Verification of Pharmaceutical Products at the Point of Dispense

An EFPIA update

Speaker : Grant Courtney

Event: GS1 Global Conference

Location: Washington
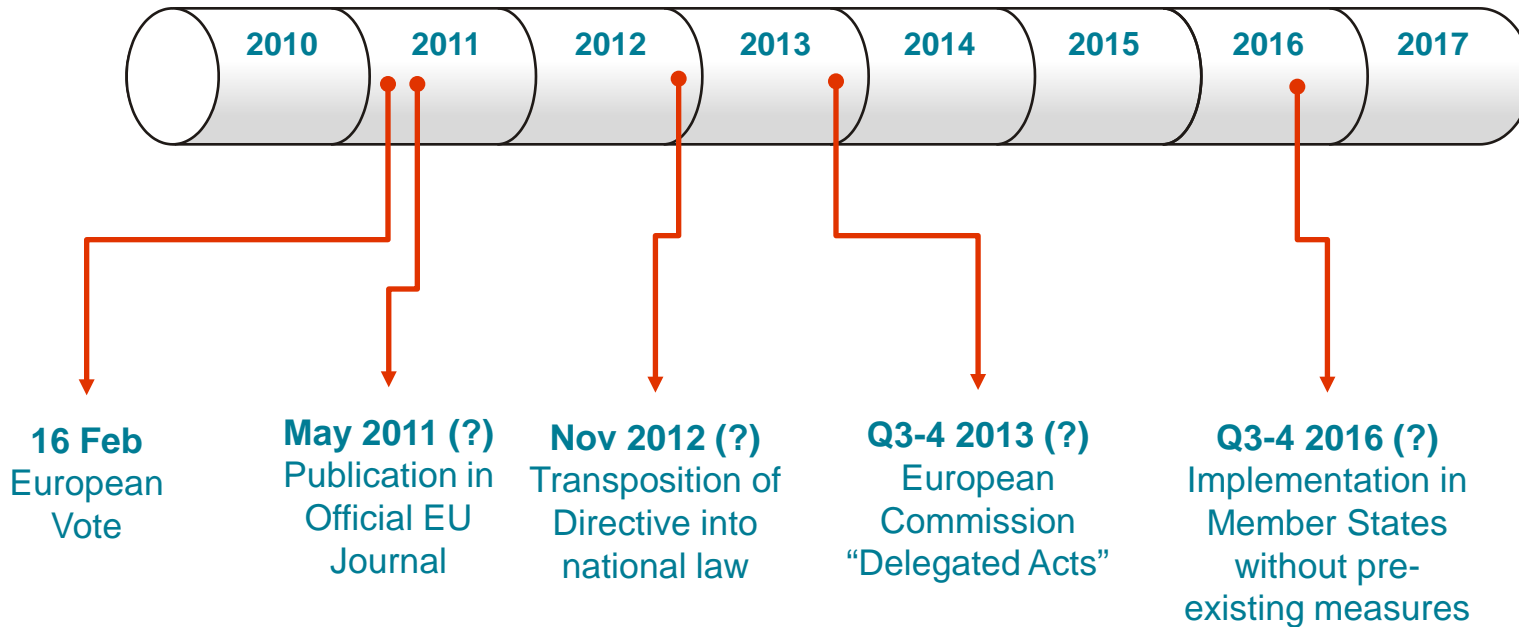
Who is EFPIA ?

- The **European Federation of Pharmaceutical Industries and Associations (EFPIA)**
  - represents the R&D based pharmaceutical industry operating in Europe
  - direct membership of 31 national associations and 44 leading pharmaceutical companies
  - EFPIA is the voice of 2,200 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world

efpia 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

| 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 |

16 Feb
European Vote

May 2011 (?)
Publication in Official EU Journal

Nov 2012 (?)
Transposition of Directive into national law

Q3-4 2013 (?)
European Commission "Delegated Acts"

Q3-4 2016 (?)
Implementation in Member States without pre-existing measures

Some countries could deploy earlier than 2016

- **Objectives & European Context**
- The model EFPIA supports
- The EFPIA Pilot Project: Results and conclusions
- Some issues to look at next

efpia Objectives

- Improving patient safety
  - **Reduce the risk of counterfeit** products being dispensed
  - **Detect expired products** automatically
  - Perform **product recalls** more effectively and efficiently
  - **Deliver the right product** to the patient

Agenda

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Three measures to protect packs

Increased Protection
(Patient/Product)

