

Council of Europe The Medicrime Convention

Combating counterfeiting
of medical products
and similar crimes



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European Directorate for the
Quality of Medicines & HealthCare

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE



What is a counterfeit medical product?

It is a product with a deliberately **false** representation of its identity and/or source, for example on its labelling or packaging. This is consistent with the connotation of “falsification”.



Counterfeiting of medical products and similar crimes involving threats to public health are a multi-billion euro industry which poses a major threat to those who are particularly vulnerable, the patients. The three examples of counterfeiting of medical products and similar crimes presented below show that these are a **problem of international proportions** which can have far-reaching and serious consequences, all the more so as these products are increasingly distributed via the **Internet**.



For over sixty years, the **Council of Europe** has been working to promote **quality** of medicines and emphasising its commitment in the fields of human rights and access to healthcare. The Council of Europe's **Medicrime Convention**⁺ is open to its member states as well as to states around the world. This innovative treaty opened for signature in October 2011 has been designed solely for protecting public health. It seeks to criminalise and sanction all acts related to counterfeiting (falsifying) of medical products and similar crimes.

⁺ Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME)

Some real examples of counterfeiting (falsification) of medical products and similar crimes involving threats to public health



Case 1

Counterfeiting (falsification) of a medicinal product

A counterfeit medicinal product for the treatment of high blood level of cholesterol was detected on the legal market in the United Kingdom in 2005. Pharmacies sold it to patients in good faith, believing it to be reliable. This counterfeit medicinal product presented a **risk** of serious side effects. It was detected by the UK regulatory authority, which identified the contaminated batch and took it off the market.

Case 2

Counterfeiting of a medical device

Counterfeit contact lenses were identified on the French market in 2004, on sale in opticians' shops. The lenses failed to correct short-sightedness and were also contaminated by *Pseudomonas aeruginosa* bacteria, which cause inflammation of the cornea. These counterfeit medical devices were identified following the investigation of consumer complaints of intolerance to the lenses and failure to correct vision.

Case 3

Sale of an illegal medicinal product, constituting a "similar crime"

A product presented as a dietary supplement was sold on the Swiss market without official authorisation. It was claimed to be effective in the treatment of cancer. This **claim** placed it in the "illegal medicinal products" category. Dietary supplements cannot be claimed to be effective in the treatment of disease. The product in question did not contain any pharmaceutical substance and was offered to pharmacists, doctors and patients. It was not "counterfeit" because there was no suggestion that it was any other product, but its medical claims were false. After warning the public, the authorities closed down the company.

 The term "medical product" includes medicinal products and medical devices.

What makes a counterfeit (falsified) medical product and similar crimes dangerous?

- the **quality** of the product is unverifiable: unexpected toxicity may come from the active ingredients, the excipients or the packaging (unsuitable plastic or glass).
- even if illegal products contain the same ingredients as the original product, uniform **distribution** of those ingredients is never guaranteed. Some batches may therefore have an excessive or insufficient dose of active ingredients.
- inappropriate storage conditions may lead to **deterioration** of the product.
- the **lack of active ingredients** is also a danger because the patient will be using an inactive medicine instead of a treatment appropriate to his or her condition. A counterfeit medicinal product is a silent killer and the consequences for the patient may be fatal.
- the use of counterfeit or illegally manufactured medicines **deprive legal industry** of revenues.



Why do we need the Medicrime Convention ?

Counterfeiting of medical products and similar crimes are **international crimes** which transcend borders and jurisdictions: a binding international treaty to protect public health is therefore necessary.

Counterfeiting of medical products and similar crimes need to be criminalised because of **the risk they represent for public health**. The treatment of disease is delayed because of the ineffectiveness of counterfeit medicines and illegal products and the proper treatment may be rendered useless because it is taken too late. Counterfeit medical products and similar crimes are silent killers because the patient will die from the underlying disease as a result of ineffective treatment. In such cases, nobody will look for counterfeiting as a possible cause.



The criminals who deliberately endanger the health and lives of patients and users, and in so doing undermine people's confidence in the public health system, therefore pose a very serious problem which all countries the world over must tackle as a matter of urgency.

Without an international treaty, the authorities responsible for public health could face legal difficulties in communicating and exchanging information not only with other official bodies at national or international level, but also with the public and private sectors.

From the criminal-law standpoint, most existing legislation has little deterrent effect. The emphasis is not on pharmaceutical crime and the risks to health. The criminals move quickly and operate in parts of the world subject to fewer controls where they can make substantial profits without any significant risk. If they are caught, they often face minor penalties for administrative offences or breaches of regulations, whereas they should be liable to dissuasive and proportionate penalties for criminal activities.



The Medicrime Convention in brief

On 8 December 2010, the Committee of Ministers of the Council of Europe adopted the new **Convention on the counterfeiting of medical products and similar crimes involving threats to public health**. This text clarifies the definition of counterfeiting of medical products and similar crimes at international level.

