On the Way to a Pan-European serialisation & product verification model

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The boring bit !
European Federation of Pharmaceutical Industries and Associations

represents the research-based pharmaceutical industry operating in Europe

brings together 31 national pharmaceutical associations and 38 leading companies
Who am I?

- 16 years supply chain and product security for GlaxoSmithKline
- Member of the GS1 Healthcare Leadership Team and Co-Chair of the Public Policy Team
- Sit on various efpiagroups addressing product coding
Design of pillars for EMVS is well underway
New EU Directive to combat falsified medicines launched

Safety Features

- Safety features to allow verification of authenticity and identification of individual packs, and provide evidence of tampering
- Risk-based approach – “white list” for prescription medicines, “black list” for OTC
- Parallel importers must replace safety features with equivalents & are held liable for damages

Repositories System

- System to contain information on the safety features
- Member states may use safety features for other purposes e.g. reimbursement
- Costs shall be borne by the manufacturing authorisation holders
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
Serialisation Status in Europe

16 Feb 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 (?) Implementation in Member States without pre-existing measures

Some countries could deploy earlier than 2016
But does it work . . . ?

- Stakeholder proposal for a Pan-European serialisation & product verification model

- Operating the proposed model in Sweden

- Current activities
Design of pillars for EMVS is well underway.

Pan-European Medicines Verification System (EMVS)
EFPIA proposes a 2D DataMatrix for pack verification

DataMatrix coding proposal using GS1 standards
(EAN 128 syntax with Application Identifiers; Data matrix ECC200)

Manufacturer Product Code (GTIN or NTIN)
Unique Serial Number (randomized)
Expiry Date
Batch Number

Example:

GTIN:  (01)09876543210982
Batch:  (10)A1C2E3G4I5
Expiry:  (17)140531
S/N:  (21)12345AZRQF1234567890
We advocate securing **all** entry and exit points of a country’s supply chain through a point of dispense authentication model.

Pharma Manufacturer → Wholesaler → Verification

GTIN:  
Batch:  
Expiry:  
S/N:
But does it work . . . ?

- Stakeholder proposal for a Pan-European serialisation & product verification model
- Operating the proposed model in Sweden
- Current activities
Pilot project overview

- **Objective** - to demonstrate the EFPIA proposal as:
  - an **aligned approach** with the EC’s pharmaceutical package
  - a **practical and effective solution** for relevant
  - a model that works based on **common standards** & mature technology
  - A **credible alternative to proprietary national systems**, aligned with government requirements

- **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
  - Operational phase from Sep 2009 – Feb 2010
Key conclusions of the Pilot

• **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. 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
What’s next . . . ?

- Stakeholder proposal for a Pan-European serialisation & product verification model
- Operating the proposed model in Sweden
- Current activities
Design of pillars for EMVS is well underway
Proposed Framework for a European medicines verification system

On the Way to a Pan-European Medicines Verification System
Stakeholder support is key to success

Pan-European Medicines Verification System (EMVS)

Regulatory Requirements
Business Processes
System Architecture
Rules for Data Ownership and Access
Organisation to build and operate system

Support of all Supply Chain Partners
### Joint view on implementation of Directive EAEPC, EFPIA, PGEU and GIRP

| **Safety Features** | • Combine tamper-evident packaging and a unique randomised serial number  
• Verify product authenticity by checking each pack against a central database at the point of dispensing |
|---------------------|--------------------------------------------------------------------------------------------------|
| **System Design**   | • Harmonised standard coding system across the EU that allows national codes to be incorporated as necessary  
• Sufficient flexibility to implement national or multi-country solutions within an overall EU technical framework |
| **Data**            | • Manufacturers do not seek, and will not have access to, individual patient / prescribing profile information  
• Transactional data belongs to stakeholder that created it e.g. pharmacists for dispensing data |
| **Governance**      | • Systems should be established and managed by the stakeholders that will use them day-to-day  
• Systems governed by independent non-profit organisations jointly managed by relevant stakeholders |

On the Way to a Pan-European Medicines Verification System
Major supply chain partners working together

- EAEPC, EFPIA, GIRP, and PGEU have:
  - agreed upon a joint position paper “Ten Core Principles to Protect Patients from Falsified Medicines”
  - elaborated a Memorandum of Understanding towards foundation of European stakeholder organisation
  - Plan to launch a Request for Proposals for implementation of European Medicines Verification System (EMVS)

- Talks ongoing with AESGP, EGA, and HOPE

AESGP  Association of the European Self-Medication Industry
EAEPC  European Association of Euro Pharmaceutical Companies
EGA  European Generic Medicines Association
GIRP  European Association of Pharmaceutical Full-line Wholesalers
HOPE  European Hospital and Healthcare Federation
PGEU  European Association Representing Community Pharmacists
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EMVO  European Medicines Verification Organisation

Schedule towards pan-European medicines verification is tight

July 1, 2011
Publication of directive in official journal of EU

Q4 2011
MoU between EFPIA, PGEU, GIRP signed

Q1 2012
System design document released

Q4 2012
MoU with additional stakeholders signed

January 2, 2013
EU member states to convert directive to national law

Q1 2013
System development Phase 1 completed

Q4 2013
EMVO stakeholder organisation established

2014 – 2016
Introduction of medicines verification systems in EU member states
Provision of coded products

2014 (est.)
Publication of add’l provisions in “Delegated Acts”

Q4 2014
EU Central Gateway in full operation

Summary

- **Point-of-Dispense Verification** model successfully operated in Sweden in 2009/2010
- **Proposed framework** for a pan-European medicines verification system in place
- Involvement of supply chain stakeholders is key for success
- EFPIA and its partners EAEPC, GIRP and PGEU are working to meet the requirements of the EU Falsified Medicines Directive
  - Contribution to public consultation on Delegated Act for safety features
  - Push forward foundation of European Stakeholder Organisation ("MoU" and Foundation Documents)
  - Prepare Request for Proposal for EMVS

On the Way to a Pan-European Medicines Verification System
So how is GS1 supporting EFPIA

- Contributed to a shared vision for GTIN across Europe
  - Worked to define the vision and support roll out
  - Development of the new AI for National Health Reimbursement Number (NHRN)
  - Working with individual countries to agree how to migrate towards GTIN

- Helping to shape legislation
  - Ensuring that the views of stakeholders are well represented as part of public consolation

- General education and support

Supporting industry to stand ready to comply with the requirements of the EU Falsified Medicines Directive