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

Use of overt and covert features to authenticate products

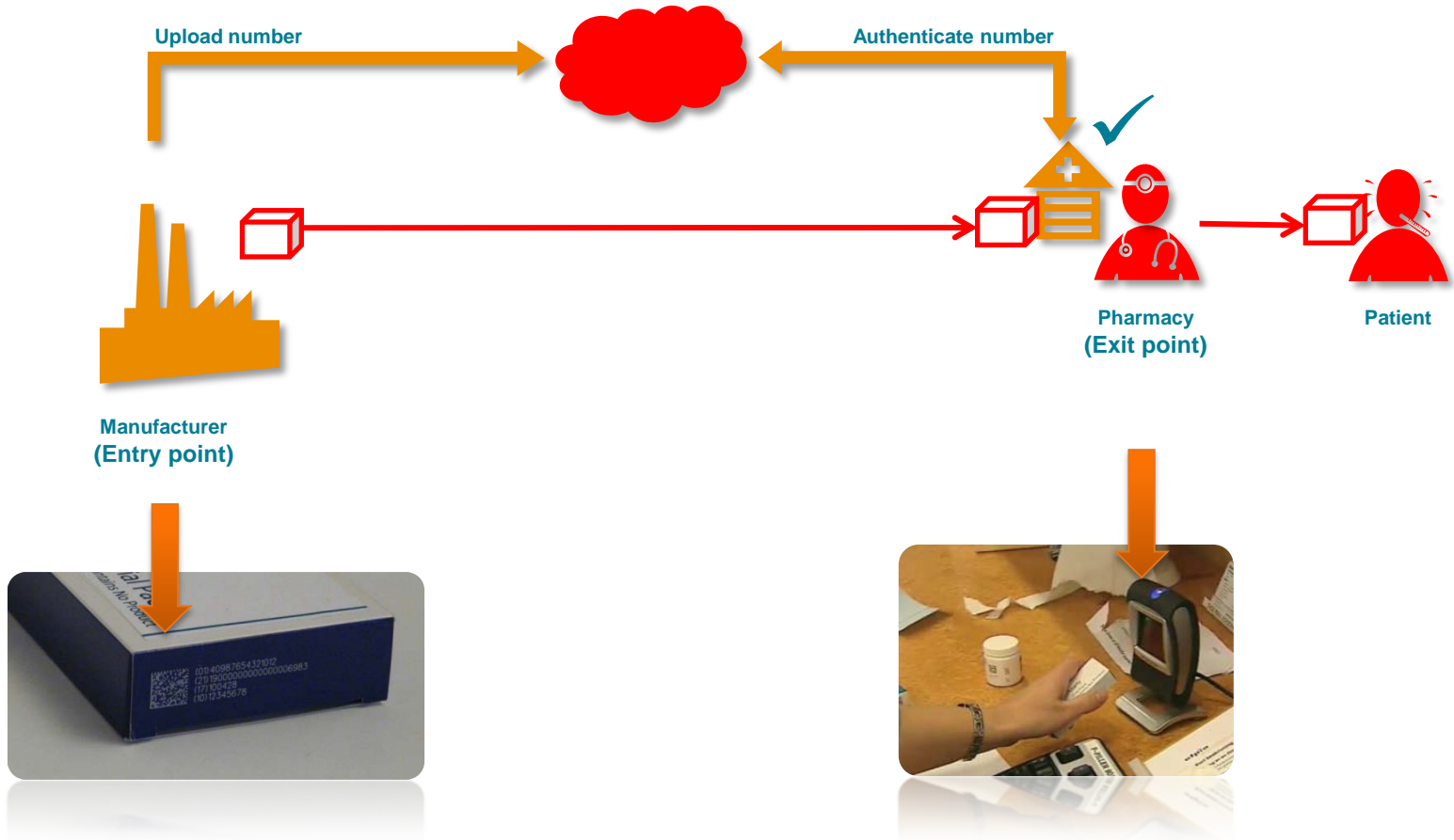**Guarantee the integrity of the original manufacturer's pack throughout the entire supply chain**

Dispensing verification confirmation

efpia

Upload number

Authenticate number

Pharmacy
(Exit point)

Patient

Manufacturer
(Entry point)

Example:

GTIN:	(01) 07046261398572
Batch:	(10) TEST5632
Expiry:	(17) 130331
S/N:	(21) 19067811811
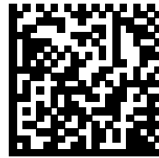
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EFPIA pilot project

- EFPIA conducted a pilot project in cooperation with pharmacists

- Objective was to demonstrate the EFPIA proposal as:
  - an **aligned approach** with the EC's pharmaceutical package

