FIGHTING COUNTERFEIT MEDICINES: the EDQM holistic strategy

François-Xavier LERY
Head of Section Pharmaceutical Care, Consumer Health Protection & Anti-Counterfeiting

The Council of Europe
Core values:
- human rights
- pluralist democracy
- rule of law

The EDQM
Council of Europe Directorate
Convention on the Elaboration of a European Pharmacopoeia (1964)
CoE/EDQM anti-counterfeiting strategy

Networking Health & Enforcement

MEDICRIME Convention

Inspection Testing

Mass serialisation

Regulatory background
Falsified Medicines Directive (FMD) 2011/62/EU

Safety features
- Identifier readable by wholesalers and pharmacies
- Tamper-proof device

Commission Delegated Regulation (EU) 2016/161
published 9 Feb 2016 to be implemented 9 Feb 2019
(except BE, GR, IT: + 6 years)

Systematic verification of safety features at dispensing
Risk-based verification by wholesale distributors
EMVS: European Medicine Verification System

Governance of EU mass serialisation system(s)

Supervisory role

Authorities

Establishment and management

Manufacturers Distributors Pharmacies

Supply chain
EMVO EDQM agreement on Conformity Assessments

Periodic conformity assessments of the European Medicines Verification System ("EMVS") and its governance by EDQM

Scope: European Hub and blueprint systems

Aim: systems designed, managed and operated in accordance with:
- standards described in the Delegated Reg.
- Falsified Medicines Directive 2011/62/EU
- other relevant state of the art standards

Timelines

<table>
<thead>
<tr>
<th>Year</th>
<th>Delegated Reg. implementation</th>
<th>Delegated Reg.</th>
<th>Conformity assessment activity</th>
</tr>
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<tbody>
<tr>
<td>2016</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2016-18</td>
<td></td>
<td></td>
<td></td>
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<td>2019</td>
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INITIAL FOCUS ON HUB
Core of the Repositories system

HARMONISATION OF SUPERVISION BY MEMBER STATES
Basis for agreement

EDQM experience, neutrality and independence
- primary trusted source for assessing medicines verification systems
- useful support to Member States for their future supervisory responsibilities

Until implementation of Delegated Reg., Conformity Assessment scheme on a voluntary basis:
- open to other systems

Goal = readiness for inspections by Member States (legal basis from Feb-19)

The Medicrime Convention

Convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health

First international treaty criminalising intentional acts:
- Manufacturing of counterfeit medical products
- Supplying, offering to supply & trafficking in counterfeit medical products
- Falsification of documents
- Unauthorised manufacture/supply/marketing of medical products not compliant with conformity requirements (‘similar crimes’)

protecting victims

promoting national & international co-operation
→ bridging health & criminal law
# The Medicrime Convention: Scope

## In scope

<table>
<thead>
<tr>
<th>Medical products:</th>
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<tbody>
<tr>
<td>• Medicines for human and veterinary use</td>
</tr>
<tr>
<td>• Medical devices, active substances</td>
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<tr>
<td>• Excipients, components &amp; accessories</td>
</tr>
<tr>
<td>• Trial / study medicines</td>
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<table>
<thead>
<tr>
<th>Counterfeit medical products:</th>
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<tbody>
<tr>
<td>• False representation of product identity/source (Convention, Art.4)</td>
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<tr>
<td>• Passing off as genuine, without connotation of Intellectual Property Rights (IPR)</td>
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<table>
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<tr>
<th>Similar crimes</th>
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<tbody>
<tr>
<td>• Products intentionally not in compliance with conformity requirements</td>
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</table>

## Out of scope

<table>
<thead>
<tr>
<th>Does NOT criminalise:</th>
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<tbody>
<tr>
<td>• Generic medical products authorised for being marketed by a competent authority</td>
</tr>
<tr>
<td>• Non-intentional breaches of quality norms, good practices / standards in the manufacture and distribution of medical products</td>
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<tr>
<th>Does NOT regulate:</th>
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<tr>
<td>• Production, distribution of medical products and businesses (e.g. internet pharmacies, brokers) where legal</td>
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</tbody>
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### Map of Countries that have signed the MEDICRIME Convention

**Signatures**
- Albania: 17/02/2015
- Andorra: 26/08/2011
- Austria: 26/08/2011
- Belgium: 02/07/2012
- Bosnia and Herzegovina: 06/12/2010
- Croatia: 09/09/2010
- Cyprus: 26/08/2011
- Denmark: 17/09/2012
- Finland: 19/10/2011
- France: 20/11/2011
- Germany: 26/08/2011
- Iceland: 26/11/2011
- Italy: 29/10/2011
- Israel: 11/11/2011
- Luxembourg: 12/02/2011
- Morocco: 18/02/2012
- Portugal: 20/10/2011
- Spain: 20/09/2011
- Switzerland: 26/08/2012
- Turkey: 29/06/2002

** Notifications**
- Armenia: 05/03/2006
- Greece: 20/09/2015
- Hungary: 06/08/2014
- Moldova: 14/08/2014
- Spain: 05/09/2013
- Ukraine: 25/08/2012

Global vocation – open for signature all over the world
MEDICRIME Article 18 – Preventive measures

Promotion of awareness-raising campaigns addressed to the general public

EDQM contribution: Psycho-pedagogical concept guide for teachers “Open Minds, Free Minds”

Using interactive storytelling as a teaching concept

Thank you for your attention!

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