What is a counterfeit medical product?

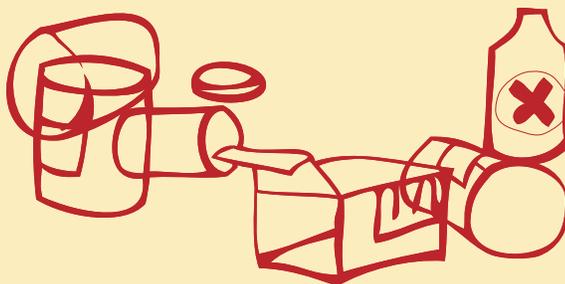
It is a product with false representation of its identity and/or source, for example on the packaging and labelling.

Therefore, its meaning is consistent with the connotation of falsification.

What are similar crimes?

The term “similar crimes” covers the production, keeping in stock, trafficking and offering for sale of medical products while intentionally bypassing the mandatory controls put in place by medical authorities; these crimes are as dangerous as counterfeiting itself and pose a comparable threat: for example, medical products used for doping and without a therapeutic indication are one of the outputs of “similar crimes” and are often counterfeit.

Counterfeiting and similar crimes affect all categories of medical products, whether or not they are protected by intellectual property rights and whether or not they are generic products, including accessories for use with medical devices and active ingredients, excipients, parts and materials used for manufacturing medical products.



⊕ **An international treaty to protect public health.** All countries across the globe are affected by the counterfeiting of medical products and similar crimes involving threats to public health. This form of crime is primarily international and the **Medicrime Convention remedies the lack of a specific international legal instrument in this field.**

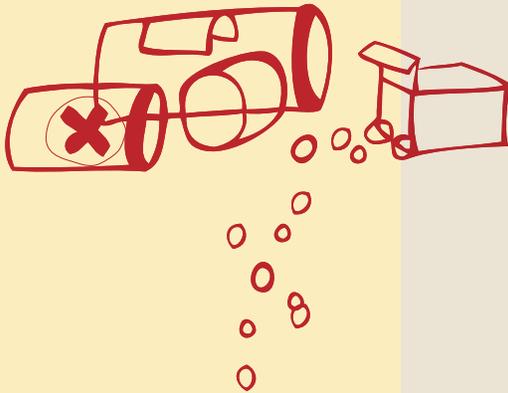
⊕ **Counterfeiting (falsifying) of medical products and similar offences are considered crimes.** Hitherto, they were treated merely as violations of intellectual property rights (manufacture of products resembling genuine products).

The new Medicrime Convention makes them **criminal offences**. Individuals or organisations manufacturing or distributing counterfeit products will be regarded as criminals seeking a quick profit to the detriment of the health and lives of patients and will be tried accordingly.

⊕ **New possibilities for international co-operation:** the convention proposes an innovative concept by requiring parties to set up points of contact within the health authorities, police and customs to exchange information and provide assistance for the operational management of cases at national level. Each country's points of contact will ensure international co-operation with their counterparts in other countries. This represents an asset for effective implementation and monitoring of the convention.

⊕ Persons suffering adverse physical or psychological effects as a result of using a counterfeit medical product or a medical product deriving from a similar crime may be recognised as **victims**.

The Medicrime Convention establishes the following as criminal offences:



- ⊗ the intentional **manufacturing** (Article 5) of counterfeit medical products, active substances, excipients, parts, materials and accessories, and any adulteration thereof.
- ⊗ the intentional **supplying** (Article 6) and trafficking of counterfeit medical products, active substances, excipients, parts, materials and accessories. The term “supplying” is understood to cover the acts of brokering, procuring, selling, donating, offering for free and promoting (including through advertising) these products.
- ⊗ the **falsification** of documents (Article 7) with the aim of deceiving the person reading or looking at the document into believing that the medical product, active substance, excipient, part, material or accessory, which the document accompanies, is legitimate and not a counterfeit.
- ⊗ similar crimes (Article 8) : the unauthorised manufacturing or supplying of medicines and the marketing of medical devices not meeting conformity requirements.
- ⊗ **aiding and abetting** the commission of these offences, and their **attempted commission** (Article 9).

What difference will the Convention make in practice?



Let us now go back to the three cases of counterfeiting of medical products and similar crimes presented previously and consider them in the light of the Medicrime Convention. New keywords bring a new perspective...

