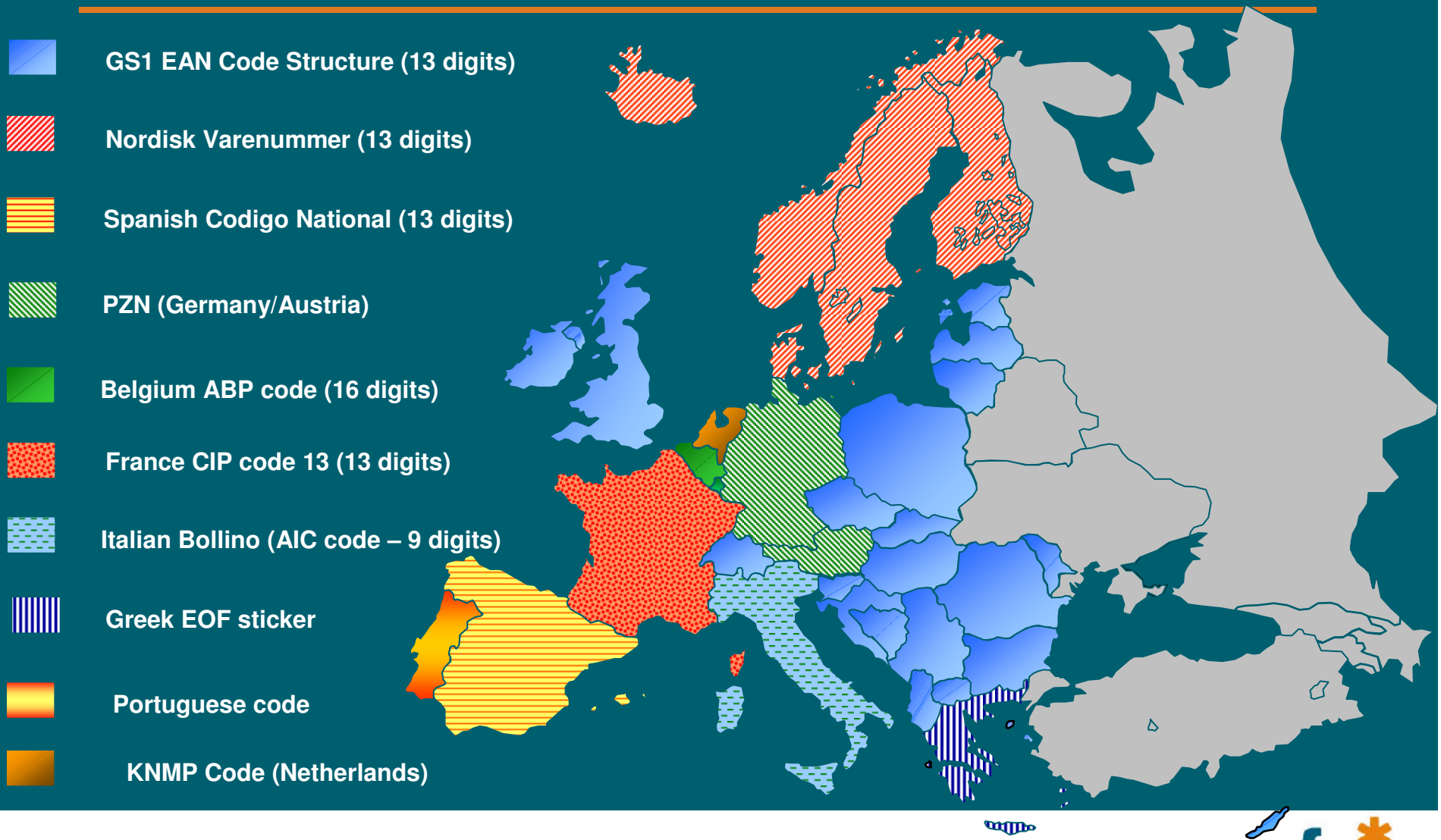
Current National Coding Systems across Europe



