

THE **MEDICRIME CONVENTION** — FIGHTING AGAINST COUNTERFEIT MEDICINE

By Oscar Alarcón-Jiménez

Summary: The Council of Europe has adopted a criminal law convention on “counterfeiting of medical products and similar crimes involving threats to public health” (MEDICRIME Convention), drafted from a public health perspective. The Convention’s main goals are to criminalise certain acts, protect the rights of victims, and promote national and international co-operation. The counterfeiting of medical products and similar crimes is a growing threat for many countries due to the low level of deterrence within national and international legislation. As the only international legal instrument to fight against falsified medical products, the Convention represents a milestone in tackling transnational organised crime.

Keywords: Public Health, Counterfeiting of Medical Products, Criminal Networks, MEDICRIME Convention, Council of Europe

Introduction

Given its lucrative character, the counterfeiting of medical products and similar crimes is a new global threat facing the international community. The control by criminal networks of both the production and trade of counterfeit goods facilitates the infiltration of these counterfeit medical products into the legal supply chain and their sale as authentic products. The opacity of these networks makes it difficult to combat these new crimes.

The counterfeiting of medical products violates basic human rights by effectively denying patients necessary and authentic medical treatment and constitutes a direct threat to individual and public health. It is a trans-border crime which needs to

be efficiently combated through close international co-operation. The factors which contribute to this state of affairs are corruption, the ineffectiveness of systems for monitoring the production and distribution of medical products, and the lack of a legal framework to prosecute such crimes. The criminals are attracted by the risk-benefit ratio involved. In fact, this activity is more profitable than drug trafficking with a significantly lower level of risk, due to the relatively low risk of prosecution and detection, the potential high gains, and the ease of advertising and supply around the world through the Internet. Moreover, it is not an isolated crime: it affects the economies of all states, with organised networks operating at a global level and jeopardises the health and lives of individuals.

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Global international response

Adoption of the MEDICRIME Convention

When facing organised crime, no single response can be effective. On the contrary, the response needs to be global. With a view to tackling this crime, international action by states was needed, in particular, harmonised international legislation to overcome loopholes, the establishment of sanctions to deter this activity, and the promotion of international co-operation. The Council of Europe (CoE), the oldest intergovernmental organisation which has been at the forefront of promoting human rights, the rule of law and democracy in Europe over the last 60 years, sees the eradication of this phenomenon as the common responsibility of the global community. It elected to take on this challenge as the counterfeiting of medical products violates human rights and undermines the values upon which the CoE is based. Thus, in 2010, the CoE's Committee of Ministers adopted the Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereafter MEDICRIME Convention) ² which was opened for signature on 28 November 2011 in Moscow.

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Harmonised definitions

The MEDICRIME Convention is a criminal-law convention ² with the ultimate goal of protecting everyone's right to life by introducing new offences and providing for the establishment of penal and other sanctions that are proportionate and dissuasive for these offences. It aims to prosecute certain acts, protect the rights of victims, and promote national and international co-operation against

these crimes (Article 1). The scope of the Convention is expressly limited to medical products by covering both medicines (for human and veterinary use), their active substances, excipients, and medical devices, parts or materials designated to be used in the production of medical products, and accessories designated to be used together with medical devices (Article 3).

It is important to stress that intellectual property rights do not fall within the scope of the MEDICRIME Convention. Moreover, the term "counterfeit" is defined as a false representation with regards to identity and/or source. 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 the Convention should be considered a victim.

Criminalising certain acts

The MEDICRIME Convention introduces four new independent criminal offences considered dangerous to public health:

- 1) **Intentional manufacturing of counterfeit medical products**, their active substances, excipients, parts, materials and accessories (Article 5); related to this offence, the adulteration of medicines and other listed products is also considered a criminal offence.
- 2) **Intentional supplying, offering to supply and trafficking** in counterfeit medical products' active substances, excipients, parts, materials and accessories (Article 6). This includes the activities of brokering and advertising online or at a distance, such as social media and through various parts of the Internet.
- 3) **Intentional falsification of documents** (Article 7). This can take place either through the making of a false document from scratch or through unlawfully amending or changing a document with regard to its content or appearance. In both cases, the aim is to deceive the person reading the document into

believing that the medical product which the document accompanies is legitimate and not a counterfeit. The MEDICRIME Convention defines the term "document" by covering not only certificates and similar documents used in trade and commerce, but also the packaging and labelling of medical products, as well as texts provided on internet sites which are specifically designed to accompany the product in question.

