

Falsified medical devices and what to do about it – a Council of Europe perspective

*Dr. Tomas Nilsson
Committee of Experts on Minimising Public Health Risks Posed by
Falsification of Medical Products and Similar Crimes
EDQM, Council of Europe*

Examples of falsified medical devices

- Dental equipment
- Self-tests (e.g. HIV/STI, pregnancy, blood glucose)
- Condoms
- Injection needles
- Dermal fillers
- Inhalers

What do I mean, falsified?

Falsified:

“A false representation as regards identity and/or source.”

Not involves **intellectual property rights**.

Seperate from **non-compliant**.

Over all strategies against falsified medical products



47 Member States
États membres

800 million Europeans
millions d'Européens



Observers:
Canada,
Holy See,
Israel,
Japan,
Mexico,
USA



Council of Europe
Conseil de l'Europe

www.coe.int



* "The former Yugoslav Republic of Macedonia"
** "L'ex-République yougoslave de Macédoine"

The MEDICRIME convention



Council of Europe Treaty Series - No. 211

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

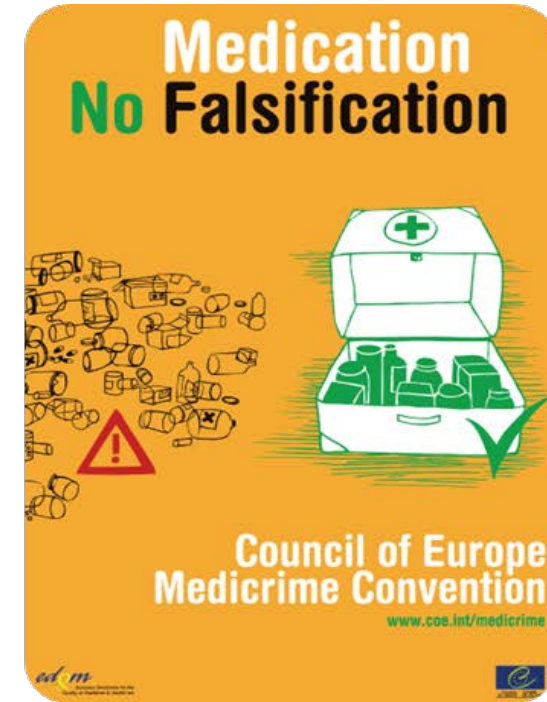
Moscow, 28.X.2011

The "MEDICRIME Convention" is the **first international criminal law instrument** allowing States Parties to

- **criminalise** certain acts,
- protect the rights of **victims**,
- promote **national and international cooperation**

MEDICRIME – examples

- **Criminalise** certain acts
(legislative)
- **Tools and resources** for
criminal investigations
(enforcement)
- Establish **quality and safety**
requirements (regulatory)
- Awareness-raising **campaigns**
(communication)
- Promoting **national and
international co-operation**
(co-operation)

