Factsheet

Counterfeit medical products and similar crimes

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Key points

The Council of Europe has drawn up the first international treaty against counterfeit medical products and similar crimes involving threats to public health, the MEDICRIME Convention, to establish as offences:

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

The Convention also lays down a framework for national and international co-operation between the competent health, police and customs authorities on both the national and international levels, measures for crime prevention by also involving the private sector, and the effective prosecution of crime and the protection of victims and witnesses. Furthermore, it provides for the establishment of a committee of the Parties to follow up the implementation of the Convention by the signatory states.

On 8 December 2010, the Committee of Ministers of the Council of Europe - representing 47 states in Europe - adopted the MEDICRIME Convention and invited the Secretary General to disseminate the Convention widely among non- member states that may be interested in becoming parties, in particular among those states with observer status with the European Pharmacopeia Commission. The Committee of Ministers decided to open the Convention for signature on 28 October 2011, at the occasion of a high-level thematic conference in Moscow. To date, 23 states have signed the MEDICRIME Convention amongst those 3 states outside of Europe, Guinea, Morocco and Israel.

As the counterfeiting of medical products and similar crimes constitute a global threat, the Convention is open to member and non-member states of the Council of Europe, as has been the case for other recent conventions. Therefore, the MEDICRIME Convention offers a legal framework for world-wide co-operation to combat the counterfeiting of medical products and similar crimes involving threats to public health.

Questions and Answers

What is a counterfeit medical product? What are similar crimes?

The Convention defines a "counterfeit medical product" as a medical product whose identity, and/or source are fraudulently misrepresented, including on the label.

"Similar crimes" are understood as the production, stock-piling, trafficking, offering for sale of medical products intentionally by-passing the obligatory supervision/control of medicines authorities: these crimes are as dangerous as counterfeiting and pose a threat of a comparable dimension. Medicinal products used for doping and without a medical indication are one of the outputs of "similar crimes", as are products offered for treatment of diseases without prior benefit risk analysis and authorisation of the competent drug regulatory authorities.

Counterfeiting and similar crimes potentially concern all kinds of medical products - medical products available without prescription and medicines for life-threatening disorders. Medicinal products for human and veterinary use, clinical trial medication for patients and healthy test persons, medical devices, active substances, excipients, components and accessories of medical devices are covered.

The legal concepts and definitions used in the Convention are fully compatible with other internationally recognised concepts and definitions. In particular, for the purposes of the Convention, it should be noted that the term "counterfeit" corresponds to the term "false" without the connotations to intellectual property rights sometimes associated with "counterfeit".

Therefore, preference for the term "counterfeiting" or "falsification with criminal intent" will not pose an issue for the use of the Convention.

How widespread is the problem?

Public health threats related to counterfeit medical products and similar crimes have now reached truly global proportions. Counterfeiting is a multi-milliard euro business that poses a major threat to patients, already particularly vulnerable. It is often linked to organised crime and generates substantial profits with low risk of being intercepted and relatively mild penalties in comparison to e.g. trafficking of narcotic drugs. Counterfeiting of medical products and similar crimes affect all countries, whether as countries of origin, transit or marketplace. As with all clandestine criminal activities, it is impossible to gauge exactly the extent of the problem. Recent estimates suggest that global sales of counterfeit medicines are worth more than € 57 milliard, having doubled in just five years between 2005 and 2010. Numerous studies have also reported large numbers of websites supplying prescription-only medicines without a prescription and people buying medicines online despite being aware of the dangers.

According to statistics from customs authorities in the European Union (EU), the number of medical products seized at the outer border of the EU (not counting patent issues) tripled between 2006 and 2009 to reach approximately 7.5 million. Medicines accounted for 10% of all seized materials in 2009.

Other statistics from customs authorities in the EU appear to confirm that sales of medicines via the internet have increased. Nearly 69% of articles seized in postal traffic were medicines. However, there are no reliable statistics on the number of counterfeit medicines reaching consumers through unregulated sources such as illegal online pharmacies.

The MEDICRIME Convention: a Council of Europe international criminal law treaty

The 47 states in Europe that are members of the Council of Europe, as well as states in other regions of the world, can sign and ratify the Convention and thus join the international co-operation under the Convention.

The MEDICRIME Convention applies to <u>all</u> medical products, i.e. products claiming that they can be used for diagnosing or treating or preventing a disease, and the various ingredients, parts and materials they are made of - regardless of whether or not these medical products are protected under intellectual property rights or are generic.

Activities OUTSIDE the scope of the MEDICRIME Convention:

- The Convention cannot be used against (legal) generic medical products authorised for being marketed by a competent authority. It is an important and essential concept of the Convention that legal "generic" medical products (i.e. a "legal copy of a patented, branded, trademarked product") are not subject to criminalisation under the Convention. Mere violations of the rights of owners of patents, brands and trademarks ("intellectual property rights – IPR") of medical products which are authorised by a competent authority for being placed on the market are not covered by the Convention.

  The Convention does not in any way hinder IPR holders from seeking legal recourse via the specific legislation applying to IPR.

