

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

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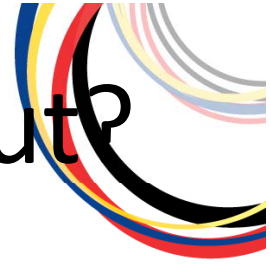


# Outline

- What fight are we speaking about?
- 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



Counterfeiters use sophisticated methods to copy genuine packaging.



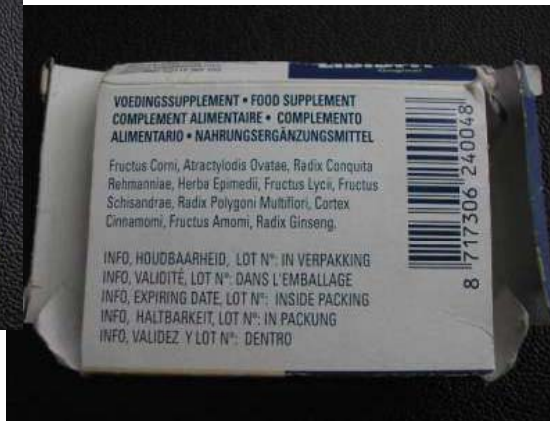


# How bad is it?



## 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  $\approx$  10 - 15% medicines world market (depending on regulatory system: 1%; 10-30%)



# How bad is it?



**MyCanadianPharmacy**  
WE SHIP TO ALL DESTINATIONS WORLDWIDE

ALL PRODUCTS LIST | ABOUT US | HOW TO ORDER | FA.Q. | CONTACT US

## Erection Pack

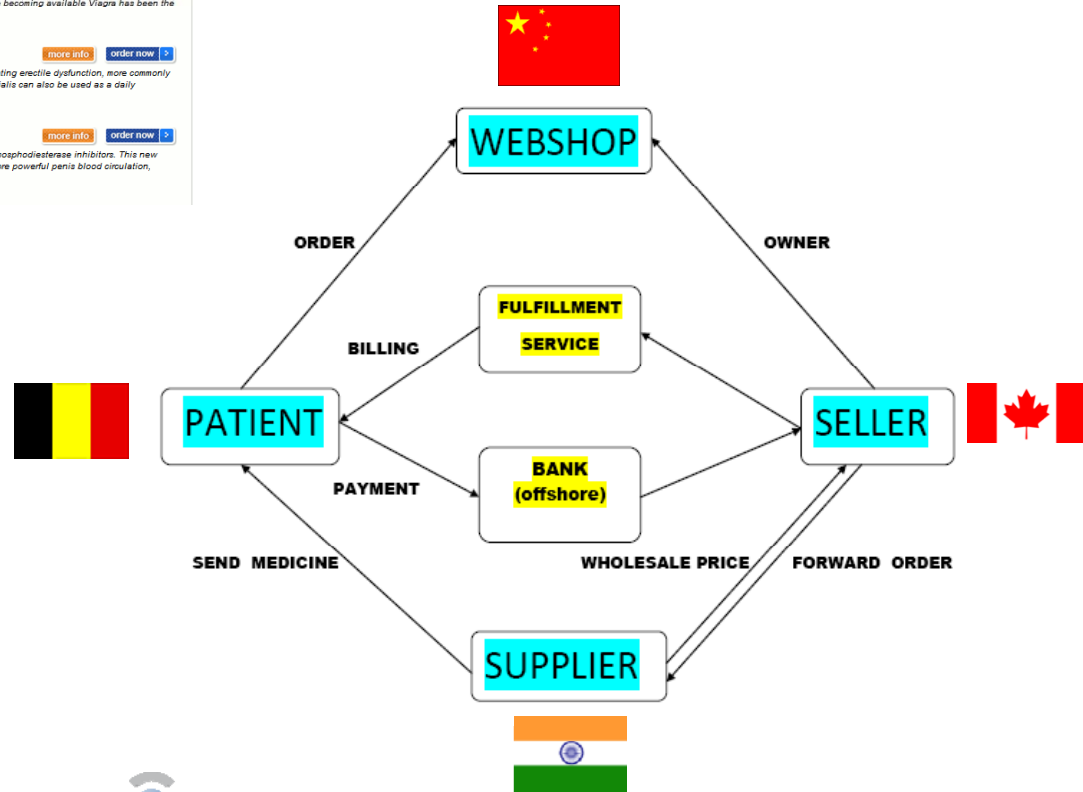
TIME LIMITED OFFER  
Two of the best ED medications in one super pack!  
The lowest price ever!  
Offer is valid till Mar 11, 2010 only!

