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**Towards the Practical Implementation of the Council of
Europe Convention on Counterfeiting of Medical products
and Similar Crimes involving Threats to Public Health
(Medicrime Convention)**

International Conference, Basel 15 – 16 April 2010

KEYNOTE SPEECH

by

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Chair, ladies and gentlemen,

Counterfeiting of medical products is no small matter. On the contrary, it is big business for the shady entrepreneurs of organised crime. Today, it is estimated to be a multi-billion euro industry and even more profitable than trafficking in narcotic drugs. It is certainly far less risky for the criminals involved! In many countries the manufacture and trading in counterfeit medical products still carry only light sanctions, such as fines.

Decades ago governments and their law enforcement authorities all over the world have realised the threat posed to society by the trade and trafficking in narcotic drugs and have taken the appropriate measures to counter it both at national and international levels. Yet we are only recently starting to appreciate the horrendous threat to both individual and public health stemming from the falsification of medical products and similar crimes.

Unlike narcotics and psychotropic substances, we are all of us – every day – surrounded by medical products. From the pain killers we take against a headache to the plaster we apply to wounds or the contact lenses we wear to improve our eyesight. What if these products were falsified? What if they did not contain the right ingredients in the right dosage, or they contained toxics, or they were not sterile, or they were made of dangerous components? What if your medicine was produced, not in a sterile and controlled laboratory environment, but in a dirty shed doubling as a hen house?

Unfortunately there are good reasons to be cautious: The World Health Organization (WHO) has found that more than 50% of medicines purchased on Internet sites that conceal their real address are counterfeit. In countries without efficient regulatory control mechanisms, counterfeit medical products similarly account for more than 50% of the value of medicines in their markets.

Counterfeit medicines are so dangerous because they seldom contain the right ingredients or components, and even if the ingredients are right, the dosage is often wrong. You should count your blessings, if a falsified medicine you have taken is just a placebo made out of a harmless substance. Often the falsified or similarly dangerous medical products contain highly toxic substances - e. g. road paint in order to give a pill the right colour - that may easily lead to organ failure and death.

Let me give you an often cited, but iconic example of how dangerous and cynical this kind of crime is and the human tragedy it entails:

In December 2004, the otherwise healthy 22 years old Veronica Diaz from the Patagonian province of Rio Negro in Argentina went to her local hospital to get an injection of an iron supplement, which she had been prescribed in order to cure a mild case of anaemia. She had already received six injections out of a total of ten, but the seventh injection – far from curing her anaemia – proved fatal. In fact the injection produced severe liver damage that necessitated a liver transplant. Ms Diaz died on 23 December 2004, before the transplant could take place. In the same region of Argentina at least eight other women having received the same treatment had to be hospitalized, and in the province of Entre Rios a second fatality was reported.

Ms Diaz and the other women were victims of counterfeiters. Analysis of the counterfeit ampoules showed that instead of the proper active ingredient (iron sorbitol) they contained a concentration of an iron derivative three times as high as in the legitimate, original product. This was the reason for the liver failure. Though the Argentinean authorities succeeded in arresting and prosecuting some of the criminals responsible for the distribution of that counterfeit medicine, the counterfeiters themselves were never found and brought to justice.

It is accordingly high time that we take action against those cowardly criminals who are so willing to risk the lives of others for profit. For once, there are no grey nuances here – no shadows of doubt about what would be the right response.

The Council of Europe has prepared the first, international criminal law instrument against counterfeiting of medical products and similar crimes involving threats to public health – the Medicrime Convention. This is a Convention with a truly global reach, as it will also allow for the accession of non-member states, which is necessary due to the global scale of the problem.

I think, it would be appropriate here to give you some information on the work of the Council of Europe in the field of criminal law:

The European Committee on Crime Problems (CDPC), which is our steering body on criminal matters, was established already in 1958 and has a distinguished record of treaty making to its name. The Committee is mandated by the Committee of Ministers to oversee and coordinate the Council of Europe's activities in the field of crime prevention and crime control. These activities, which are dealt with by a number of expert committees under the CDPC, cover a whole range of topics from general issues such as mutual legal assistance in criminal matters and extradition of suspects to specialised criminal law conventions, recommendations and guidelines. In addition, the Committee deals with prison issues and law enforcement related questions in general.

The recent conventions elaborated by the CDPC cover such issues as cybercrime (where we are currently a world leader), trafficking in human beings, sexual abuse of children and now also falsification of medical products and similar crimes. As you can see, the Council of Europe has a long and successful history of assisting states in combating crime at international and national levels.

The Medicrime Convention targets the following crimes because of the danger they pose to public health:

- the manufacturing of counterfeit medical products;
- supplying, offering to supply and trafficking in counterfeit medical products;
- the falsification of documents linked to medical products;
- the unauthorised manufacturing or supplying of medicinal products and the marketing of medical devices that do not comply with conformity requirements.

The Medicrime Convention obliges Parties to ensure that sanctions imposed on convicted criminals are effective, proportionate and dissuasive. Knowing full well that the criminals are in this business for the money, the Convention also enables Parties to seize and confiscate materials used in the manufacturing process and proceeds from the criminal activities.

When it comes to defining the aggravating circumstances of an offence established under the Medicrime Convention, special emphasis is put on persons abusing their professional position in relation to the commission of the offence; on the offences of supplying or offering to supply being committed having resort to means of large scale distribution, including the Internet; on the fact that an offence was committed in the framework of a criminal organisation. All of these aggravating circumstances are hallmarks of the business of counterfeiting of medical products and the other dangerous practices covered by the Convention.

We are confident that the Medicrime Convention will prove to be a very useful criminal law tool for governments to crack down on this extremely dangerous and cynical form of organised crime.

If we do not act now – together – the already far too long list of victims of counterfeit or otherwise dangerous medical products will only grow. We must act now to avoid that our citizens' trust in the protection of public health is not further undermined. Most importantly, we must act to save lives, wherever we can!

I therefore call on you all to ensure that the sufferings of Ms Diaz and the countless other victims around the world have not been in vain. By working together, making use of the Medicrime Convention, we can now bring to justice those who manufacture and supply counterfeit medical products, or who engage in the similar crimes enumerated in the Medicrime Convention – no matter where they hide.

Thank you for your attention.