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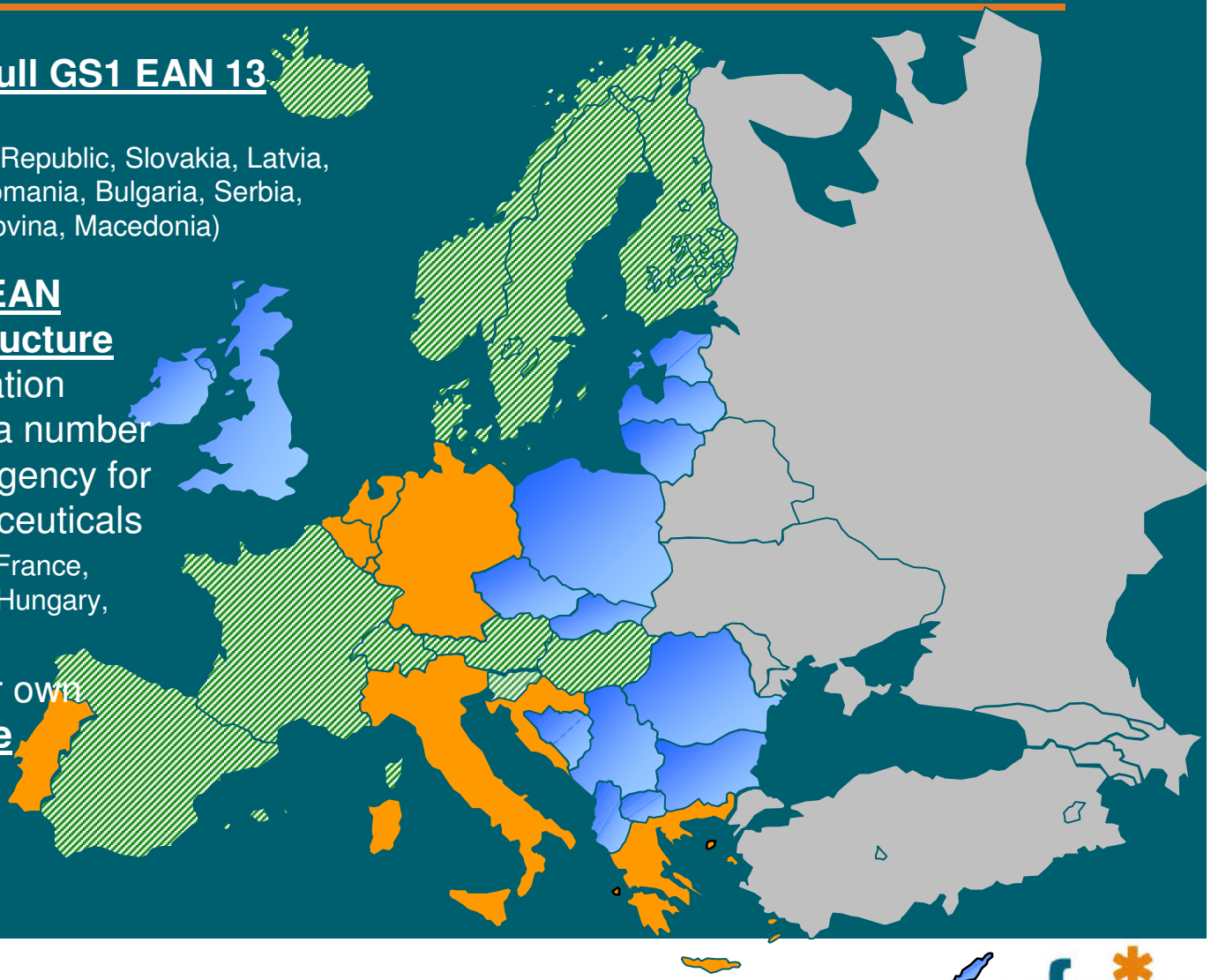
Overview of National Codification Systems

15 countries have a **full GS1 EAN 13 code structure**
(UK, Ireland, Poland, Czech Republic, Slovakia, Latvia, Lithuania, Estonia, Malta, 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, Netherlands, Germany, Italy, Greece, Portugal



Why implement a unique coding solution ?

