Council of Europe activities to fight counterfeit/ falsified medical products & similar crimes

MEDICRIME Convention
Practical measures & assistance

IX Encuentro de Autoridades Competentes en Medicamentos de los Países Iberoamericanos (EAMI)

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Overview

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• 2. What are counterfeit medical products-similar crimes?
• 3. The problem is widespread...
• 4. What is a Council of Europe Convention?
• 5. What is the purpose of the MEDICRIME Convention?
• 6. Why should counterfeiting medicines-similar crimes be considered offences?
Overview

7. How does the MEDI CRIME Convention ensure co-operation between health-police-customs officials?

8. Is the MEDI CRIME Convention globally applicable?

9. What about criminals abusing the internet?

10. Follow-up and implementation?

11. Context – what is the Council of Europe?
   - Its role in criminal law?
   - The role of the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe
1. Key points: MEDI CRIME Convention

First international treaty

- **criminalising**: intentional
  - manufacturing of counterfeit medical products;
  - supplying, offering to supply and trafficking in counterfeit medical products;
  - falsification of documents;
  - the unauthorised manufacture or supply of medicinal products or the marketing of medical devices that do not comply with conformity requirements (‘similar crimes’)

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1. Key points: MEDI CRI ME Convention

**Protects patients** through preventing & combatting Counterfeiting of medicines & similar crimes

- Framework for **national and international cooperation**, 
- **Global vocation - open for signature by all states**
- Measures for crime prevention involving also the private sector
- **Active follow up of implementation**: Committee of the signatory states (“parties”)

- **28 October 2011**: Opening for signature, Moscow, RUF
- **20 September 2012-19 signatures**: AR, AT, BE, CH, CYP, DK, F, FIN, DE, ISR, ICE, IT, LUX, LIE, MD, PT, RUF, TRK, UKR - **ratified**
2. What is a counterfeit medical product/similar crime?

- **Counterfeit** medical product = false representation of product identity/source (label) (Art 4)
- **Similar crimes** = (slide 4)

- All types of medical products affected:
- the Convention covers:
- medicines for human & **Veterinary use, Medical devices**, active substances, excipients, components & accessories of medical devices, **trial/study medicines**.
- **Examples**
2. What is a counterfeit medical product/similar crime?

- **Criminal BEHAVIOUR** affecting: →
- products protected under intellectual property rights + generics + non-protected products

- **Important:**
- Counterfeit = false ("...passing of as genuine...") without connotation of Intellectual Property Rights (IPR)

- **Protection medicinal PRODUCTS, human use, & DISTRIBUTION CHAIN** from contamination with falsified medicinal products: ← EU Directive 2011/62 on Falsified Medicines
The MEDI CRI ME Convention does NOT target:

- (legal) generic medical products authorised for marketing by a competent authority (around the world)
- IPR-holders can seek legal recourse via specific IPR legislation.
- breaches of quality norms, good practices/standards in the manufacture and distribution of medical products (non-intentional)

does NOT regulate:

- production, distribution of medical products & businesses (e.g. internet pharmacies, brokers) where legal
3. The problem is wide spread.....

- Global threat for particularly vulnerable, patients, & health care system integrity
- Linked to organised crime
- Generates substantial profit – low risk of interception – mild penalties
- Abuse of the internet: not always obvious for users whether e-pharmacies operate legally

- MEDI CRI ME Convention legal framework for worldwide fight against counterfeiting medical products/similar crimes
3. The problem is wide spread.....
4. What is a Council of Europe convention ....

• **international criminal law treaty**
• binding for signatories
• follow-up of implementation
• MEDI CRIME Convention:
• **47** of Council of Europe member states, observer states, states having negotiated can sign

• **any other state in the world** can sign (invitation Committee of Ministers) & participate in international co-operation under the Convention.
5. What is the purpose....

- **PREVENT** and **COMBAT** medicrime through
  - criminalising offences,
  - protecting victims,
  - promoting national & international cooperation
6. Why is medicrime a criminal offence?

- **Genuine medical products**: highly trained professionals, strict controls by public authorities – ensuring best possible medication outcome.

- **Counterfeit medical products/similar crimes**: individuals or organisations - quick profit, risking health and undermining trust in authorities & healthcare systems.

- **Attack right to live** (European Human Rights Convention) – withholding possible treatment to patients
7. How cooperation of officials ensured...?

- **Art 17 /Art 22** ....**Legal minimum** for states parties
- **NATIONAL**: innovative concept: **points of contact**
  within the national health, medicines reference laboratories, police and customs authorities
- → exchange of information & assistance in the operational management of cases on a national level.