- Breaches of quality norms, good practices and standards in the manufacture and distribution of medical products are not subject to this Convention as long as they are not carried out with criminal intent.

- The Convention does not regulate the production and distribution of medical products under legal circumstances, and under which circumstances businesses (e.g. internet pharmacies, brokers) legally operate. Therefore, it does not interfere in any way with the freedom of the internet as long as it is not misused by criminals for unlawful activities.

What is the purpose of the MEDICRIME Convention?

The Convention provides States Parties with a powerful tool to combat the counterfeiting of medical products and similar crimes from the perspective of the protection of patient health and users of medical products, the introduction of common minimum standards on substantive and procedural criminal law, as well as provisions aimed at improving co-operation and information exchange between the competent authorities at both national and international levels.

With the adoption of an innovative concept ensuring that points of contact exist within the national health, medicines reference laboratories, police and customs authorities, the Convention will ensure the exchange of information and assist in the operational management of cases at the national level. A single point of contact (SPOC) in each country will ensure trans-border co-operation with other SPOCs and also be of value for the effective implementation and follow-up of the Convention.

Why should the counterfeiting of medical products and similar crimes be considered a criminal offence?

The manufacture of genuine medical products is done by highly-trained professionals and takes place under strict public authority control - all to ensure that the lives of patients and users are not put at risk and the best possible medication outcome can be achieved.

In contrast, counterfeit medical products are manufactured by individuals or organisations solely seeking a quick profit, without having any interest in the health of the patients and those buying their products. Hence, inactive ingredients, wrong dosages and even harmful substances are often used in the manufacturing process.

Intentionally putting the health and lives of patients and users at risk in this way – and, in the process, undermining trust in public health systems – is thus a very serious matter that states all over the world must urgently address, including through criminal law measures, in order to be able to bring the criminal individuals and organisations involved to justice, to seize any

proceeds from the crime and to protect public health.

How can the MEDICRIME Convention be used against criminals abusing the internet for counterfeiting and similar crimes?

Counterfeiters and their associates in crime often make use of the internet to promote counterfeit and otherwise dangerous medical products. The World Health Organization (WHO) has found that over 50% of medicines purchased on internet sites that conceal their real address are counterfeit. The domestic courts of law of States Parties to the Convention may consider the use of the Internet as an aggravating circumstance and raise the level of sanctions correspondingly, where appropriate.

How does the Convention protect the integrity of healthcare systems and prevent waste of scarce healthcare resources?

In many countries of the world counterfeiting of medical products and similar crimes results in enormous waste of scarce healthcare resources and fuels other illegal activities to the detriment of social security and prosperity. Combatting these crimes will support sustainable development and free up resources for social welfare.

Is this a global instrument or is its usefulness limited to Europe?

All states around the world are affected by the counterfeiting of medical products and similar crimes involving threats to public health. Hence, the Council of Europe has decided to open the Convention to participation by non-member states upon invitation by the Committee of Ministers of the Council of Europe. The criminal law concepts and measures used in the Convention are globally applicable.

What is the role of the Council of Europe and its European Directorate for the Quality of Medicines & HealthCare (EDQM) in assisting states to combat counterfeiting and similar crimes and to implement the MEDICRIME Convention?

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) elaborates conventions, agreements, recommendations and reports in the fields of criminal law and procedure, criminology and penology, implements these activities and makes proposals to the Committee of Ministers.

The mission of the EDQM is to contribute to health, a social human right, through access to good quality medicines and healthcare, and to promote and protect human and animal health. In line with the spirit of the MEDICRIME Convention ranking high the prevention of counterfeiting of medical products and similar crimes besides combating such crimes, the EDQM co-ordinates the work of bodies, such as the Committee of Experts on minimising public health risks posed by counterfeiting of medicinal products and similar crimes to protect public health: through risk management and prevention of such crimes, and improved co-operation of member states and other stakeholders in Europe and beyond. It develops specific risk management and prevention approaches, improves cooperation between member states and stakeholders, and collaborates with national and international organisations.

The Committee of the Parties run by the Signatory states may make use of the expertise and

working results co-ordinated by the Council of Europe and its EDQM to support the follow-up of the Convention after its entry into force.

What other reference texts does the Council of Europe have in this field?

- Resolution ResAP(2001)2 of the Committee of Ministers concerning the pharmacist's role in the framework of health security.
- Resolution ResAP(2007) 2 on good practices for distributing medicine via mail order.
- PACE Recommendation 1673 (2004) on counterfeiting: problems and solutions.
- A Council of Europe survey on counterfeit medicines (2006).
- A model for a network and single points of contact (2007).
- PACE Recommendation 1793 (2007) on the need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods.
- PACE Recommendation 1794 (2007) on the quality of medicines in Europe.

A practical guide, available in several languages, to enable users to distinguish between reliable and unreliable medical information and warn them about the risks they run if they buy medicines on-line.

More information

www.coe.int/medicrime and www.edqm.eu

Press contact

Estelle Steiner, Media Officer
Tel.: +33 (0)3 88 41 33 35
Mobile: +33 (0)6 08 46 01 57
estelle.steiner@coe.int

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