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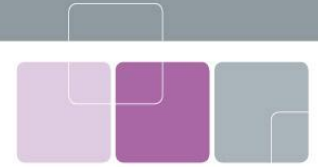


## Coding and identification of pharmaceuticals

EFPIA pilot projet and approach pharma.be

18 October 2010

# Agenda



- I. EFPIA's Product Verification System and pilot projet in Sweden
- II. Approach proposed by pharma.be

- European proposal for a directive
- To improve patient safety and enhance control of the supply chain
- Fragmented supply chain in Europe with different coding schemes implemented or proposed by different Member States
  - Manufacturing complexity, production costs and high supply chain differentiation
  - Individual systems inefficient to protect European borders

⇒ **EFPIA's proposal for a standardised coding & identification of pharmaceuticals consistent with existing international standards**

## 1. Coding of product packs using

- Data Matrix (DM) code (GS 1 standard)
- Randomized serial number
- + product code, batch number, expiry date

## 2. Verification at point of dispensing

- Objectives
  - In line with EC's proposal
  - Practical and effective solution for stakeholders
  - Common standards and mature technology
  - Credible alternative to national systems
- Key figures
  - 25 pharmacies (Apoteket AB) - 180 dispensing points
  - 25 products - 110,000 packs
  - 14 manufacturers
  - 4 months (start 09 / 2009)
- Wholesalers label and distribute packs

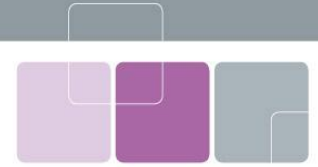
# efpia\* Key conclusions of the Pilot

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- Works in practice
- Without significant additional effort
- Easy to use when fully integrated
- Should be customised to existing pharmacy workflow, regulatory requirement, etc.
- More than one code on pack causes confusion
- Security technically ensured
- Interest : expiry date and batch n°

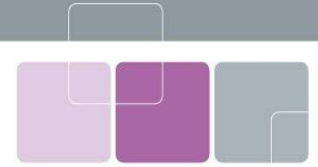
- Long-term project to improve supply chain security and patient safety
- Approach
  - Cooperation with key stakeholders
  - Open standards
  - Feasible, interoperable, efficient, and cost effective
  - Flexible for future extension
- Involves costs for all parties
- Requires definition of governance structures between key stakeholders
- Government and European Commission support is critical to
  - Establish legal frameworks for harmonised coding system at national/EU level
  - Deliver requirements for pack integrity and verification at point of dispensing

# Approach proposed by pharma.be - What do we want?



- To reduce the risk of counterfeit medicines delivery
- To improve traceability
- To detect expired medicines automatically
- To provide more efficient (on-line) control of effective dispensing by pharmacists
- To avoid processing errors (e-prescription)

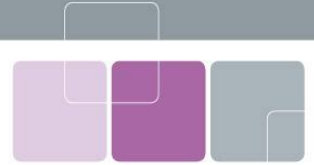
# Approach proposed by pharma.be – How ?



- Solution interoperable at European level
- Takes into account Belgian framework (unique barcode CBU)
- Effective
  - Placing security devices on packaging >< Repackaging/splitsing
- Reasonable cost

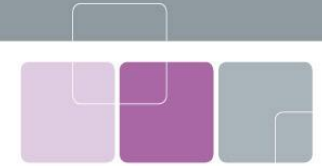
# Approach proposed by pharma.be

## What possible developments for CBU?



- One code / secondary packaging
- Data Matrix (ECC 200)
  - Reimbursables & « risk » medicines  
Product identification n° + **serial n°** + batch n° + expiry date
  - Others : idem without serialisation
- « On-line & end-to-end » control
- Governance mode ? → to be discussed with NA & stakeholders
- Later : hospital packagings?

# In conclusion : request to GS1



- We supports harmonization product codes across EU (GTIN/ NTIN)
- Different coding standards used by NA)(reimbursement)
- In some countries : compromise needed between international standards and national requirements to ensure interoperability
- Intermediate approach: The National Trade Item Number (NTIN) allows NA to place national product codes (NPC) in GTIN field → common code structure and continued use of existing identification schemes.
- Need to develop clear picture NPC and progress alignment programme