- **INTERNATIONAL**: **Single points of contact** (SPOCs)
  → trans-border co-operation with SPOCs from other countries (effective implementation/ follow-up Convention.

- **Best practice**: Model for a network between SPOCs
  (Council of Europe) (all countries encouraged to follow)
8. Criminals abusing the internet....

- 50% of medicines purchased on internet sites that conceal their real address are counterfeit. (WHO).

- The use of the internet for MEDI CRIME as an **aggravating circumstance**, raising the level of sanctions (Art 13).
9. Global vocation of the MEDICRIME Convention....

• All states affected by counterfeiting of medical products & similar crimes: production, transit, market place

• → the Convention is open for participation by non-member states upon invitation by the Committee of Ministers of the Council of Europe.

• The criminal law concepts and measures used in the Convention are globally applicable.

• July 2012: Guinea invited to sign

• Morocco: June 2012 requested to be invited to sign
10. Context: The Council of Europe

- Founded on 5 May 1949 by 10 states
- International organisation based in Strasbourg (France)
- Pan-European membership: 47 member states in Europe
- Observer states: Holy See, United States, Canada, Japan, Mexico
- Mr Thorbjørn Jagland, Secretary General since 1 October 2009 (Norwegian)
Human Rights... Democracy... Rule of Law

Objectives:

• to protect human rights, democracy and the rule of law;
• to promote awareness and encourage the development of Europe's cultural identity and diversity;
• to find common solutions to the challenges facing European society;
• to consolidate democratic stability in Europe by backing political, legislative and constitutional reform.
The Council of Europe
NOT to get confused with...

• **Distinct from the European Union**

• **European Council**: The EU's main decision-making body. It defines the general political direction and priorities of the European Union.

• **European Union (EU)**: It’s a unique economic and political partnership between 27 European countries ⇒ 498 million citizens.
Role in the **criminal law** field....

- Since 1958.... activities in the field of *crime prevention and crime control*.
- **The European Committee on Crime Problems (CDPC)** → priorities for inter-governmental legal co-operation, proposals to the Committee of Ministers on activities in the fields of criminal law and procedure, criminology and penology,
  - elaborates conventions, agreements, recommendations and reports
  - criminological research conferences and colloquia, and conferences of directors of prison administrations.
The EDQM European Directorate for the Quality of Medicines & HealthCare (EDQM)

Council of Europe Directorate General of Democracy

Vision: leadership in protecting public health by:
- enabling the development,
- supporting the implementation,
- monitoring the application

of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia is legally binding in European Union member states.
Convention on the Elaboration of a European Pharmacopoeia

.. international dimension: member states & observers
Current EDQM priorities **promoting medicines quality** & protection from **medicrime** ....

**Medicines of insufficient quality?**
Pharmacopoeia Europaea standards

**Counterfeiting of medical products and similar crimes (Medicrime)?**
risk management & prevention of medicrime
European Network: Official Medicines Control Laboratories (OMCL)
mass-serialisation services (eTACT) to protect the legal
production/distribution chain
support for the implementation of the MEDI CRI ME Convention

**Consumers’ unawareness of risks of buying medicines via unauthorised distribution channels & risk-taking behaviour?**
Recommendations for good practices for mail ordered medicines
Models for consumer awareness campaigns, risk-communication,
identification of signals of health damage
EDQM- Risk management & prevention of Medicrime

- Committee of Experts on minimising public health risks posed by counterfeiting of medical products & similar crimes
  - **Members:** states parties of the Convention on the Elaboration of a European Pharmacopoeia
  - Other Council of Europe member states; Consulting experts (hearings); Guest - experts

- **Tasks:**
  - 1. networking (health/law enforcement/Laboratory)
  - 2. risk management & prevention - tools/approaches;
  - 3. support for the implementation of national/international specific legislation (MEDICRIME Convention)
  - 4. training (for teams of health/law enforcement officials)
Committee of Experts on minimising public health risks posed by counterfeiting of medical products & similar crimes

- **1. Networking**
- **Model:** Network of SPOCs for combating counterfeiting of medical products and similar crimes involving threats to public health (2009 rev 2010)
1. Networking- Council of Europe Best practice Model

• (3.) Purpose
  • This model could provide a basis for countries reinforcing their existing networks or establishing a new national SPOC network. ...a multisectorial approach for detection, communication, investigation and prosecution. The lack of communication, information exchange and joint operational action between them gives the lead to the criminals, waste of time/ resources.

• (5. Objective, procedures..)