- **Need to improve patient safety at a European level and enhance the control of the supply chain**
  - Dispensing and dosing errors risk
  - Reimbursement fraud & counterfeits cases increase
  - Lack of transparency of the supply chain/Repackaging
  - Difficulties in tracking and tracing medicines for efficient batch recall
- **Fragmented supply chain in Europe with different coding schemes implemented or proposed by different Member States (⇒ 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 boarders

⇒ EFPIA's proposal for a standardised coding & identification of pharmaceuticals in Europe

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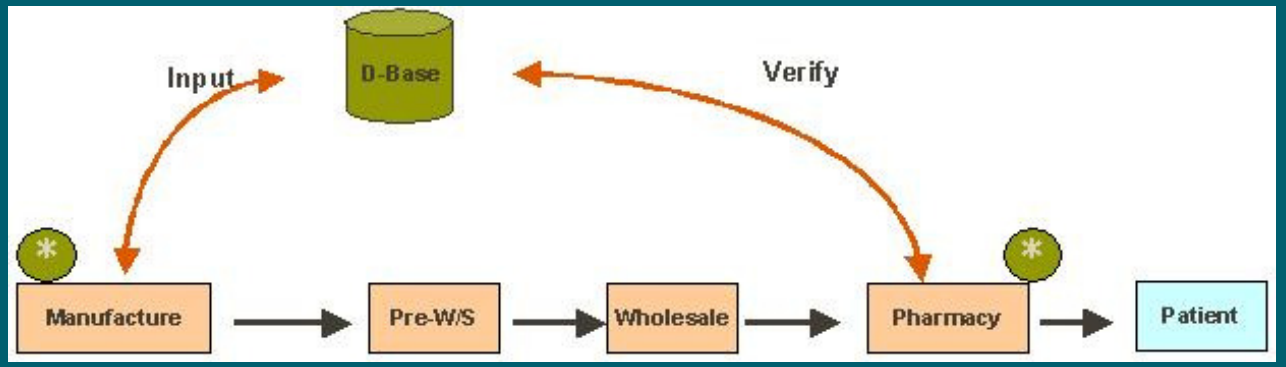
EFPIA Concept (I)

The EFPIA concept on identification and coding of pharmaceutical products consists in two parts:

1. The harmonisation of pharmaceutical products codification throughout Europe via the implementation of a serialized Data Matrix (ECC 200) on secondary packaging of all products sold in Europe
2. The verification of pharmaceutical products at their point of dispensing



Coding Standards

EFPIA proposal for harmonisation of pharmaceutical products codification throughout Europe:

- Implement a Data Matrix ECC 200 barcode on all secondary packaging of pharmaceutical products sold in Europe
- Containing the 4 following pieces of information :

1. The **manufacturer product code** (14 digits)
   ⇒ GTIN" ('Global Trade Item Number') according to GS1 Standards
2. a **unique** serial number (randomized - 20 digits)
3. the **expiry date** (6 digits - yy/mm/dd)
4. the **batch number** (10 alpha-numeric characters)

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GTIN Definition & Information Content of Datamatrix

- **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 throughout the world (GS1 codification standard)**

Indi-cator	Company code (owner of the Market Authorisation)							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)

Implementation of Data Matrix ECC 200 on line has engineering and information systems impacts

- Project specific to each pharmaceutical company – EFPIA guidelines about technical aspects of Data Matrix implementation have been provided on 20 March 2007
- 5 technologies available for data matrix printing/engraving on packaging lines: continuous inkjet, Laser (C02 scribing), drop on demand, thermal inkjet and thermal transfer
- Data matrix codes are read by imaging devices (Charge Couple Devices video Cameras) which capture a picture and search for the locator pattern of the code. Then starts the decoding process
- Need to constitute an internal company database including all the serial numbers applied on products packs

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Example of serialized data matrix product

