The Council of Europe and the fight against illegal and counterfeit (falsified) medicines

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Outline

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• How bad is it?
• What can authorities do?
• The Falsified Medicines Directive of the EU
• The MEDICRIME Convention of the CoE
• Appeal to ratification
What fight are we speaking about?

the fight against counterfeit / falsified and illegal medicines

What ‘s in a name? Let’s not fight about terminology!

Counterfeit /Falsified medicines are fake medicines that pass themselves off as genuine medicines with a marketing authorization issued by a competent regulatory authority, trying to mimic existing medicines by false representation of identity, source or history.

Illegal medicines are fake medicines that do not try to mimic the representation of authorized medicines.

All these counterfeit /falsified/illegal medicines have not been properly evaluated to check their quality, safety and efficacy as required by strict EU/ and national authorization procedures. They have to be considered as a danger to public health.
How bad is it?

Counterfeit/Falsified
How bad is it?

Illegal medicines

for instance adulterated food (supplements)
How bad is it?

Traffic in counterfeit/falsified/illegal medicines has become a new mechanism in organised crime making **easy money with relatively low risk and low sanctions** compared to drug trafficking for instance.

**WHO**

The traffic of counterfeited medicines is 25 x more profitable than the sale of drugs.

**FDA**

Counterfeited medicines ≈ 10 - 15% medicines world market (depending on regulatory system: 1%; 10-30%)
How bad is it?
How bad is it?

Pangea VII, May 2014:

one week yearly global operation targeting counterfeit and illegal medicines

- 111 countries worldwide participated
- 9.4 million counterfeit and illicit medicines seized during the operation: slimming pills, cancer medication, erectile dysfunction pills, cough and cold medication, anti-malarial, cholesterol medication and nutritional products.
- the seizure of nearly USD 36 million worth of potentially dangerous medicines.
- > 9,000 websites closed
What can authorities do?

We (need to) fight with two tools:


= PREVENTION by NEW RULES in ADMINISTRATIVE LAW

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

= PREVENTION, COMBATTING and SANCTIONING according to CRIMINAL LAW
The Falsified Medicines Directive
NEW regulatory measures for legal supply chain

• The EU has a strong legal framework for the licensing, manufacturing, distribution and dispensing of medicines (Directive 2001/83)

• Scope FMD: strengthening of existing legal framework by new measures for prevention of entry of falsified medicines into the legal supply chain:
  - on manufacturing of the Active Ingredient Control
  - on manufacturing of the final product:
    - Safety features: mass serial authentication of outer packaging (CoE participating)
    - Tamper proof
  - Identifying all actors in the supply chain, including brokers
  - a common, EU-wide logo to identify legal online pharmacies
FMD alone is not enough

Scope limited to medicinal products for human use on EU territory

But, criminals do not stop at borders of countries, or the EU:
« Les frontières poreuses » « internet » « street dealing »

Fighting organised crime requires national and international cooperation between drug regulatory authorities, police, customs, justice and industry

Medicines Laws is simply not made to deal with organised crime and does not foresee sanctioning as under criminal law
Medicrime Convention of the Council of Europe
The ideal complementary tool to FMD

**Broader Scope**

**Medical products**: medicinal products for human and veterinary use, clinical trial medicines, medical devices

**Action field** broader than European Union territory

**Crime = Counterfeit**: a false representation as regards identity and/or source

**Plus Similar Crimes**

- manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market **medicinal products without authorization or non conform MD’s**
- the commercial use of original documents outside their intended use within the legal medical product supply chain
Medicrime Convention of the Council of Europe

The ideal complementary tool to FMD

- Criminalisation
  - criminal offences and not just administrative ones
  - Creating a common legal space;
  - First international binding international instrument in the criminal law field on medical products
  - Aggravating clauses: organised crime; perpetuated via mass media (internet)

- Promoting national and international co-operation:
  between drug regulatory authorities, police, customs, justice and industry:
  provision not contemplated as part of FMD

- Protecting the rights of victims of the offences established under this Convention
SPOC network of the Medicrime Convention:
Belgian national SPOCs Network served as example

- Customs
- Drug regulatory Authority inclusive OMCL
- Justice
- Police
- Food regulatory authority

Cooperation between international SPOCs
FMD – Medicrime: two sides of a coin recent example from reality

Theft of expensive autorised anti-cancer medicines from hospitals and trucks in Southern European MS
Infiltration in legal circuit in Southern European MS after buying with fake invoices from fake wholesalers
in Eastern European MSs and distribution to several Western European MSs of
• the stolen product
• vials that had the anti-cancer ingredient criminally replaced by an anti-biotic (counterfeit)

Under the Medicines Law/Falsified Medicines Directive:
falsified: misrepresented as regards source
Measures to handle quality defects: Recall of the identified stolen or counterfeit batches
If safety features had been in place: possibly/probably? discovered earlier
Try to prove that involved wholesalers were aware of buying illegal medicines: offence is buying from
an unlicensed wholesaler = administrative offence

Measures possible if this case would have been handled under the Medicrime Convention =
counterfeit (falsified) : misrepresented as regards source

Theft and Manufacturing of counterfeit medicines are crimes
Unauthorised distribution is a similar crime
The Medicrime Convention of the Council of Europe

What does it take to get this powerful legal instrument to enter into force?

CoE Convention Number 211

Signature: 23 countries among which Belgium

Ratification: 5 needed of which 3 members of the CoE

Now 4 countries, Ukraine, Spain, Hungary, Moldova

Who will be the 5th?

This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five signatories, including at least three member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of the preceding paragraph.
Bearing in mind the Universal Declaration of Human Rights/ European Convention of Human Rights and Essential Freedoms

All States of the world can in principle sign and ratify the Convention.
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