• (6.) Profile and function of a SPOC within the national network and for international cooperation
2. Risk management & prevention - tools/ approaches

A. Risk communication (models/publication)

- Link: “Risk communication model” on: www.edqm.eu – go to healthcare
  - How to minimise public health risks posed from counterfeit medical products/similar crimes
  “Risk communication-Medicrime”, 11/2011

B. Identification of signals of health damage (pilot study/tool)

- Tool identify, evaluate and report signals of health damage due to counterfeit/falsified medical products and similar crimes at the time of anamnesis

C. Inventory of experiences (analytical data) with confirmed cases of medicrime – OMCL network (database) – planned extension risk management information (other public administrations)
3. Support for the practical implementation of national/ international MEDICRIME Convention

- Council of Europe & Danish Health and Medicines Authority to boost the fight against medicrime in Europe & other regions of the world
- **International Conference, 16 May 2012 in Copenhagen**
- ...the conference adopted a structured approach supporting the implementation of the Council of Europe MEDICRIME Convention
- Step “O” identify co-operation partners
- Step “1”: make an analysis
- Step “2”: map next practical steps towards implementation...

- Link: [www.edqm.eu](http://www.edqm.eu) – go to healthcare/Medicrime Convention
4. Training....

**A vehicle** for know-how-transfer, networking, practicing tools/approaches, information exchange

**Aim:** ongoing training platform to support member states, health & law enforcement authorities

**Approach:**
- national teams of police, customs & health authorities
- evaluated & followed up by trainers’ board
- train the trainers approach – national authorities to co-organise with training platform regional/local training
- national authorities propose participants
- regular surveys of training needs & impact
- beginners & advanced level training
4. Training

**Results:** 2007 – ongoing **160** officials trained (Europe & other regions)

- **6** beginners training courses; **2** advanced level training courses
- Lisbon 2010 regional training: teams of health & enforcement officials from countries represented in the **EAMI**
- **in preparation:** specific training for SPOCs (December 2012); beginners’ training for CIS (November 2012)
- **Link:** “Counterfeit medicines training” on: [www.edqm.eu](http://www.edqm.eu) – go to healthcare
CoE/EDQM anti-counterfeiting strategy: Protection of legal product and legal chain

- Police, Customs & Health authorities
- Medicrime
- Inspection
- Testing
What is mass serialisation?

• Unique identifier
  ⇒ human readable
  ⇒ machine readable

• Distinguishes items from each other
EDQM Traceability service - eTACT

- Manufacture
- Distribution
- Pharmacy
- Internet Mail-order
- Patients

Generation of UMI = Unique Medicine Identifier

Traceability & Verification of UMI

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eTACT Why a Public Pan-European Governance Model (1)

- Confidentiality of data
  - Preventing conflict of interest between users and administrators of system
- Regulatory bodies to be integrated
- Different national systems without pan-European governance => lack of interoperability
- Cost control
  - phasing of implementation
  - economies of scale
- eTACT - Why a Public Pan-European Governance Model (2)
  
  - Extensive EDQM ability to guarantee confidentiality
  
  - Certification of Active Pharmaceutical Ingredients (APIs)
  
  - Preventing mass serialisation from being used for blurring the border between patient information and advertising
General overview of eTACT

Phase 1: Concept development

2a: System development

2b: Workshops

Phase 2: Live demo
2010 – 2012

Phase 3: Service development

2009-2010

From 2013

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eTACT Benefits

- Creates a harmonised approach
  - Inter-operable and flexible

- Protects confidentiality of data
  - Public governance

- Allows patients to verify their medicines
eTACT

- Medicrime (legal treaty) &
- an instrument for authorities and stakeholders, notably patients, to verify the authenticity of a medicine are two important preconditions for effectively combating and preventing counterfeiting of medical products.

The adoption of the MEDICRIME convention and EDQM’s traceability project, eTACT, are significant contributions to this fight.
Current EDQM anti-counterfeiting priorities.....

**pluriannual strategy 2012-2015**

- **Goals:**
  - Safe access to human/veterinary medicines for patients/consumers – empowered to avoid unsafe products
  - Support the implementation of the Medicrime Convention, focus on regulatory systems/procedures, interdisciplinary cooperation (e.g. SPOCs), drug enforcement
  - Know-how for officials – application Medicrime provisions & best practice models

- **Value:** value for states’ cooperation under Medicrime, synergies in protecting the legal chain and combating crime, establishment of strong evidence base for best practices, experiences, new criminal trends, harm, impact evaluation
Thank you for your attention!

More information:

www.coe.int
www.edqm.eu
www.coe.int/medicrime