Improving patient safety across Europe through serialisation

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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 efpiamia groups addressing product coding
Serialisation Status in Europe

- **16 Feb 2010**: European Vote
- **July 2011**: Publication in Official EU Journal
- **Jan 2013 (?)**: Transposition of Directive into national law
- **Q3-4 2013 (?)**: European Commission “Delegated Acts”
- **Q4 2016 (?)**: Latest implementation in Member States without pre-existing measures

Timeline:
- 2010
- 2011
- 2012 ~24m
- 2013 18m
- 2014
- 2015
- 2016
- 2017
The EU Falsified Medicines Directive

• On 27 May 2011 the EU Council formally adopted Directive, which will be released in the EU Official Journal in July 2011.

• The Directive should be transposed in Member States’ national laws by January 2013, in summary:

  – All prescription-only medicines will have to bear safety features (i.e. a unique serial number placed on each pack together with tamper evident packaging). Certain products or product categories of prescription-only medicines might be exempted according to a risk assessment; OTCs are excluded in principle from the scope of the Directive unless there is a risk of falsification

  – The Commission will decide the specifications of the serial number allowing identification/authentication of individual packs and will set out the provisions for establishment, management and accessibility of databases in the so-called ‘Delegated Acts’ (implementing rules)

  – The Delegated Acts should be released with the next 12-24 months and companies will have then 3 years to comply with the technical requirements as of the date of publication of the Delegated Acts.
National numbers
Challenges – national numbers

- Multiple processes need to be accommodated by the barcode information on the pack e.g. verification, reimbursement, product identification etc
- In some countries these processes can be achieved through the use of the GTIN alone
- Other countries use national numbers to operate some of these processes
Challenges – national numbers

- We need to ensure that we don’t have a proliferation of barcodes on the pack.
- Pharmacists want a single barcode to scan and a minimum impact on their working practices when product verification is introduced.
- There are challenges to move to GTIN to facilitate all processes (current systems, processes, legislation etc).

So what is EFPIA and GS1 doing?
Challenges – national numbers

• A vision is being developed where the end point should be a GTIN on the pack and other numbers looked up using the GTIN

• To allow a transition towards this vision GS1 is looking at introducing a new AI to carry the national reimbursement number in the same barcode as an attribute on the GTIN

• This approach will only be required in a very few number of cases and should be viewed as a stepping stone towards the vision of using the GTIN
The coding situation in Europe today: Overview of National Codification Systems - updated

17 countries have a **full GS1 GTIN** code structure
(UK, Ireland, Czech Republic, Slovakia, Latvia, Lithuania, Estonia, Malta, Netherlands, Turkey Romania, Bulgaria, Serbia, Albania, Bosnia and Herzegovina, Macedonia)

5 countries use an **NTIN** (EAN 13 compatible code structure) with product identification number allocated by a number bank or an external agency for the coding of pharmaceuticals
Austria, France, Greece, Slovenia, Spain,

7 countries allow NTIN **AND** GTIN
(DK, Finland, Iceland, Norway, Poland, Sweden, Switzerland)

4 countries have their own **non-GS1 compatible solution**
Belgium, Germany, Italy, Portugal.

(1) GTIN: Global Trade Item Number
(2) NTIN: National Trade Item Number
Thank you

Grant Courtney

www.efpia.org

http://www.youtube.com/watch?feature=player_detailpage&v=JMDohjlkMsg
Current work
• Criminals will exploit gaps between these systems to introduce counterfeit product

Systems will have to be interoperable to ensure patient safety
Pan European Verification System

- Manufacturer
- Wholesaler
- Repacker
- Pharmacy
- EU Central hub

Regional / national system 1
Regional / national system n
Regional / national system 2

Pharmacy: mandatory verification transaction
Manufacturer: data upload + voluntary verification transaction
Wholesaler: voluntary verification transaction
Repacker: mandatory verification transaction + data upload
Periodic cross-region update
• Propose 5 lines of code in the data carrier
  – NHRN                           - see below
  – GTIN                           - AI (01)
  – Expiration date               - AI (17)
  – Lot Number                    - AI (10)
  – Serial Number                 - AI (21)
The need for standards

• Multiple codes
  – Confusing and time consuming, especially if several are required during dispensing
  – Risk to patient safety if the incorrect code is scanned
  – Issue caused for multi-market packs

The barcode must be unique and allow all requirements to be covered in a single scan
We advocate securing all entry and exit points of a country’s supply chain through a point of dispense authentication model.
Stakeholder Governed Pan European System must:

- Ensure product and patient safety
- Be accepted and supported by many stakeholder organisations
- Accommodate different needs in different regions
  - Link with reimbursement or e-prescription systems
- Be based on same principles in different regions
  - Mandatory coding and verification
  - Harmonised coding system
  - Same basic procedures to be followed in case of exceptional events
- Provide interoperability between regional systems
- Be scalable to be extended over time
- Be cost effective
Summary Key benefits of model

- Use of Datamatrix code reduces required space on pack & provides higher robustness compared to linear barcode

- “Point of dispense verification” is far less complex than Track & Trace

- Including batch number and expiry date in the code allows for logistic and Patient Safety advantages

- Stakeholder governance focuses on patient safety and avoids expensive solutions that may potentially be required by authorities or other parties

- European hub provides a single point of data entry for manufacturers

- European hub facilitates multi market packs

- Model provides Pan European interoperability connectivity at lower costs