Industry needs a closer and more aligned working relationship with GS1

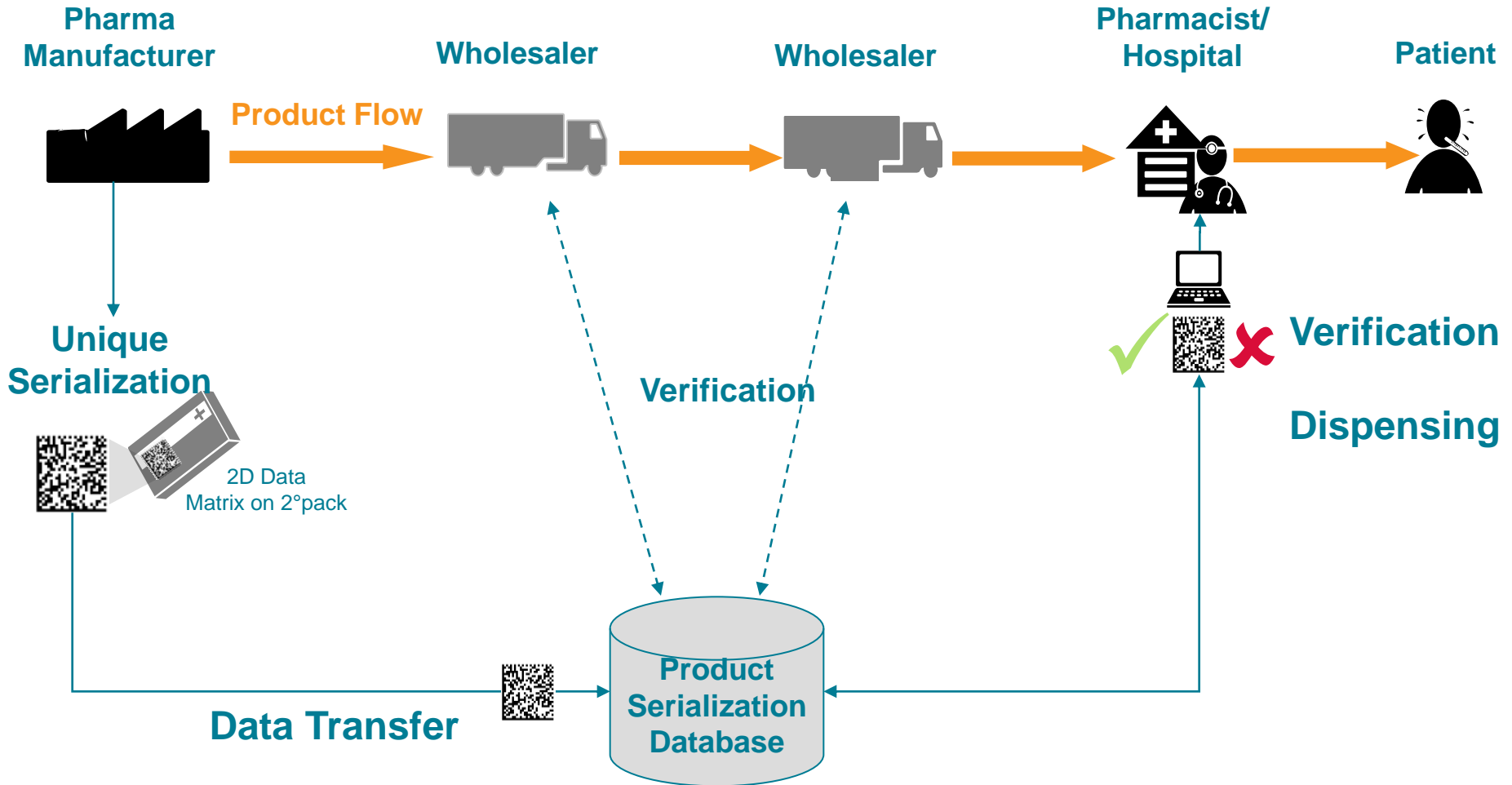


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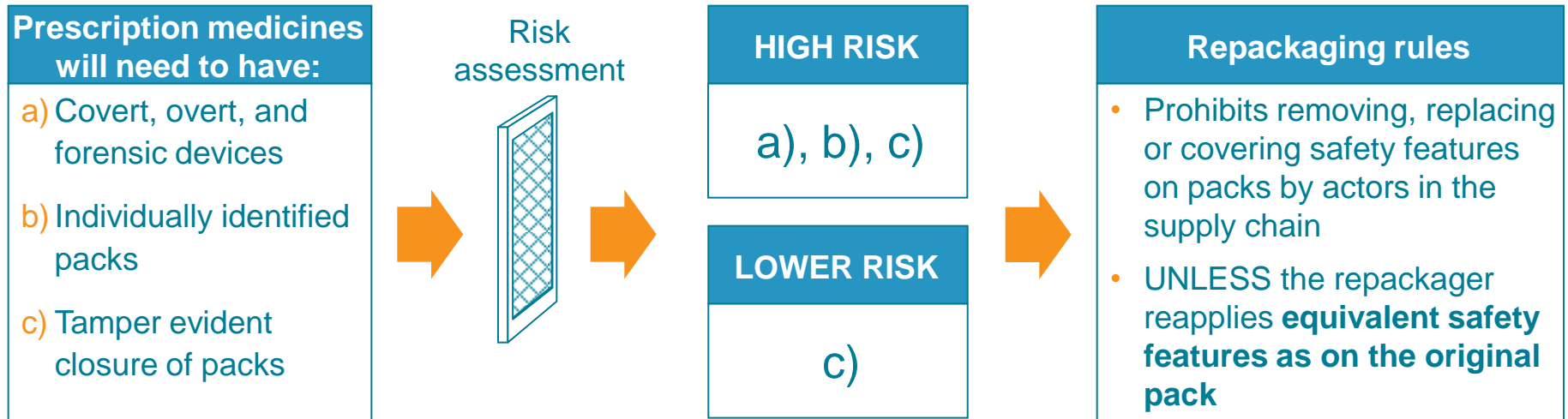
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## Product and Data Flow End-to-End With the EFPIA concept



## Visual summary of Draft EC pharma package



What are the consequences ?

- **Mass serialization in Europe should be a reality over the next 3-5 years**
- **Need for a unique standard for adoption in Europe in order to ensure the introduction of an efficient and cost-effective system (serialized Data Matrix)**