Verification of pharmaceutical products

Verification of pharmaceutical products will take place at the point of dispensing (pharmacy) and implies:

- Availability of company data (serial numbers) to health professionals (pharmacies, hospitals…) through a web specific professional network in order to verify the identity of the products (packs) to be delivered to patients
- Common professional project to the entire Pharma Industry

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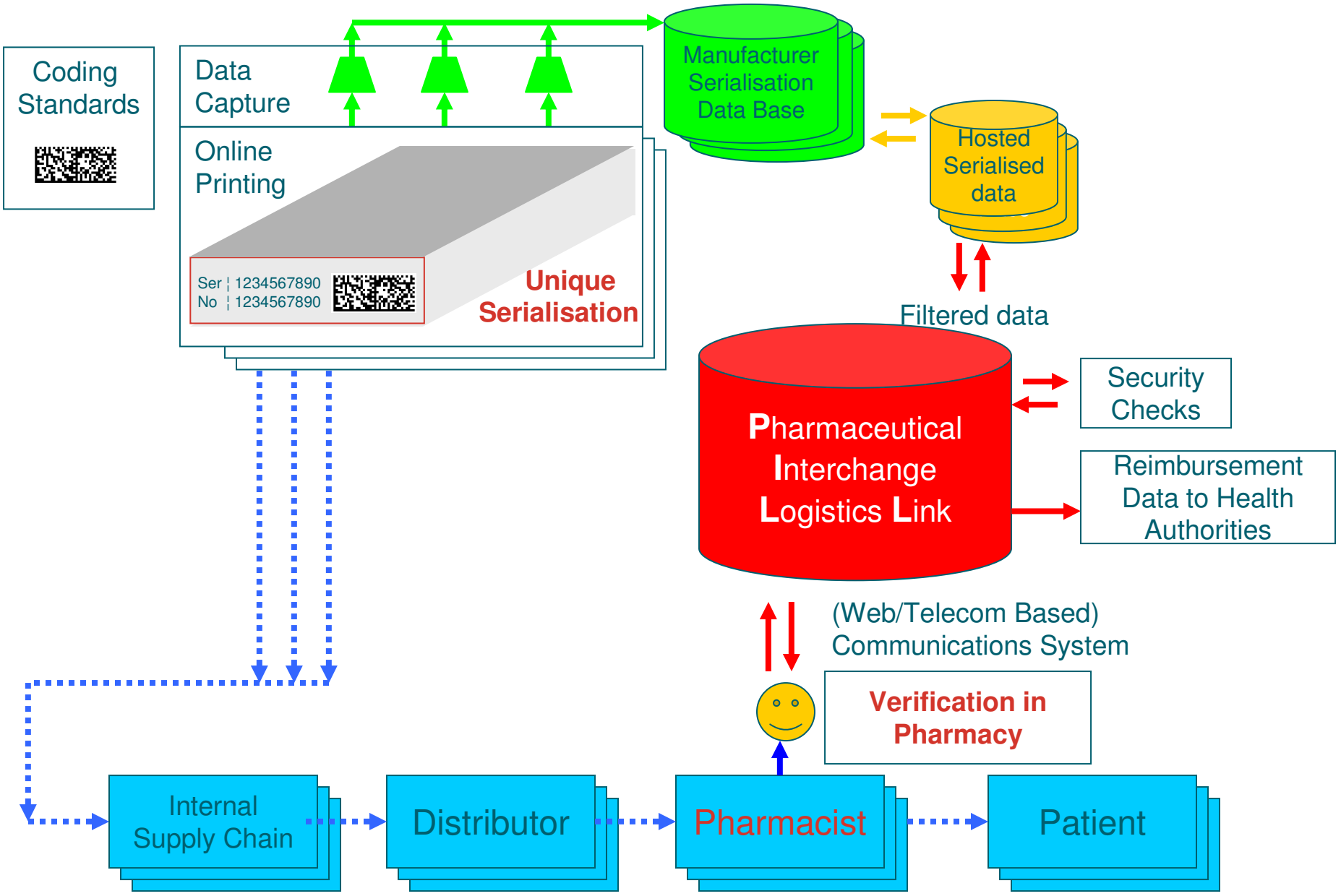
Coding Standards
Data Capture
Online Printing
Ser ¦ 1234567890
No ¦ 1234567890
Unique Serialisation
Manufacturer Serialisation Data Base
Hosted Serialised data
Filtered data
Pharmaceutical Interchange Logistics Link
Security Checks
Reimbursement Data to Health Authorities
(Web/Telecom Based) Communications System
Verification in Pharmacy
Internal Supply Chain
Distributor
Pharmacist
Patient