10 PILLS + 10 PILLS  
VIAGRA + CIALIS = **\$74.95**

**ORDER NOW**

Most Popular Products

- Viagra as low as €1.24**  
Generic Viagra, containing Sildenafil Citrate, enables many men with erectile dysfunction to achieve or sustain an erect penis for sexual activity. Since becoming available Viagra has been the prime treatment for erectile dysfunction.
- Cialis as low as €1.61**  
Cialis is a highly effective orally administered drug for treating erectile dysfunction, more commonly known as impotence. Recommended for use as needed, Cialis can also be used as a daily medication.
- Viagra Super Active+ as low as €1.87**  
Viagra Super Active represents the fourth generation of phosphodiesterase inhibitors. This new formulation of a world-known medication provides even more powerful penis blood circulation, increased stamina and sensitivity to stimulation.



# 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:

## The Falsified Medicines Directive of the EU Directive 2011/62/EU

of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

= 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**

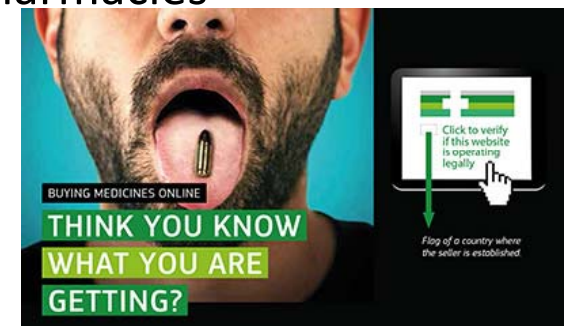


# The Falsified Medicines Directive

## 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

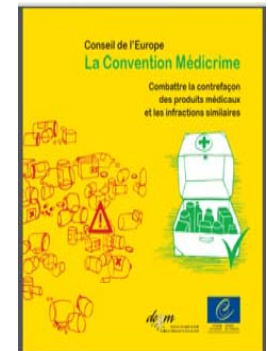
**Medical products:** medicinal products for human and veterinary use, clinical trial medicines, medical devices

**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; perpetrated 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

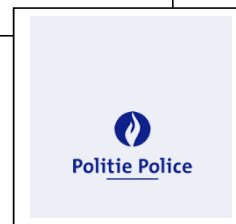
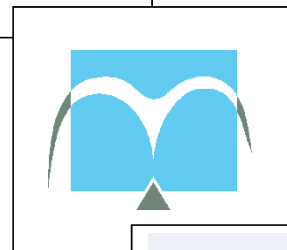
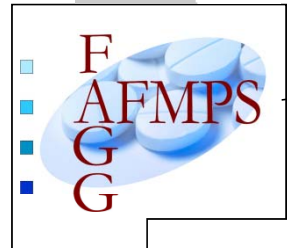
Drug regulatory  
Authority inclusive OMCL

Justice

Police

Food regulatory  
authority

Cooperation  
between  
international  
SPOCs



# FMD – Medicrime: two sides of a coin

## recent example from reality



Theft of expensive authorised 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.





# Status of signature and ratification



# Acknowledgements



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To the famhp's CEO, Mr Xavier De Cuyper, in appreciating the importance of hosting an enforcement unit at our Agency



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Senior Pharmacist Inspector

Head of the Special Investigation Unit

Co-founder of the Belgian SPOC network (multidisciplinary hormone unit)

One of the Founding Fathers of the Medicrime Convention

