Introduction

* Grant Courtney

* Previously a member of the EFPIA Serialisation & Coding Steering Team

* Member of GS1 Healthcare Leadership Team

* 20 Years experience in healthcare
Implementation of the Falsified Medicines Directive (FMD) required until 2018

Objective: Protection of patients from counterfeited medicines in the legal distribution chain

Content: Pan-European system to verify the authenticity of medicinal products
Delegated Acts will mandate rules for medicines verification

Serialization by manufacturer
+ Verification at point of dispense

Code (‘safety feature’)
+ Tamper evidence

System set up and governed by stakeholders under supervision of authorities

GTIN (01) 09876543210982
Batch (10) A1C2E3G4I5
Expiry 31 May 2014
SN (21) 12345AZRQF1234567890
Pan-European System: National Systems connected by the European Hub
## European Stakeholder Model: Status

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FMD</strong></td>
<td>- Publication of Delegated Acts announced for Q4 2015</td>
</tr>
<tr>
<td><strong>Stakeholders</strong></td>
<td>- EMVO founded on 13 February 2015</td>
</tr>
<tr>
<td><strong>System</strong></td>
<td>- European Hub: Final test in April 2015</td>
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<tr>
<td></td>
<td>- Negotiations with Blueprint providers started</td>
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<tr>
<td><strong>Member states</strong></td>
<td>- First “Advisory Group” meeting to inform national stakeholders on progress of negotiations with Blueprint providers in February 2015, next end of May.</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>- Progress audit agreement with EDQM</td>
</tr>
</tbody>
</table>
Full operation phase: Who will have to pay?

Installations for pack coding

Installations for pack verification

Repository system (Hub & national systems)

Marketing Authorisation Holders

Pharmacists, wholesalers, ...

Marketing Authorisation Holders

MAHs selling products in a Member State pay for respective national system and a share of the European Hub
Pan-European architecture: The „National Blueprint System“ approach
The Blueprint approach provides substantial benefit

* Complexity reduction for NMVOs:
  * Allows national stakeholders to build national system without starting from scratch
    * Based on a “standard” national verification system providing all necessary functionality
  * Strong support by EMVO during deployment & operation (system management)

* Cost reduction for payers through economy of scale
  * Fewer, but bigger (aggregate) systems are less costly than many (individual) smaller systems

* Benchmark for Total Cost of Ownership
The National Blueprint System: Governance & management

- **Governance** by National stakeholders
- **Management** by EMVO on behalf of the respective national stakeholders
- **Operation** by IT provider as preselected by EMVO
Timeline (as of 01/2015)

- **11/2014**
  - Start info for nat’l

- **10/2014**
  - Start frame contract

- **03/2015**
  - Frame contracts agreed

- **04/2015**
  - Start selection process

- **07/2015**
  - Formation of first bundle

- **2015 - 2017**
  - Continue selection process

- **06/2015**
  - Expectation: Adoption of DA

- **01/2016**
  - Go Live of first Blueprint
What are the actions/tasks at national level?

* Agreement between stakeholders
  * Principles for cooperation
  * Foundation of National Medicines Verification Organization (NMVO)
  * Definition of technical requirements
  * Select IT provider out of the EMVO selection
  * Provide funding
* Cooperation with competent authority
* System implementation

⇒ System complete in 2018!
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EMVO Interim Organisation (Responsibilities until Q2-Q3 2015)

**EMVO STATUTORY GENERAL ASSEMBLY**

**EMVO Board of Directors**
- President: John CAHVE (PGEU)
- Vice-President: Adrian van den Hoven (EGA)
- Treasurer: Monika Dercque-Pois (GIRP)

**Interim General Manager**
A. WALTER (EFPIA)

**Advisor**
M. FRIEDRICH (BTS)

**Quality Assurance**
H. HANSEN (Novo Nordisk)

**Operations Team**
K. VAN GOEMPEL (Ordina, tbc)

**Operations**
P. MILLS (Melior Solutions)

**Operations Team**
P. HÜBL (BTS)

**Administration & Finance**
H. KOBELT (EAEPC)

**Commercial / Partner Management**
J. VERHAEGHE (EGA)

**Onboarding Manager**
M. MEYER (BTS)