Case 1

Counterfeiting of a medicinal product for the treatment of high blood level of cholesterol

Case 2

Counterfeiting of a medical device: counterfeit contact lenses

Case 3

Sale of an illegal medicinal product, constituting a “similar crime”: a dietary supplement claimed to be effective in the treatment of cancer

The advantages of the Medicrime Convention

- ⊕ It brings legal clarity to the definition of what constitutes counterfeiting of medical products and similar crimes (previously there was no common definition which was legally binding at international level).
- ⊕ It establishes certain types of activity related to counterfeiting of medical products and similar offences as crimes liable to effective, proportionate and dissuasive sanctions (previously, many legal systems treated counterfeiting of medical products mainly as a violation of intellectual property rights).
- ⊕ It improves co-operation between legal and health authorities at national level (previously, information sharing between the different national authorities involved in the fight against counterfeiting of medical products and similar crimes could present difficulties, with the result that cases were poorly handled).
- ⊕ It improves co-operation between competent national authorities at international level, particularly through information sharing (previously, states did not have access to a dedicated multilateral and legally binding framework for co-operation in the fight against counterfeiting of medical products and similar crimes involving threats to public health).

What types of programmes are co-ordinated by the Council of Europe's EDQM at European level to combat counterfeit (falsified) medicines?

The European Directorate for the Quality of Medicines & Health Care (EDQM) co-ordinates a work programme **to protect public health against the dangers posed by counterfeiting of medical products and similar crimes through risk prevention and management strategies** and the enhancement of co-operation between member states and other stakeholders, in Europe and beyond.

Its current priorities include

- transferring know-how and proven practices between national health and law-enforcement authorities through specific training (since 2007),
- providing model approaches and strategies, in particular for explaining the risks to the general public,
- promoting a co-operation network between health and law-enforcement (police and customs) officials to protect public health,
- developing a specific information system to build knowledge and intelligence through systematic, structured analysis in order to provide governments with aids to decision-making in terms of risk management and prevention.

Findings are also shared with other organisations pursuing relevant initiatives at international level, such as the World Health Organisation (WHO).

As part of its anti-counterfeiting strategy, the EDQM has set up a number of operational projects.

The EDQM is exploring an **eTact service concept for traceability of medicines through mass serialisation**. Each pack of medicine will be provided with a Unique Medicine Identifier (UMI) allowing distributors, wholesalers, pharmacists and patients to verify the authenticity of a medicine by means of a secure UMI database.

The EDQM is also setting up a **secure database of "fingerprints" (or signatures) of active substances and excipients used in the manufacture of medicines**. The fingerprints, which describe the profile of an active substance or excipient in order to identify the source of a medicine, are established by analytical methods. This database will help Official Medicines Control Laboratories (OMCLs) to detect counterfeit substances and provide decision-making bodies with relevant evidence.

What is the EDQM's mission within the Council of Europe?

Within the Council of Europe, the **EDQM's mission** is to contribute to the basic human right of access to good-quality medicines and health care, and to promote and protect human and animal health by:

- establishing and providing official standards which apply to the manufacture and quality control of medicines in all signatory states of the Convention for the Elaboration of a European Pharmacopoeia and beyond,
- ensuring the application of these official standards to substances used for the production of medicines,
- co-ordinating a network of Official Medicines Control Laboratories (OMCLs) to collaborate and share expertise between member states and optimise the use of available resources,
- establishing ethical and quality standards for the collection, storage and use of blood components relevant to blood transfusion and for organ transplantation, including tissues and cells,
- collaborating with national and international organisations in efforts to eliminate counterfeit medicines and illegal medical products,
- providing policies and model approaches for the safe use of medicines in Europe, including guidelines on pharmaceutical care,
- establishing standards and co-ordinating controls for cosmetics and food packaging.

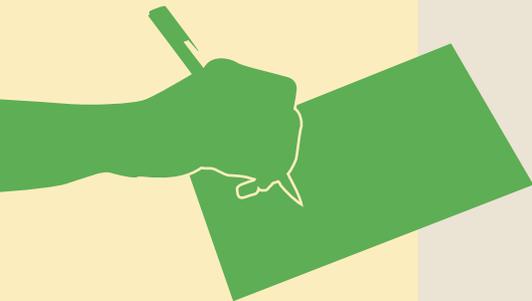


What is the Council of Europe's role in the criminal-law field? ?

Since 1958, the Council of Europe has carried out numerous activities in the field of crime prevention and crime control.

The European Committee on Crime Problems (CDPC), in which all member states of the Council of Europe are represented, identifies priorities for intergovernmental legal co-operation, makes proposals to the Committee of Ministers on activities in the fields of criminal law and procedure, criminology and penology, and implements those activities.

The CDPC draws up conventions, agreements, recommendations and reports. It organises criminological research conferences, criminological colloquia and conferences of prison directors.



The Council of Europe's mission

With its 47 member states, the Council of Europe, based in Strasbourg (France), covers virtually the entire European continent. Established on 5 May 1949 by 10 founder states, the Council of Europe aims to promote a common democratic and legal area in Europe, organised around the European Convention on Human Rights and other reference texts on protection of the individual.



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Editorial direction: Public Relations and Branding Division in co-operation with the European Directorate for the Quality of Medicines & Health Care (EDQM) and the Directorate General I - Human Rights and Rule of Law

Design : www.insecable.com

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