Challenges & Key Questions

1. Harmonization of product codes
2. Coding standards
3. System critical requirements
4. Obtaining support from key stakeholders
5. System governance model - principles
6. Pilot country

Harmonization of product codes

EFPIA proposal for Coding Standards:

- Adopt preferentially the GS1 standard "GTIN" ('Global Trade Item Number'/14 digits) throughout Europe
- In case of existing national codes (different from a GTIN) accept as an interim solution the integration of the national code in a 13-digits structure compatible with GS1–128 syntax in order to read data matrix information in an harmonized way in Europe

  ⇒ **Pseudo GTIN concept (Example : CIP 13 in France) a.k.a 'Restricted Trade Item Number'**

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EFPIA recommendation for pharmaceutical products coding in EUROPE

Coding Standards

EFPIA (2D Data matrix)

Manufacturer Product Code	14 digits [GTIN or pseudo GTIN]
Unique Serial Number	20 digits
Expiry Date	6 digits (yy/mm/dd)
Batch Number	10 alpha-numeric characters

GTIN: 12345678901234

Batch: A1C2E3G4I5
Expiry: 07-2008

Ser Num 1234567890
1234567890

GS1 Standards :

Sq. Min: 24 x 24

Rect. Min: 16 x 48

Pixels/Cell: 8

No. of Char: 65

ECC: 200

Text:~501123456789012342112345678901234567890~d029170812071 0A1C2E3G4I5~d029

EFPIA proposal for additional GS1 Standard

- Size of data matrix code matters
- Impact on speed of printing also a concern

It may be possible to fit the data into a new standard matrix of size 16 x 32

Sq. Min: 22 x 22

Rect. Min: 16 x 36

Pixels/Cell: 8

No. of Char: 54

ECC: 200

Text:~53112345678901234123456789012345678901234567890081207A1C2E3G4I5

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System Critical Requirements

- **System Security**
  - Most crucial element – need ultra secure system
- **Data Segregation**
  - Stratified central database system - segregation by manufacturer, linking back to respective company product database
- **System design**
  - the server design is likely to consist of clusters
- **Integration into pharmacy system (software)**
- **Response time**
  - under 1 second from the time of scanning
- **System reliability/robustness**
  - Likely > 99.9%_⇒ in case of system downtime, need store transaction on local system for verification at later stage

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Conditions for Stakeholders Support – Phase I

Customize EFPIA concept to national & european needs

Industry

- **Data matrix mass serialization**
- **<u>Success factors</u>:**
  - **Harmonized approach in Europe**
  - **Control at dispensing point**
  - **Shared system costs or value information in return**

Patient Safety

Pharmacists

- **Control at dispensing point**

<u>Success factors</u>:

- **Seamless integration into pharmacy practice in Europe**
- **Governance and management to be shared**
- **Management of wholesalers' needs and expectations**

Member States Health Authorities

- **Mandate codification and control at dispensing point**
- **<u>Success factors</u>: Traceability improvement + counterfeiting prevention**
- **Improve reimbursement system (avoid fraud & reduce complexity/costs)**

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System Governance Model: Principles

- Central independent non-profit organization governed by stakeholders
- System will be self-financed through neutral release of sales information based on **regional brick data** in return (not individual pharmacy information)
- Stakeholders can organize themselves country by country (i.e. CIP/GERS model in France)

Pilot Project – Country selection

Countries assessed so far:

- **Greece – rejected**
  - Complex and cumbersome political situation
  - No data matrix but serialized vignette (linear barcodes/Sequential serial numbers)
- **Spain – still under consideration**
  - Parallel project for traceability ran by government – need to secure crucial market
  - Local industry keen to get involved
  - Situation unclear with pharmacists
  - Authorities appear to be supportive
  - Timeline unclear
- **Germany – under assessment**
  - Political opportunity – Discussion of local stakeholders over revision of National product code (PZN)
  - Industry/pharmacist/wholesaler appear keen to get involved
  - Need further assessment of the environment
- **France – under assessment**
  - Data matrix already place
  - Organisations already in place (CIP/GERS)
  - General support from all parties (including authorities)

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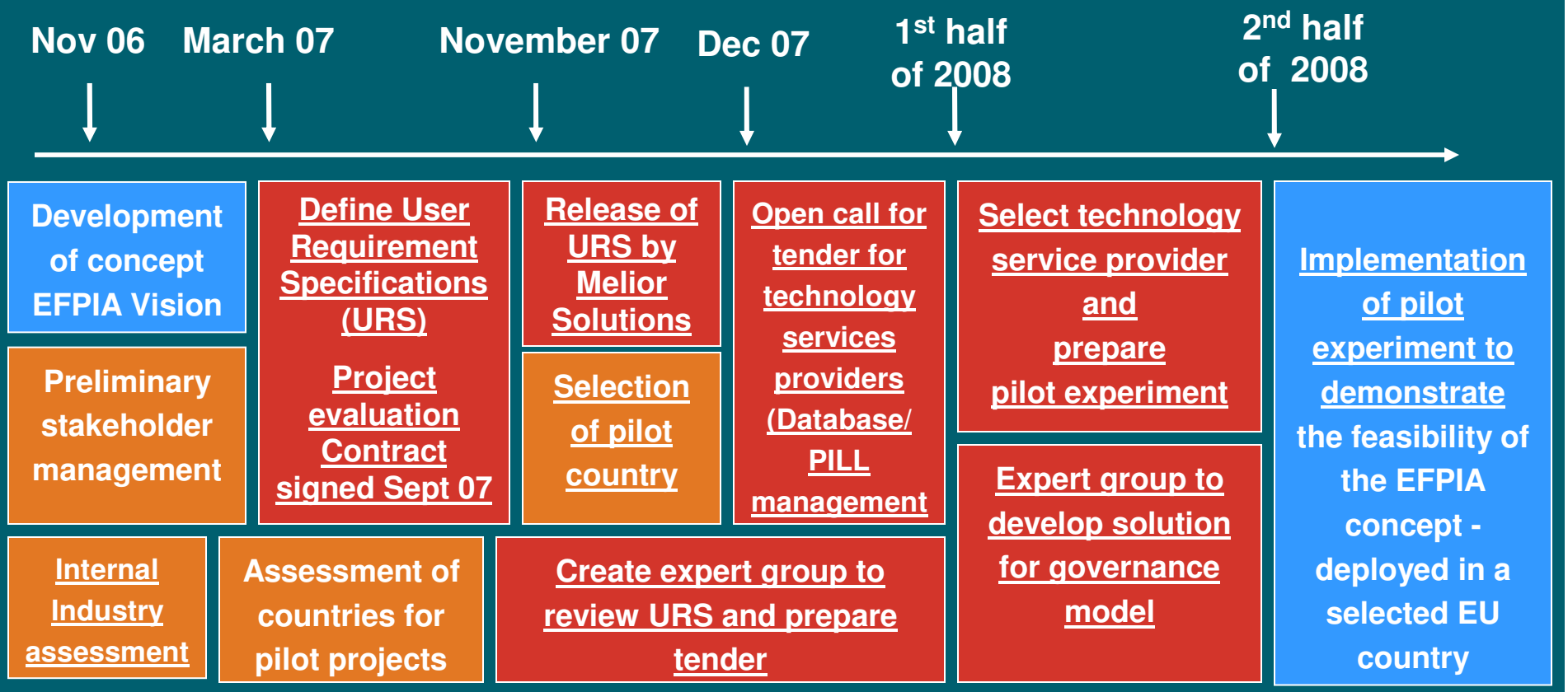
Project Timeline



