EDQM activities around counterfeiting and traceability

GS1 Healthcare Conference
Lisbon, 23-25 October 2012
The eTACT project

1. Introduction
   - What is the background to the project?
   - EDQM proposal
   - Focus on some demo functionalities
   - Progress of the project – workshops and beyond
   - Benefits
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Council of Europe / European Directorate for the Quality of Medicines & Healthcare (EDQM)
European Pharmacopoeia

- Official standards for the quality control of medicines in Europe
- **Legal** and **scientific** basis
- Principles of elaboration keep pace with
  - regulatory needs of Public Health authorities
  - technological/scientific advances and industrial constraints
CoE/EDQM anti-counterfeiting strategy

- Multisectorial training
- Medicrime
- Inspection Testing

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### The opportunities: mass serialisation

<table>
<thead>
<tr>
<th>Public</th>
<th>Business</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bollino (IT)</td>
<td>GS1</td>
</tr>
<tr>
<td>CIP-13 (FR)</td>
<td>Aegate (BE, GR)</td>
</tr>
<tr>
<td>eTACT (CoE/EDQM)</td>
<td>EFPIA (SE 2010 -&gt; ESM)</td>
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<tr>
<td>FMD (EU)</td>
<td>Securpharm (DE)</td>
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</table>
Current situation:
Point-of-Dispense verification

Manufacture → Distribution → Retail pharmacy

Generation of item code → Verification at dispensing point
Falsified Medicines Directive (FMD)

- Directive 2011/62
  - Safety features
    - Identifier that is readable by wholesale distributors and pharmacists
    - Tamper-proof device (outside scope of eTACT)
  - Public consultation Nov 2011-Apr 2012
  - Impact study → Delegated Acts 2014
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Generation of UMI = Unique Medicine Identifier

Traceability & Verification of UMI

Pharmacy Internet Mail-order

Patients

Verification of UMI
Public governance

- EDQM / Authorities
- Business stakeholders
- Confidentiality of data

More information at the eTACT workshop 14-15 Nov Sofia
Unique Medicine Identifier (UMI)

GTIN (01): 7680303330054
SERIAL (21): 0402748246
BATCH (10): 1446C1214
EXPIRY (17): 111130
NHRN (90): 049-75241456
Architecture

Queries from authenticated stakeholders and patients
Manufacturers landscape & interactions

Manufacturers sending UMI = MSU
Manufacturers not sending UMI = MNSU
Scope

- Any pharmaceutical products
- Actors:
  - Any registered business stakeholders
  - Authorities
  - Patients
- 36 member states of the European Pharmacopoeia and beyond
- Secondary packaging
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Level of Confidence (LoC)

Manufacturer B

Commissioning

Distributor A

Point-of-Dispense verification model

Shipping

Commissioning

Receiving & shipping

Commissioning, packing, shipping

 Pharma A

Direct to pharma

LoC 1

LoC 2

LoC 3

LoC 4

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VERIFYING UMIs BY MOBILE PHONE

In case the UMI exists in the repository:

- Verified UMI
- Status: “UMI Known in the eTACT service”
- Product Name
- Product Brand Owner
- Product Expiry Date
- Product Batch
- Disclaimer

In case the UMI does not exist in the repository or the UMI exists but was not dispensed:

- Verified UMI:
- Status: “UMI unknown in the eTACT service” or “UMI registered but not dispensed”
- Disclaimer

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VERIFICATION RESULTS

Product name: Simvastatin Lab B
Product brand owner: Lab B
Status: Counterfeit (on 11/10/06 15:57:13)

DETAILS

Product code: 7680303330016
Serial number: 8877212564

DISCLAIMER

Provided by EDQM without warranty
Hospital pharmacy
Hospital pharmacy

eTACT
Business rule management system

Separate logical decisions from the application

RULES

Dispensing: if UMI status= « decommissioned » then « This box cannot be dispensed... »

RULEENGINE

APPLICATION

This box cannot be dispensed...
Participants from authorities and supply chain stakeholders / 53 requests for functionalities

- Demo system: 24.5%
- Production system: 39.6%
- To be discussed: 34.0%
- No action: 1.9%
Functionalities by category (%)

- Manufacturers: 33.3%
- Pharmacies: 24.1%
- Regulatory Authorities: 20.4%
- Packaging line manufacturers: 5.6%
- Coding Authorities: 7.4%
- Distributors/Wholesalers: 7.4%
- Patients: 1.9%
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General overview of eTACT

Phase 1: Concept development

2a: System development

2009-2010

2b: Workshops

Phase 2: Live demo

2010 – 2012

Phase 3: Service development

From 2013
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Benefits...

• Creates a harmonised approach
  ⇒ Inter-operable and flexible

• Protects confidentiality of data
  ⇒ Public governance

• Allows patients to verify their medicines

...to protect Public Health