Council of Europe

European Directorate for the Quality of Medicines & HealthCare (EDQM)

EDQM anti-counterfeiting Traceability service for medicines

François-Xavier LERY, EDQM
Global GS1 Healthcare Conference – 4-6 Oct. 2011, Amsterdam, NL
The Council of Europe

- Founded in 1949
- Development of European common and democratic principles
- 47 member countries
- Headquarters in Strasbourg
- Core values:
  - protection of human rights
  - pluralist democracy & the rule of law
European Directorate for the Quality of Medicines & HealthCare (EDQM)

• A Council of Europe Directorate, based on the Convention on the Elaboration of a European Pharmacopoeia (PA, 1964)

• Mission: to contribute to a basic human right: access to good quality medicines and healthcare
EDQM contribution - European Regulatory Network

- European Authorities
  - European Union
    - European Medicines Agency
      - EMA London
      - NCAs
        - National Competent Authorities
  - Council of Europe
    - European Directorate for the Quality of Medicines & Health Care
      - EDQM Strasbourg
        - Pharmaceuticals
        - Pharmaceutical care
        - Blood Transfusion
        - Organ Transplantation
        - Cosmetics/food packaging
        - Ph. Eur.
        - Certification
        - OMCL Network

©2011 EDQM, Council of Europe, All rights reserved
EDQM anti-counterfeiting strategy

Multiple actors / multifocal threat

Multi-level ("holistic") strategy

• Custom level (importation)
• Legal instruments (pharmaceutical crime)
• Pharmaceutical level
  • Inspection
  • Testing (detection / provide enforcement officers with evidence)
• Surveillance of pharmacovigilance reports from users
• Packaging (traceability of serialised items)
INTRODUCTION

The Council of Europe drafted a convention which constitutes, for the first time, a binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention).

The Council of Europe has long been concerned about the absence of harmonised international legislation, non-deterrent sanctions that were not proportionate to the harm caused to patients, and the involvement of criminal organisations which operate across borders.
Proposed EDQM Traceability service

Manufacture
- Distribution
- Pharmacies
- Internet/mail-order pharmacies

Generation of UMI
Tracing & Verification of UMI

Patients
Verification of UMI

Governance: EDQM as an intergovernmental organisation guaranteeing sustainable confidentiality of data
EU Pharma package

• Amended Dir 2001/83/EC (adopted – EP 16/02/2011, EU Council 27/05/11) on prevention of the entry into the legal supply chain of falsified medicinal products

Safety features making possible
– for wholesale distributors and pharmacists
– to verify authenticity and identify individual packs

©2011 EDQM, Council of Europe, All rights reserved
EDQM Traceability Service

1D barcode coding for product number only

NOW

NEXT

GS1 GTIN (product number)  B. Serial Number  C. Expiry date  D. Batch Nr.  EDQM AI with variable length (max. 20 digits). The first 3 digits are the GS1 country code. The rest include the national product code.

UMI
Directory vs. Repository

1 - Manufacturers uploading their UMIs

2 - Manufacturers with own UMI repositories

UMI Queries: pharmacies, patients, customs, etc.
Real time (one source)
- No point-to-point information sharing
- All data on request based on traceable item identifier

Repositories for data search

Information flow
- Manufacturer
- Distributor
- Provider

Physical flow
Scope of the EDQM project

• Any Pharmaceutical products on a voluntary basis
• Any registered business stakeholders within distribution / patients / authorities
• Any of the 36 member states of the European Pharmacopoeia and beyond if interested
• Secondary packaging (e.g.: folding box, bottle)
General overview on EDQM project

Phase 1: Concept development
Alignment with stakeholders and users and business requirements
Dec 09-March 2010

Phase 2: Live demo
Apr 2010 – 2012

Phase 3: Service development

2a: System development

2b: Workshops

26-27 Jan 2012: EDQM workshop

From 2012
Aim of the workshops

• Showing functionalities of the demo system by simulating the lifecycle of pharmaceutical packs in the supply chain
• Audience: pharmaceutical authorities and business operators from the supply chain
• Objectives:
  – collecting comments to fine tune the concept
  – Discussing with stakeholders on the suitability of:
    • technical approach
    • project governance
    • implementation strategy
What will be shown in the eTACT live demo

- Simulation of the supply chain
- A real ERP for manufacturers
- A real Point of Sales (PoS) system for the retail pharmacies
- A set of applications simulating other actors and patients
- Business intelligence tools providing advanced reporting and analytics capabilities (business space)
What will be shown in the eTACT live demo (2)

- Core eTACT system able to collect information about the entire lifecycle of serialized pallets, cases, and individual items as they are commissioned, moved through the supply chain, dispensed, and finally decommissioned.
A bit of flavour from the eTACT system

eTACT is the name for the service provided by EDQM for verifying whether packs of medicines distributed in the supply chain are genuine. The service allows as well authorities and business stakeholders increasing the transparency of the supply chain using tracking and tracing tools they can use on a voluntary basis.

Together with the Council of Europe MEDI/CRIME Convention which is the first instrument to criminalise counterfeiting of medical products and similarly dangerous crimes, while providing a framework for proportionate sanctions, victim protection and international cooperation, and a number of other projects including a “fingerprint” database for active pharmaceutical ingredients and multisectorial training for government officials, the eTACT project is part of a holistic strategy to combat counterfeit medical products in order to protect Public Health.

- **Patients**: Verify a pack of medicine
- **Business stakeholders**: Create an account, log to your account, track, trace or verify your products
- **Authorities**: Create an account, log to your account, verify products
- **Documentation**: Service documentation, legislative texts

©2010 EDQM, Council of Europe, All rights reserved
eTACT

Business Stakeholders

Learn how to use this service

Register now!

Directory of products tracked by the EDQM

Login
Password
Login

HOME | TERMS AND CONDITIONS | CONTACT | SUPPORT

The eTACT service is maintained and operated by the EDQM. Access to the platform is granted on verification of appropriate credentials. The content of the service is at the discretion of the authorities. For this reason, the EDQM accepts no responsibility or liability whatsoever ensuing but not limited to any direct or consequential loss or damage it might incur by you accessing and using the information on the directory.

©2010 EDQM, Council of Europe, All rights reserved
Example of actors interfacing

Internet Pharmacy

Receive & Verify

Dispense

Decommission
UMIs ready for dispense: 1

- Compliant: 1
- Compliant - Near to Expire: 0

UMIs not ready for dispense: 0

- Expired: 0
- Not Ready: 0
- Counterfeit: 0
- Suspicious: 0
- Status unavailable: 0
Business intelligence tools

Product Visibility Report for Actor Lab R / Username: LR_137

- Manufacturer, Event Type:
  - Lab R - commissioning
  - Lab R - packing
  - Lab R - shipping

- Nb of Events:
  - 2011 Year

Product Visibility Report for Actor Lab R / Username: LR_137

- Nb of Events:
  - 2011 Q1 2011

- Lab R, commissioning
  - Minoxidil - commissioning
Business intelligence tools (2)
eTACT
Patients

Verification interface

Input mode selection

- UMI only
- Composed input

UMI: [Input field]

[Image]

Check

HOME | TERMS AND CONDITIONS | CONTACT | SUPPORT
Looking forward to seeing stakeholders in Strasbourg for eTACT workshops!
Contact details:

• EDQM project team:
• Francois-Xavier Lery
  Email: francois-xavier.lery@edqm.eu
  Tel: +33 (0) 3 88 41 33 62
• Hans-Joachim Bigalke
  Email: hans.bigalke@edqm.eu
  Tel: +33 (0) 3 88 41 22 86