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The MEDICRIME Convention: criminalizing the falsification of medicines and similar crimes

Susanne Keitel, PhD

Trade in falsified/counterfeit medical products is a growing global criminal industry, posing a major threat to patients and healthcare systems. Falsified/Counterfeit medical products circulate via unregulated channels, especially the Internet. The Council of Europe's 'Convention on counterfeiting of medical products and similar crimes involving threats to public health' [1] is the first international treaty that establishes a legal framework for combating this trade. It provides for the criminalization of certain acts, protects the rights of victims of the offences, and promotes national and international cooperation.

Keywords: Council of Europe, counterfeit medicines, criminalization, falsified medicines, international treaty, MEDICRIME convention

Introduction

Threats to public health related to falsified/counterfeit medical products and similar crimes have now reached truly global proportions. Trade in falsified/counterfeit medical products represents a multi-billion euro industry that poses a major threat not only to patients, who are particularly vulnerable, but also to the integrity of healthcare systems. It is often linked to organised crime and generates substantial profits, with a low risk of being intercepted and relatively mild penalties in comparison, for example, to the trafficking of narcotic drugs.

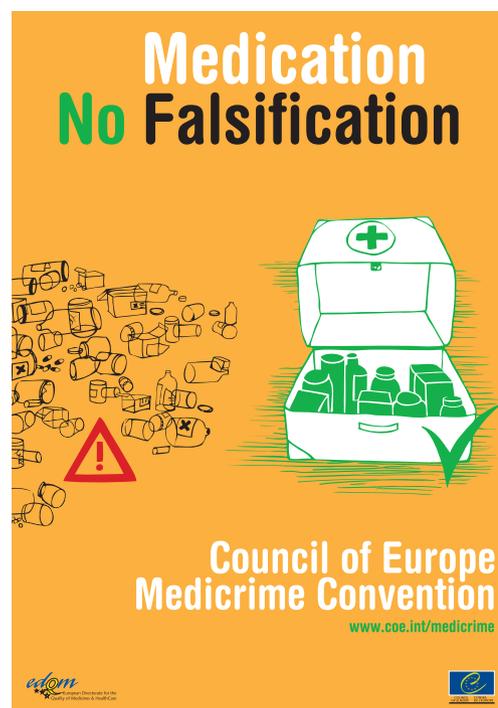
Falsification/Counterfeiting of medical products and similar crimes affect all countries, be it as countries of origin, transit or marketplace. As with all clandestine criminal activities, it is impossible to gauge exactly the extent of the problem. According to World Health Organization (WHO), falsified/counterfeit medical products account for less than one per cent of market value in developed countries, where there are efficient regulatory control mechanisms [2]. But many countries in Africa and parts of Asia and Latin America have areas where more than 30 per cent of the medicines on sale can be counterfeit, while in many of the countries of the former Soviet Union the proportion of falsified/counterfeit medicines is over 20 per cent of market value [3].

Falsified/Counterfeit medicines and devices circulate globally via unregulated channels, especially through widespread use of unauthorised online pharmacies, due to the fact that it is not always obvious for users whether e-pharmacies operate legally. Estimates suggest that global sales of counterfeit medicines were worth US\$75 billion (approximately Euros 60 billion) in 2005 and were expected to double in just five years between 2005 and 2010 [4]. 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 [4].

A 2008 report by the European Alliance for Access to Safe Medicines found that 62 per cent of medicines ordered online and without a prescription were substandard and/or counterfeit (68 per cent were unlicensed imitations; the rest were counterfeit

branded medicines). Even among the 38 per cent of genuine medicines, 16 per cent were illegal non-EU imports and 33 per cent had no patient information leaflet [4].

The Council of Europe's 'Convention on counterfeiting of medical products and similar crimes involving threats to public health' (MEDICRIME Convention), adopted on 8 December 2010, establishes a legal framework for the worldwide fight against falsified/counterfeit medical products and similar crimes, applying a three-fold focus: providing for the criminalisation of certain acts, protecting the rights of victims of the offences established under the Convention, and promoting national and international cooperation (*Article 1*).