  - a **practical and effective solution** for relevant stakeholders (manufacturers, pharmacists, wholesalers)
    - That can be fully integrated into their existing operations

  - a model that works based on **common standards** & mature technology
    - High performance and a secure system

  - A **credible alternative to proprietary national systems**, aligned with government requirements

Pilot project overview

- **Key figures**
  - 25 pharmacies in the greater Stockholm area (owned by Apoteket AB) with a total of 180 dispensing points
  - 25 products (SKUs) with total of 110.000 packs
  - 14 manufacturers
  - 4 months duration of operational phase

- **Operational phase**
  - Started with 3 pharmacies on 17 September
  - Remaining 22 pharmacies joined on 24 Sept

- **Wholesalers labelled and distribute packs**[*]
  - Kronans Droghandel
  - Tamro

  (*) Serial number management system provided by Melior Solutions

Final results – quantitative

- Number of packs sold:
  - Ca. 95.000 packs which is ca. 84 % of packs coded

- Excellent system response times
  - ~ 94,5 % of transactions completed in < 0.5 sec
  - ~ 99,7 % of transactions completed in < 1.0 sec
  - ~ 99,9 % of transactions completed in < 2.0 sec

- System >99,9 % online

- Exception alerts
  - 180 verification / dispense transactions for packs with incorrect serial number
  - 373 packs verified after having been marked as dispensed (cf backup slides for explanation)
  - 283 packs sold although already marked as dispensed

Why were there exception alerts

Simplified example

1. Pack 1 is scanned and verified

2. Pack 2, of the same product, is scanned and verified

3. Patient decides not to collect both packs

4. Pack 1 is checked back into the system

5. Pack 2 is returned to the shelf

. . . Some time later

1. Pack 2 is scanned and fails to verify – already shown as dispensed

Understanding all the processes undertaken within the pharmacy is critical to ensure the system operates correctly

Response from pharmacists

Feedback

- Confirmed very positive feedback for overall system
- Expect high value from automatic detection of expired or recalled products
- Clearly prefer to have **only one code on the pack**
- Would like to see the **same code type on all packs**
- Would like to see more information provided by the system:
    - Description of tablet colour and shape (is it easy to split it to obtain half dose ?)
    - Photograph of a pack / blister / tablet
- The system may become discredited if it does not provide the right answer under all circumstances

- Scanners:
    - More sensitive than existing ones
    - Minor issue with new scanner for poor quality linear bar codes (low contrast)

Key conclusions of the Pilot

- The model EFPIA supports **works in practice** and allows for effective identification of fake packs

- System availability and performance **allow pharmacists to work at normal pace** and without significant additional effort

- System is **easy to use** when fully integrated into pharmacy workflow and existing IT system

- System **must provide correct** answer to all transaction requests to achieve sustained credibility

- System **should be customised to existing pharmacy workflow**, processes, local conditions and regulatory requirement. It is therefore recommended to run a pilot phase for each deployment (region) so that defects can be eliminated before roll-out

- The presence of **more than one code on the pack causes confusion for the user and will jeopardise user acceptance**

- Necessary **data segregation and security** can be technically ensured

- Pharmacists are highly **interested to get expiry date and batch number in machine readable form** through the 2D data matrix

efpia Agenda

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- The EFPIA Pilot Project: Results and conclusions
- **Some issues to look at next**