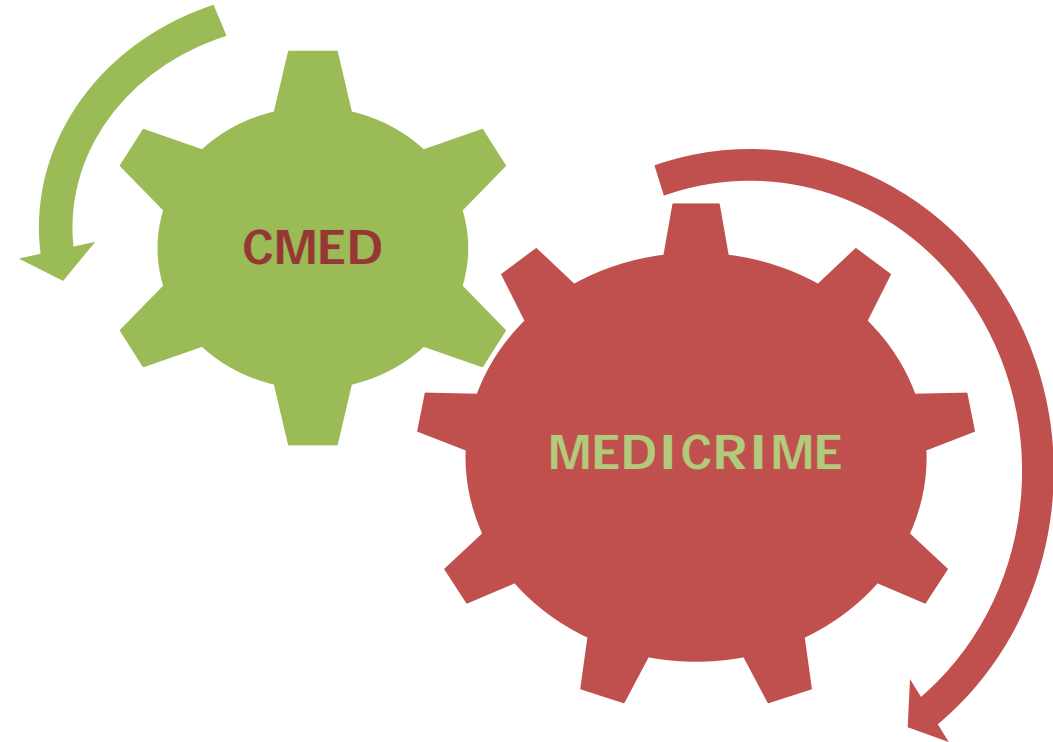


CMED & MEDICRIME

Committee of experts

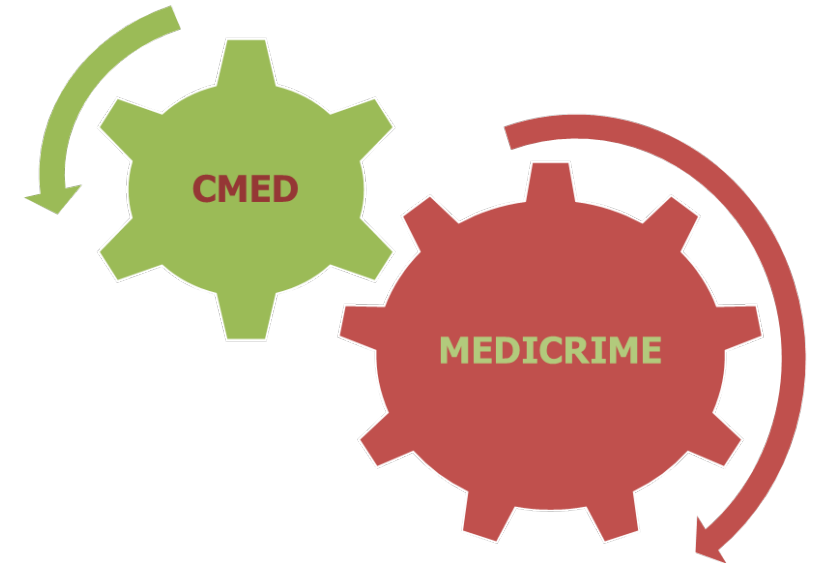
- Pharmacopoeia member states
- Health authorities, law enforcement or customs

CMED = Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes



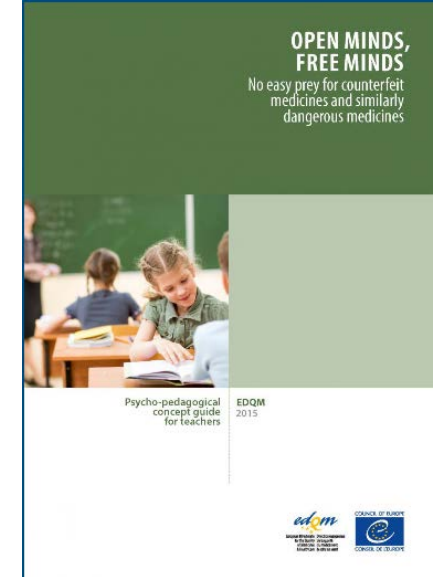
CMED – Key Tasks

- **Promote** the MEDICRIME convention and its Committee of the Parties
- Provide **support** for the convention's implementation
- **Facilitate networking** and co-operation among Member States
- Develop supportive **tools for information exchange**
- Communication and **raising awareness activities**, provide guidance to health authorities
- Establish and **maintain links** with national, European and international institutions and organisations
- Provide multi-sectorial **training**



CMED – Activities

- Conferences and workshops
- Single Point of Contact (SPOC) network
- Database for information sharing (KnowX)
- Implementation guidance
- Best practices
- Publications
- Communication materials
- Trainings



What about today?

- Crime?
- Priority?
- Knowledge?
- Co-operation?
- Sharing of information?



