EFPIA & The EU’s Falsified Medicines Directive

Working Together for Patient Safety

Rob Bruchet
Director, International Public Affairs
Pfizer Inc. &
Member of the EFPIA Senior Oversight Group for Coding & Serialization

October 2011
GS1 Healthcare Conference
Amsterdam, Netherlands
**Introductions**

**Who is EFPIA?**

- The Voice of the innovation-based pharmaceutical industry in Europe
  - The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe.
  - Direct membership of 31 national associations and 38 leading pharmaceutical companies including their affiliates
  - EFPIA is to promote pharmaceutical research & development and the best conditions in Europe for companies to bring to patients new medicines that improve human health and the quality of life around the world.
Who am I?

- Director of Public Affairs in Pfizer’s Brussels office
- 10+ years of experience in the pharmaceutical industry across many commercial functions
- Member of key EFPIA work groups related to the Falsified Medicines Directive
July 2011
Publication in Official EU Journal

Jan 2013
Transposition of Directive into national law

2011

2015

2017
Safety Features – Member States without pre-existing measures

D+ 3 years

2020
D+ 9 years

2023
Safety Features – Member States with pre-existing measures

July 2011
Publication of final “Delegated Acts”
# The Directive – Safety Features

## What Does the Directive Mandate?

- Safety features that enable relevant persons to
  - “verify...authenticity”
  - “identify individual packs”
  - Tamper evidence
- Rx included all OTCs excluded. Some exceptions based on a risk assessment
- Govts can use the system for reimbursement and/or pharmacovigilence purposes
- MAHs will pay for the “repositories systems”

## What Will Be Decided by Delegated Acts?

- Characteristics & technical specifications of the “unique identifier”
- Criteria for the risk assessments & process for notification of products included
- “Extent and modalities of verification of the safety features” to “ensure the verification of authenticity of each dispensed pack”
- Establishment (including accessibility) of the “repositories”
EFPIA’s 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
The Point-of-Dispense Model

Secure All Entry & Exit Points

Pharma Manufacturer

Product Flow

Wholesaler

Verification

GTIN:
Batch:
Expiry:
S/N:

Verification

The Point-of-Dispense Model

Secure All Entry & Exit Points

Pharma Manufacturer

Product Flow

Wholesaler

Verification

GTIN:
Batch:
Expiry:
S/N:

Verification

The Point-of-Dispense Model

Secure All Entry & Exit Points

Pharma Manufacturer

Product Flow

Wholesaler

Verification

GTIN:
Batch:
Expiry:
S/N:

Verification

The Point-of-Dispense Model

Secure All Entry & Exit Points

Pharma Manufacturer

Product Flow

Wholesaler

Verification

GTIN:
Batch:
Expiry:
S/N:

Verification
Testing the Concept

• A pilot project in cooperation with pharmacists
• Objective was to demonstrate the EFPIA proposal as
  – an **aligned approach** with the Falsified Medicines Directive
  – 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
Swedish Pilot 2009-10

- **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
Key Conclusions

- **Works in practice** and allows for effective identification of fake packs.
- System availability and performance **allowed pharmacists to work at normal pace** and without significant additional effort.
- System was **easy to use** when fully integrated into pharmacy workflow and existing IT system.
- System **should be customised to existing pharmacy workflow**, processes, local conditions and regulatory requirement.
- The presence of **more than one code on the pack causes confusion for the user and will jeopardise user acceptance**.
- Pharmacists are **highly interested to get expiry date and batch number in machine readable form** through the 2D data matrix.
## Looking Ahead - Key Success Factors

<table>
<thead>
<tr>
<th>Issues</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cross border movement and multi-market packs.</td>
<td>• Systems will have to be interoperable to maintain patient safety</td>
</tr>
<tr>
<td>• Difficulty of multiple codes and ensuring uniqueness</td>
<td>• Single unique code to scan for all purposes e.g. verification, reimbursement, etc</td>
</tr>
<tr>
<td>• Many stakeholders are involved in getting the product to the patient</td>
<td>• Stakeholders are going to have to work together and define the governance to design, deliver and run solutions</td>
</tr>
<tr>
<td>• Access to data</td>
<td>• System must be highly secure, with strict control</td>
</tr>
<tr>
<td></td>
<td>• Additional access requirements for some scenarios – i.e., negative verifications, recalls</td>
</tr>
</tbody>
</table>
Stakeholders Working Together Across Europe

EU Solution

- Manufacturer
- Re-packer
- Distributor/Wholesaler
- Pharmacy
Stakeholders Working Together

Tamper evidence with unique serial number

Continuity of protection throughout the entire supply chain

A single pack coding / identification system across Europe

Ensuring product verification database systems can work together across the EU

Verifying every pack at pharmacy level

Maximising the benefits of mass serialisation

Focus on securing patient safety and protecting patient privacy

Safety features that are simple, robust and cost effective

Working together in the interests of patients

Involving other stakeholders

EFPIA / GIRP / PGEU Joint Position Paper

Involving other stakeholders

Working together in the interests of patients
Pan-European Model

- Manufacturer
- EU Central hub
- Re-packer
- Pharmacy
- Wholesaler

Regional / national system 1
Regional / national system n

Pharmacy: mandatory verification transaction
Manufacturer: data upload + voluntary verification transaction
Wholesaler: voluntary verification transaction
Repacker: mandatory verification transaction + data upload
Periodic cross-region update
Key Benefits of the Pan-EU 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 and provides needed improvements in patients safety

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

- Based on **common principles** and can accommodate **regional needs**

- Stakeholder governance is critical to **ensure a responsive, cost-effective system that works for patient safety**

- European hub provides a **single point of data entry** for manufacturers, facilitates multi-country pack s, and accounts for parallel traded packs
Status & Next Steps

Continue Progress Towards Implementation

• Approach endorsed by the EFPIA Board
• Continue building the partnership with PGEU & GIRP
  – Joint work streams already in place on stakeholder involvement / governance, system development, and communications
• Seek support of other key stakeholders
• Work with national level stakeholders to develop and implement national level systems