Some of the issue which will need to be addressed

Issue

- Cross boarder movement and multi-market packs

- Difficulty of multiple codes and ensuring uniqueness

- Many stakeholders are involved in getting the product to the patient

Cross boarder and Multi market packs
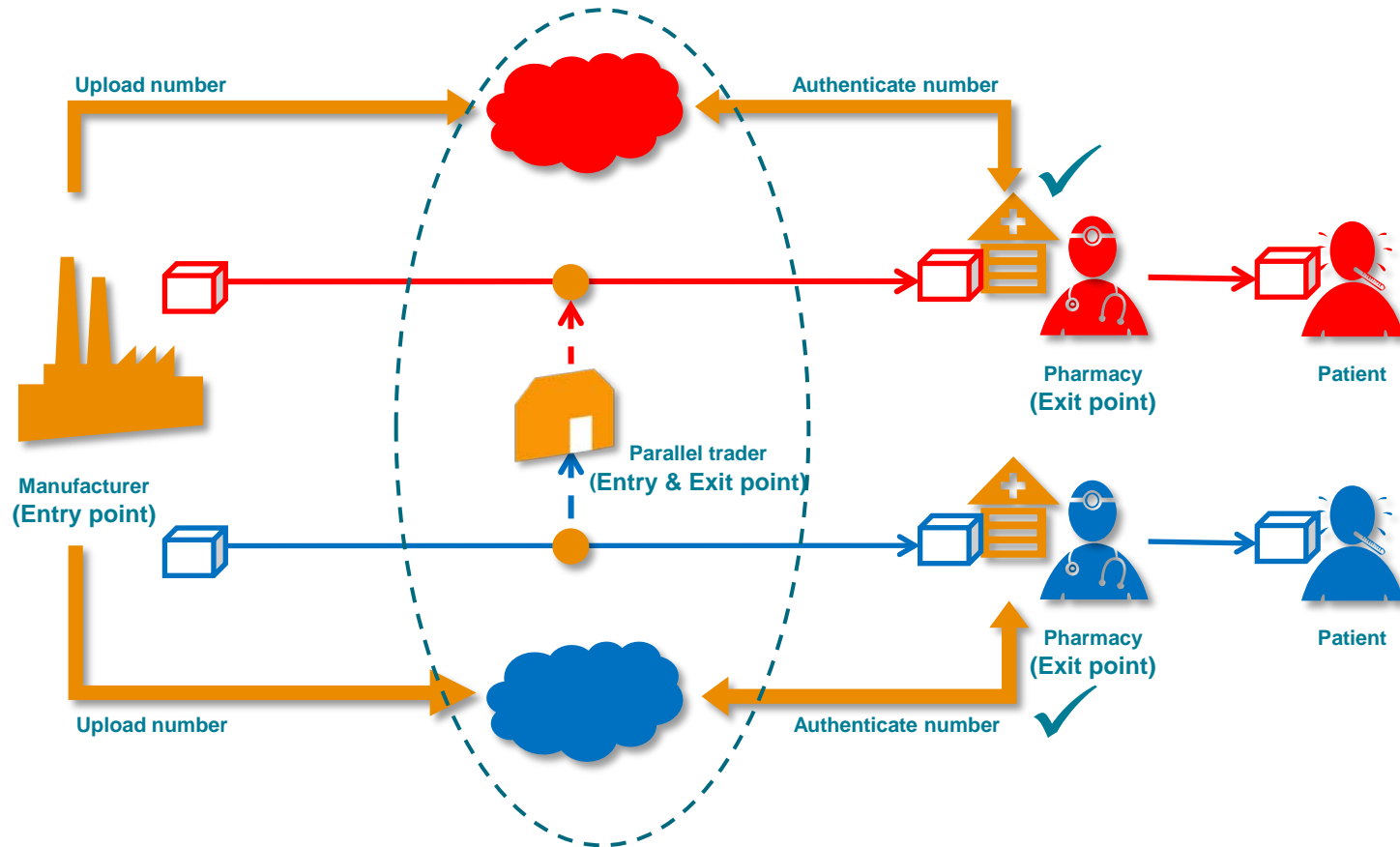
- Criminals will exploit gaps between these systems to introduce counterfeit product

Systems will have to be interoperable to ensure patient safety

Single standard for coding and product identification

- Multiple codes
  - Confusion of which to scan especially if several are required during dispensing