Survey to non-EU countries

Answers from

BA, IS, MD, ME, NO, RU, RS, CH, TR, UA

Do you experience falsified medical devices?

No: About half of the countries.

Survey to non-EU countries

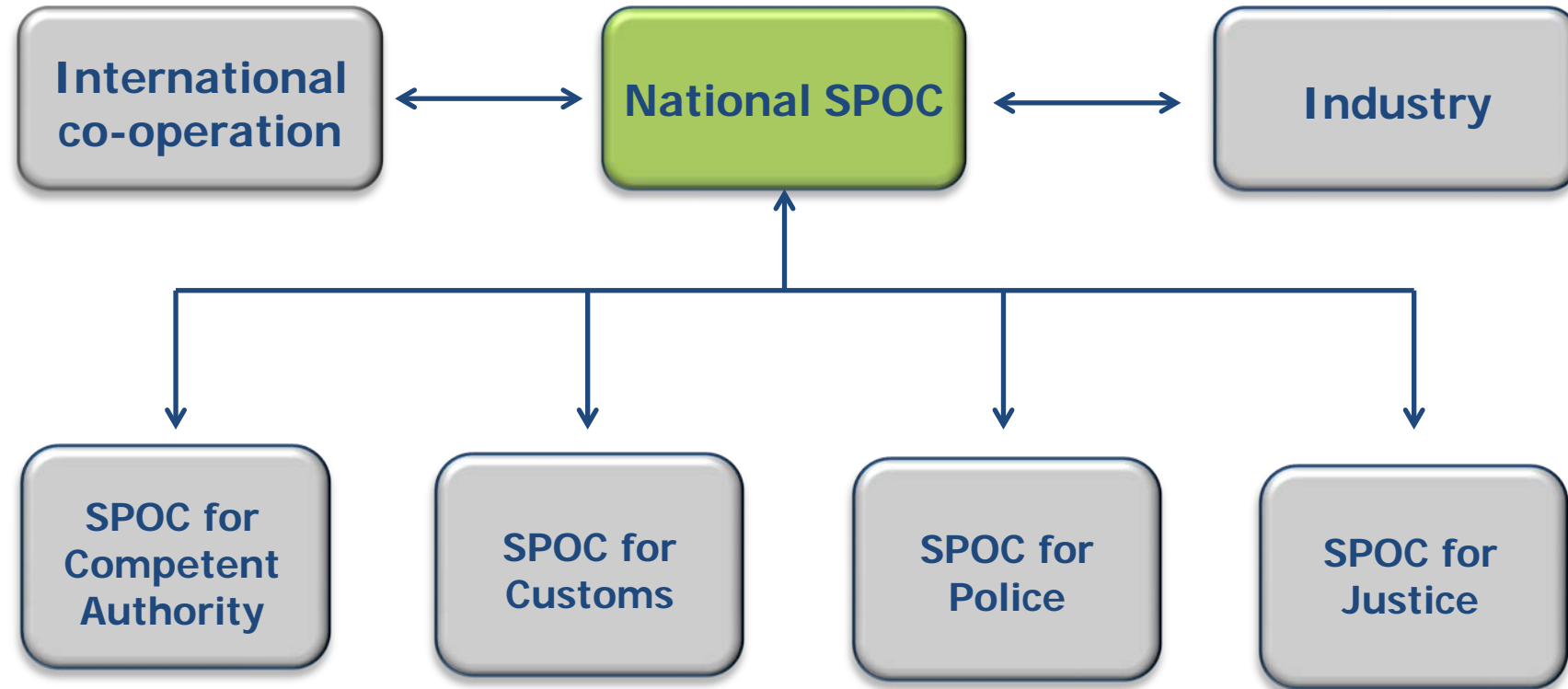
Do you contact the country of origin when handling imported non-compliant or falsified medical device?

- No country answered yes.
- Countries participating in COEN contact them.

Would you benefit from a closer cooperation with other countries within the Council of Europe regarding enforcement of non-compliant or falsified medical devices?

- All non-EEA countries answered yes.

SPOC Network – Model



Examples of needs

- How to implement Medicrime convention for MD (e.g. criminal acts)?
- Best practice of handling falsified MD (with no legal manufacturer or authorised representative)?
- Cooperation and information sharing?
- Awareness, e.g. healthcare?

Thank you for your attention



medicrime@edqm.eu

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