Author: Susanne Keitel, PhD, Director, European Directorate for the Quality of Medicines and Healthcare, Council of Europe, 7 allée Kastner, CS 30026, FR-67081 Strasbourg, France

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The Council of Europe's contribution to the solution

The Council of Europe (CoE), founded in 1949 by 10 states, now has 47 Member States spanning the whole of Europe, and as observers Canada, Holy See, Israel, Japan, Mexico and USA. Building on its values, which include protecting human rights and the rule of law, and finding common solutions to the challenges facing European society, the CoE has been active in the field of crime prevention and crime control since 1958. The CoE's European Committee on Crime Problems identifies priorities for intergovernmental legal cooperation; makes proposals to the Committee of Ministers (its decision-making body) on activities in the fields of criminal law and procedure, criminology and penology; elaborates conventions, agreements, recommendations and reports; and organises criminological research conferences.

The CoE has drawn on this rich experience and its cooperation with national and international bodies involved in combating falsified/counterfeit medicines—including EU agencies, WHO and the OECD—in elaborating the MEDICRIME Convention, using criminal law concepts and measures that are basic and globally applicable. Reflecting the global impact of the problem of falsified/counterfeit medical products and similar crimes, the Convention is open for ratification by any country in the world, including major producer countries such as China and India, upon invitation by the Committee of Ministers (*Article 28*).

Definitions and scope

The MEDICRIME Convention defines the term 'counterfeit' as 'a false representation as regards identity and/or source' (*Article 4*), and 'similar crimes' as the unauthorised manufacture or supply of medicinal products or the marketing of medical devices that do not comply with conformity requirements (*Article 8*).

The Convention's broad definition of counterfeit medical products is matched by its wide scope, which 'concerns medical products whether they are protected under intellectual property rights or not, or whether they are generics or not' (*Article 3*) and includes medicines for human and veterinary use, medical devices, active substances, excipients, components and accessories of medical devices, and medication used in clinical trials or studies. This broad scope will, for example, allow gaps to be filled in national legislation in cases where criminal and administrative liability for the manufacturing, distributing and selling of counterfeit medicines is not covered by current trademark and patent legislation ('falsified medicines').

However, one important and essential concept of the MEDICRIME Convention is that it cannot be used against (legal) generic medical products, i.e. ones authorised for marketing by a competent authority. Also, 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 marketing, are not covered by the Convention. The Convention does not in any way hinder IPR holders from seeking legal recourse via specific legislation applying to IPR. Breaches of quality norms, good practices and standards in the manufacture and distribution of medical products that are committed without criminal intent are also not subject to the Convention, nor does the Convention regulate



the production and distribution of medical products under circumstances that are legal in domestic law, e.g. legal Internet pharmacies.

Meeting a global need

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

On the other hand, falsified/counterfeit medical products are manufactured by individuals or organisations solely looking for a quick profit, without any interest in the health of the patients and users buying their products. Hence, no or wrong ingredients, wrong dosages and even toxic substances are often used in the manufacturing process, which typically takes place in an unhygienic and dangerous environment as production costs are kept to a minimum.

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 an attack on the right to live under the European Convention on Human Rights (withholding possible treatment to patients). States all over the world must address this urgently through criminal law measures, in order to be able to bring the criminal individuals and organisations involved to justice, seize any proceeds from the crime and protect public health.

The MEDICRIME Convention is the first international treaty that establishes as offences with criminal intent: the manufacturing of falsified/counterfeit medical products (*Article 5*); supplying, offering to supply and trafficking in falsified/counterfeit medical products (*Article 6*); the falsification of documents (*Article 7*); 'similar crimes' (*Article 8*); and aiding and abetting the commission of crimes under the Convention (*Article 9*). It aims to both prevent and combat 'medicrime' by providing for sanctions and measures that are 'effective, proportionate and dissuasive' (*Article 12*).

The need for effective policing

Care has been taken to lay down the framework for effective policing of the MEDICRIME Convention. Each state that is party to it must take the necessary legislative and other measures to ensure exchange of information and cooperation between health authorities, customs, police and other competent authorities in the operational management of cases on a national level (*Article 17*). Similarly, special provision is made for international cooperation on policing and legislation (*Article 21*), and effective implementation is aimed for through the designation

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of single points of contact (SPOCs) for cross-border cooperation (*Article 22*).

The role of the Internet in the global trade in falsified/counterfeit medical products is the subject of particular focus, among other things reflecting the fact that WHO figures show that 50 per cent of medicines purchased on Internet sites which conceal their real address are counterfeit. The MEDICRIME Convention therefore defines the use of the Internet related to falsification/counterfeiting as an aggravating circumstance, raising the level of sanctions (*Article 13*), without reducing the freedom offered generally by the Internet.