  - Time consuming locating the correct codes and scanning several times

  - Risk to patient safety if the incorrect code is scanned

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

Multiple stakeholders are involved

Re-packer

Manufacturer

EU Solution

Pharmacy

Distributor/ Wholesaler
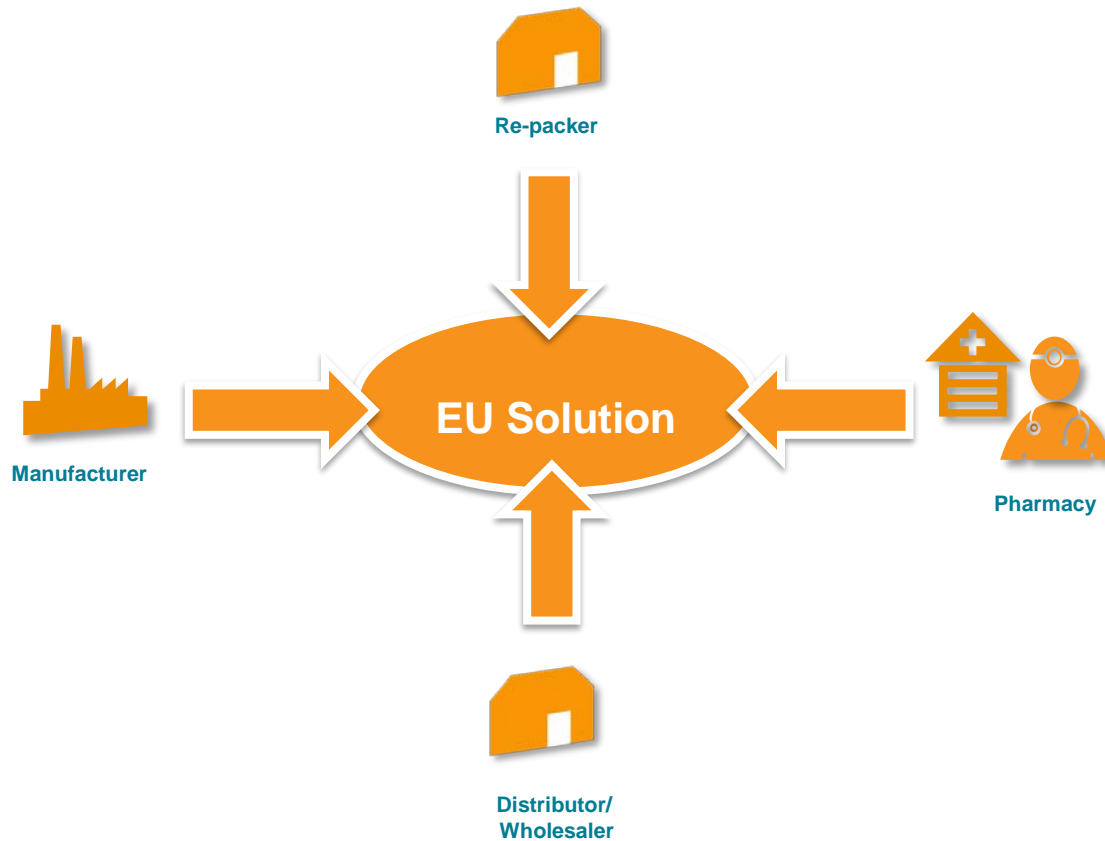
Stakeholders will have to work together to deliver a solution across Europe which delivers the patient safety objectives

efpia Some of the issue which will need to be addressed

Issue

- Cross boarder movement and multi-market packs

- Difficulty of multiple codes and ensuring uniqueness

- Many stakeholders are involved in getting the product to the patient

Requirement

- Systems will have to be interoperable to maintain patient safety

- Single unique code to scan for all purposes e.g. verification, reimbursement, etc

- Stakeholders are going to have to work together and define the governance to design, deliver and run solutions

Conclusion

- Product verification at the point of dispense
  - Is an ambitious and **long term project** which will improve supply chain security and patient safety
  - Involves costs for all parties and requires **definition of governance structures between key stakeholders**

- EFPIA proposes an approach that is
  - Based on **cooperation with key stakeholders**
  - Based on **open standards**
  - **Feasible, interoperable, efficient, and cost effective**
  - **Flexible for future extension**

- Governments and European Commission support is critical to deliver requirements for pack integrity in the supply chain and verification at point of dispense

All stakeholders are going to have to work in partnership if we are going to secure the patient safety objectives

efpia **Thank you**

Grant Courtney

www.efpia.org

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

Some minimum standards are required for a pan-European product verification system

Minimum standards required[1]

	Minimum standards	**Common to all**

Model / System	• End-to-end verification system (not track and trace)
	• Mandatory verification at point of sale (using serial number)
	• Storage of product data and dispensing data in national databases
		• Flexibility (within limits) to allow for national level solutions
		  – Different timelines to implementation
		  – Different national regulations e.g. on data storage and availability
		  – Flexibility in terms of service providers

Pack	• Two mandatory elements required for the packs
	  1. Product verification based on standardized mass serialization (applied on **outer package**, e.g. folding box)
	  2. Pack integrity by tamper evident packaging (individual solutions feasible)	

Data	• Data carrier as Data Matrix code
	• Information content (in GS1 format):
	  – Product number (GTIN or NTIN)
	  – Batch number
	  – Expiry date
	  – Serial number (randomized)
	• Link between original manufacturer's code and replacement code issued by repackager	

(1) *These are independent of the governance model*

How does the EFPIA product verification solution work?

Product verification: the action of comparing data held within the product code with a secure product record on a database and confirming that:

a) Product record exists and matches data held on package

b) Product record has not been previously marked as 'dispensed'

c) Product record does not contain any warnings or advisory notices (such as recalled, expired, etc)

Product verification
- Any duplicate instance of product code can be detected prior to widespread proliferation of a potential problem
  - Any copying/counterfeiting of the 2D Matrix code will be identified by the system

Does not guarantee the genuine nature of the product contained within the coded product pack