Ensuring patients have access to safe medicines

A European Medicines Verification System

Fighting counterfeit medicines to ensure patient safety in Europe

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Grant Courtney

- Part of EFPIA team working on the ESM
- Member of the GS1 Healthcare Leadership Team
- 18 years in product security for GlaxoSmithKline
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
ESM Stakeholders

- EFPIA is one of the 4 stakeholders developing the ESM solution.

- The ESM solution is being developed by the stakeholders who will use it day-to-day.

- Talks ongoing with AESGP, EAHP, EGA and HOPE.

AESGP  Association of the European Self-Medication Industry
EAHP  European Association of Hospital Pharmacists
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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Introduction
The threat of falsified medicines penetrating the European supply chain is substantial and growing.

The EU Falsified Medicines Directive (FMD) is an important step in protecting patients from counterfeit medicines, adoption on July 1, 2011.

ESM are developing a system that will meet the requirements of the FMD.
What is the ESM?

ESM
A medicines verification model for Europe

- A cost-effective solution for medicines verification
  - Run on a non-profit basis

- A pan-European system called the EMVS (European Medicines Verification System) enabling medicines to be verified at point of dispensing
  - Developed by the stakeholders who will use it on a day-to-day

- Immediate verification of the pack
  - Ensures safe access to medicines
  - Is interoperable solution
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Proving the concept
Swedish pilot project (Sep 09 - Feb 10)

25 pharmacies in greater Stockholm. 180 dispensing points
- 25 products. 110,000 packs. 14 manufacturers

Key findings
- Allows pharmacists to work at normal pace
- Is customised to existing workflows
- Is integrated into existing pharmacy software
- Pharmacists and wholesalers are keen to get expiry date and batch number in machine-readable form

Sweden exceeded expectations and proved the concept in practice
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Building the shared vision
**ESM view on implementation of the FMD**

<table>
<thead>
<tr>
<th><strong>Safety Features</strong></th>
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<tbody>
<tr>
<td>• Combine tamper-evident packaging and a unique randomised serial number</td>
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<tr>
<td>• Verify product authenticity by checking each pack against a central database at the point of dispensing</td>
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<th><strong>System Design</strong></th>
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<td>• Harmonised standard coding system across the EU that allows national codes to be incorporated as necessary</td>
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<td>• <strong>Sufficient flexibility to implement national or multi-country solutions within an overall EU technical framework</strong></td>
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<th><strong>Data</strong></th>
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<td>• Manufacturers do not seek, and will not have access to, individual patient / prescribing profile information</td>
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<tr>
<td>• <strong>Transactional data belongs to stakeholder that created it e.g. pharmacists for dispensing data</strong></td>
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<th><strong>Governance</strong></th>
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<td>• Systems should be established and managed by the stakeholders that will use them day-to-day</td>
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<td>• <strong>Systems governed by independent non-profit organisations jointly managed by relevant stakeholders</strong></td>
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The ESM uses a 2D barcode, developed to internationally recognised standards.

Four key data elements:
- 14 digit Manufacturer Product Code
- Randomised Unique Serial Number
- Expiry Date
- Batch Number (up to 20 alpha-numeric characters)

Example:

Product #: (01)09876543210982
Batch: (10)A1C2E3G4I5
Expiry: (17)140531
S/N: (21)12345AZRQF1234567890
Model and process

European Hub

National System 1 - n

Verification upon Dispense to Patient

Upload Data

Product # Batch Expiry S/N

Product Flow

Pharmaceutical Manufacturer and Parallel Distributor

Wholesaler

Wholesaler

Pharmacist

Patient

Random/risk-based verification by Wholesale distributors

Random/risk-based verification by Wholesale distributors

European Hub

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Infrastructure overview

System design for interoperability and efficiency

Pharmaceutical Manufacturer

National System 1

National System (Blueprint)

National System 2

Parallel Distributor

Pharmacy

Wholesaler

Pharmacy

Wholesaler

Pharmacy

Wholesaler

Parallel Distributor: mandatory verification + data upload
Manufacturer: data upload + voluntary verification
Periodic cross-region update
Pharmacy: mandatory verification
Wholesaler: voluntary verification
The ESM will be operated by a *not-for-profit* independent organisation called the European Medicines Verification Organisation (EMVO).

Governance of the EMVO will include representatives from the stakeholder organisations in an EU Stakeholder Board.

EMVO will:
- Develop and control EMVS policies and processes
- Communicate with authorities and the broader public
- Establish relationships (and contracts) with national stakeholder organisations (NMVO)
- Oversee development of European Hub and Blueprint Template
- Provide reports to stakeholders
- Manages the operation of the Hub and national Blueprint System(s)
EMVO – stakeholder-led governance structure

- EMVO will govern EU hub, set standards for the system, and conclude legally binding agreements with national system governance bodies.
- National systems will have to create their own stakeholder-based, legal entities (Medicines Verification Organisations, MVO) that would contract with the EMVO.
- Blueprint system to be governed nationally, but managed and operated on EU level.
Key milestone to date

- **2009 – 10**: Sweden Pilot
- **2010**: EFPIA, GIPR and PGEU issue a joint position paper
- **July 2011**: Publication of the FMD
- **June 2012**: ESM officially launched (MoU in place)
- **2013 Q2**: Vendor selected and ESM Hub development started
- **Jan 2013**: EU Members transpose Directive into national law
- **Today**:
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Next steps
Next major milestones

- **Q4 2013**: Establish EMVO
- **2013 Q2**: Vendor selected and ESM Hub development started
- **Q4 2013**: ESM Hub targeted to be complete
- **Q1 2014**: ESM Hub Link to securPharm national system
- **2014**: Publication die of FMD – Delegated Acts
- **2017**: Expected mandatory application of medicines verification in EU
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Thank you

http://www.esm-system.eu/home.html
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Back up slides

*Will not be presented but may be distributed*
EMVO – Membership

Members Are Allocated to a Constituency

- PGEU
- Pharmacy
- Innovators
- Repackagers
- HOPE
- Girp
- Wholesalers
- Generics
- Ega
- Otc
- EfpiA
- EaePC
- Aesgp
- Plus affiliate members
Memorandum of Understanding (MoU) provides the foundation

European level:

- Negotiated between EAEPC, EFPIA, GIRP and PGEU
  - Have elaborated and formally endorsed a MoU providing the foundation for the pan-European system
  - Talk ongoing with other constituents

- Contents
  - General goals and expectations
  - The 10 Core Principles
  - System Architecture
  - Entry & Exit Points
  - Data Access
  - Governance
  - Technical Annexes
## Principles of sharing the cost of the verification system

| Overall policy framework | • ESM is not-for-profit  
|                          | • Costs to be shared in a fair and equitable manner |
| Scope                    | • Repositories system only |
| Cost allocation          | • To be based on value and volume components  
|                          | • Value based on total sales in specific market |
| Consistency              | • Clear rules to avoid excessive variations |
| European Hub cost        | • To be shared between connected national systems on the basis of the pack data transferred |
| Invoicing                | • Market by market  
|                          | • Include share of European Hub |