Impact on patients

Patients and other users of medical products are given strong protection by the MEDICRIME Convention. A victim of crimes under the Convention is defined very broadly as 'any natural person suffering adverse physical or psychological effects as a result of having used a counterfeit medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8' (*Article 4*).

The rights and interests of victims are protected in particular by: ensuring that victims have access to information relevant to their case and which is necessary for the protection of their health; assisting victims in their physical, psychological and social recovery; and providing for the right of victims to compensation from the perpetrators in domestic law (*Article 19*). Parties to the Convention must also take the necessary legislative and other measures to protect the rights and interests of victims at all stages of criminal investigations and proceedings, including providing full access to information regarding those proceedings, access to proper legal representation (and legal aid if necessary), and protection against intimidation (*Article 20*).

Impact on healthcare professionals

Overall, the MEDICRIME Convention is designed to strengthen public confidence in health authorities and healthcare systems. By ensuring the quality, safety and distribution of medical products—a prerequisite for safe health care and practices—the high value of service provided is protected and enhanced.

In particular, the Convention calls among other things for the training of healthcare professionals and providers in the matter of prevention of counterfeiting, in tandem with awareness-raising campaigns for the general public (*Article 18*). Also, the Convention treats an offence committed by persons abusing the confidence placed in them in their capacity as professionals as an aggravated circumstance (*Article 13*).

Impact for industry

As part of its focus on protecting public health, the MEDICRIME Convention includes measures which enhance the legal distribution chain.

As well as establishing the falsification of documents (e.g. customs documents, invoices, certificates, labelling) as offences (*Article 7*),

the Convention also promotes cooperation and information exchange by industry (*Article 17*), thus facilitating the management of risks by competent authorities, and encourages industry to introduce the necessary quality and safety requirements for medicinal products, as well as safe distribution measures (*Article 18*).

Implementation

On 28 October 2011, the MEDICRIME Convention was opened for signature to the CoE's 47 Member States, the CoE's observer states, the EU and the non-Member States that participated in drafting the Convention. It is also open for signature by any other non-Member State upon invitation by the CoE's Committee of Ministers.

As of 1 September 2012, the Convention had been signed by 17 states: Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Iceland, Israel, Italy, Liechtenstein, Luxembourg, Portugal, Russian Federation, Switzerland, Turkey and ratified by one state (Ukraine). It will enter into force when ratified by five states, including three CoE Member States.



The role of EDQM

The European Directorate for the Quality of Medicines & Health-Care (EDQM) is part of the Council of Europe and aims to lead in protecting public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. EDQM's standards are recognised as a scientific benchmark worldwide, and its *European Pharmacopoeia* is legally binding in EU Member States.

Drawing on its expertise and experience in constructing the *European Pharmacopoeia* with 36 Member States, EDQM started the eTACT project in mid-2009, as part of the Council of Europe's holistic strategy to combat falsified/counterfeit medical products. The project aims to develop a secure, harmonised and standardised traceability and mass-serialisation system that will be efficient, cost-effective and flexible, and can be used by authorities and all stakeholders—including manufacturers, suppliers, distributors, pharmacists, healthcare professionals and patients—whatever the distribution route, including legitimate Internet pharmacies.

As well as developing the eTACT project, EDQM is also setting up a secure database of 'fingerprints' or signatures of active substances 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 to detect counterfeit substances and provide decision-making bodies with relevant evidence.

EDQM's current priorities include risk management and prevention—the transfer of 'know-how' and proven practices to

national health and law enforcement officials, e.g. through specific training, in particular a specific training platform on combating counterfeit medicinal products and protecting public health since 2007, as well as cooperation between SPOCs—and the protection of legal medical products and the legal supply chain.

Part of EDQM's strategy is to provide international support for the implementation of the MEDICRIME Convention, focusing on regulatory systems and procedures, interdisciplinary cooperation, e.g. SPOCs, and drug enforcement.

EDQM will also seek to improve 'know-how' for officials in terms of applying the provisions and best practice models described in the MEDICRIME Convention, adding value to state cooperation under the Convention: synergies in protecting the legal supply chain and combating crime, and the establishment of a strong evidence base for best practices, experiences, new criminal trends, harm and impact evaluation.

Further information

As a political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide.

It also develops common responses to social, cultural and legal challenges in its 47 Member States.

Competing interests: None.

Provenance and peer review: Commissioned; externally peer reviewed.

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