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)
    - National Competent Authorities (NCAs)
  - Council of Europe
    - Commission
    - Parliament
    - DG Health and Consumers Brussels
  - European Directorate for the Quality of Medicines & Healthcare
    - Strasbourg
  - EDQM
    - Ph. Eur.
    - Certification
    - OMCL Network
  - Pharmaceuticals
    - Pharmaceutical care
  - Blood Transfusion
  - Organ Transplantation
  - Cosmetics/food packaging

©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.

NEWS

- **International High-Level Conference:** The Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (Medicrime Convention) - Countering the spread of counterfeit medical products - Moscow, 26-28 October 2011: More Information

- **The MEDICRIME Convention** was adopted by the Committee of Ministers of the Council of Europe on 8 December 2010: Press Release
Proposed EDQM Traceability service

Manufacture

- Distribution
- Pharmacies
- Internet/mail-order pharmacies

Generation of UMI

Tracing & Verification of UMI

Patients

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

Verification of UMI
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
EDQM Traceability Service

NOW

1D barcode coding for product number only

NEXT

eTACT

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.
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:
- From Manufacturer to Distributor
- From Distributor to Provider
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

26-27 Jan 2012: EDQM workshop

2a: System development
2b: Workshops
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 services 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 MEDICRIME 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 multilateral training for government officials, the eTACT project is part of a holistic strategy to combat counterfeit and falsified medical products in order to protect Public Health.
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 for verification of pharmaceutical medicines. The content of the service is a decision of the authorities. For this reason, the EDQM accepts no responsibility or liability whatsoever concerning but not limited to any direct or consequential loss or damage which may occur if you access or use the information on the website.

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

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
## Business intelligence tools (2)

![Service Usage - Commissioning Events](image)

<table>
<thead>
<tr>
<th>Year</th>
<th>Capture Source Location</th>
<th>GLN</th>
<th>Event Time</th>
<th>UMI EPC</th>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>Lab R</td>
<td>7601001394148</td>
<td>Feb 20, 2011 5:57:08 PM</td>
<td>umepcidiuril:7680209000037.0D620Y34K7XM77YYM491 umepcidiuril:7680209000037.0EC5WK0AY152D7MG8K8C umepcidiuril:7680209000037.0ETT3015CSM1MR7RN8G umepcidiuril:7680209000037.0EY70W9VGH5F3G603N7R umepcidiuril:7680209000037.0FSK5NFMK725E7G3E7A umepcidiuril:7680209000037.0GHV3HSE9FG3N6P6S9X umepcidiuril:7680209000037.0GR7801GWPKPPEP9EDPH umepcidiuril:7680209000037.0HGT7F8GC7MN0EX046X umepcidiuril:7680209000037.0HPDRX5SP5G5FCDF1EP9 umepcidiuril:7680209000037.0HRPDMA24A4K2V846AG umepcidiuril:7680209000037.0KVFPKRA14TG91RK65S umepcidiuril:7680209000037.0MS88E4TFM9H2KGV78GT umepcidiuril:7680209000037.0NEHR3STPY11H00WKEA umepcidiuril:7680209000037.0REH75E1REVDSAB1X umepcidiuril:7680209000037.0T49MP6PFBN230SCV12W</td>
<td>Minoxidil</td>
</tr>
</tbody>
</table>
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