Conclusion

- The EFPIA project is a long-term project. It is ambitious but represents an achievable, effective and efficient solution for delivering much needed improvements in patient safety
- The project is a concrete response to various governments' proposals for specific national coding solutions
- The project is scalable allowing the extension to a full track & trace system in the future
- The project is expensive (But so is cost of non action)
- All stakeholders need to work together constructively to deliver real patient safety benefits
- Need to start a pilot ASAP to demonstrate feasibility & benefits

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Back up slides

Benefits of a standardised coding system

- Harmonized and unique codification concept in Europe based on mass serialization
- More effective and efficient products recalls
- Improved traceability for pharmacy and hospital management systems allowing reduction of dispensing errors
- Prevention of counterfeit medicines
- Improved borders protections (customs control)
- Effective, efficient reimbursement system with lower administration cost and prevention of fraud (governments)

⇒ More efficient and secured medicines supply chain

⇒ Reduction in liability risks, meeting better duty of care

⇒ **Improved Patient safety**

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Why Data Matrix ECC 200 ?

- Data matrix is a EAN.UCC (GS1) standard since July 2004
- Data matrix uses the international syntax EAN.UCC 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 (thermal transfer, Inkjet, laser)
- Data matrix cost is very competitive (0.1 to 0.3 cents of €)

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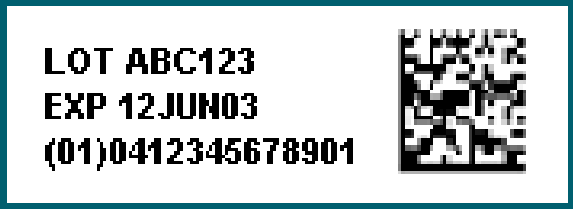
The 2D Data matrix barcode: Key benefits

- Data matrix is the smallest code for a given quantity of information.
- It is robust (40% information redundancy) and highly cost competitive
- Data matrix will be mandatory in France on the 1st of January 2011 for each pharmaceutical packaging (product code+ batch n° + expiry date)
- Data matrix (ECC200) is the harmonized solution recommended by EFPIA for products identification in Europe (on secondary packaging)
  - Recommendation includes serialization, i.e. attribution of a unique number per box
  - In future, control of serial numbers at the dispensing point (Pharmacies & Hospitals) could protect patients from counterfeit



Data matrix (ECC 200)

Data matrix code (ECC 200)

(01) **34009300000122** (10) **n°de lot** (17) **AAMMJJ**

- The Data matrix symbol is a matrix made of black and white dots representing respectively 1 or 0
- Matrix can be square or rectangular
- Data are encoded in bytes and several additional bytes are added (redundancy) for errors detection and errors correction (in case of damage for example)

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Data matrix vs. RFID (unit of sales)

	Data Matrix	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 tagging ? High volumes ?		
Volume of data to manage? Network complexity (EPC Global)		
Harmonization of Standards (EU /US/Asia) ?		
Privacy issues/objections/public concerns ?		
RFID Tag cost= 0.20 € to 0.40 € Serialized Data Matrix cost = 0.002€ to 0.003 € (~100 times cheaper)		

RFID Assessment

- Experience within the pharmaceutical industry (pilot projects) and other sectors have shown that the technology is not mature enough and is not able to meet all expectations of the industry for the time being.
- Indeed, a number of problems remain to be worked out, namely reliability of the technology, readability issue (interference with liquids and metals), high costs, but also lack of common standards as well as public concerns due to privacy issues.
- The adoption of a 2D system does not prevent the adoption of an RFID system at a latter stage nor does it represent a double cost. In fact, RFID offers significant benefits in terms of logistics management and would certainly be a natural progression of the system once the technology has matured.

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