- 4) **Similar crimes involving threats to public health**: despite not being counterfeited, products intentionally manufactured, kept in stock for supply, imported, exported, supplied, offered to supply, or placed on the market without authorisation (medicinal products) or without being in compliance with the essential conformity requirements (medical devices) equally pose a serious threat to public health (Article 8). Therefore, these crimes are considered to be similar to the counterfeiting of medical products. An example of this offence is the existence of a sprawling black market for medicinal products for hormonal treatment produced without authorisation. This Article shall only apply when the previous Articles (5-7) are not applicable.

The above criminal offences should be made punishable under domestic law by those countries which have ratified the MEDICRIME Convention and which should foresee and lay down accompanying "effective, proportionate and dissuasive sanctions".

Aggravating circumstances

When sentencing offenders, judges may take into consideration some circumstances (although they are under no obligation to apply them) in the determination of the sanction for the above offences, such as:

- the offence caused the death of, or damaged the physical or mental health of, the victim;
- the offence was committed by persons abusing the confidence placed in them in their professional capacity;

- the offence was committed by persons abusing the confidence placed in them as manufacturers and suppliers;
- the offences of supplying and offering to supply are committed through the use of large-scale distribution, including through information technology systems (the Internet);
- the offence involved a criminal organisation;
- the perpetrator has previously been convicted of offences of the same nature as those established under the Convention.

Enhanced co-operation of authorities and information exchange

The MEDICRIME Convention paves the way for solid co-operation and information exchange at both national and international level. Networking at national level based on a multidisciplinary and multisectorial approach is a key element in the fight against the counterfeiting of medical products and similar crimes. The wide range of authorities (justice, law-enforcement and health authorities) involved in this new crime usually requires a strengthening of the existing frameworks for co-operation. The CoE model based on a network of Single Points of Contact (SPOC model) is a successful system already used in other fora (i.e. EU, WHO, INTERPOL).

The MEDICRIME Convention clearly provides a legal basis for a platform for co-operation, with a view to avoiding any requirement for further bilateral agreements. Mutual legal assistance is a formal process by which states grant assistance to one another with the purpose of gathering evidence for use in criminal trials. The Convention encompasses all existing forms of Mutual Legal Assistance (e.g. rogatory letters*, transfer of proceedings). For some states, the Convention may be the only treaty between itself and other states, particularly since one particular aspect

of the Convention is that it provides the possibility for third states to join (see below).

The legal bases applicable in the context of extradition and the principles enunciated there are applicable, *mutatis mutandis*, in the field of mutual legal assistance, which is broader than extradition. Moreover, given the importance of the victims of counterfeit medical products and similar crimes, whether as a result of their suffering or because of the potential they offer as witnesses, special attention is paid to them even in the provisions relating to international criminal co-operation.

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Prevention and protection measures

One innovation introduced by the Convention is the inclusion of victims. It should be recalled that the protection of, and assistance to, victims of crime has long been a priority in the work of the CoE. Taking into account the potential grave consequences for victims of counterfeited medical products and similar crimes, the Convention provides for the protection of such victims (Chapter VI), ensures that they be kept informed by the competent national authorities on relevant developments in their cases, and gives them the possibility to be heard and to supply evidence.

Additionally, the MEDICRIME Convention provides for some preventive and protective measures (Article 18) in combating the counterfeiting of medical products and similar crimes, namely the introduction at national level of quality and safety requirements for medical products as well as measures ensuring the safe distribution of such products. Additional preventive measures (capacity building activities for justice, law-enforcement, health care professionals and providers in order to better prevent and combat these crimes; awareness-raising campaigns;

the prevention of illegal supply) are also envisaged. Moreover, victims would have access to information, assistance in their physical, psychological and social recovery and have the right to compensation from the perpetrators.

A global Convention

The MEDICRIME Convention is not confined to CoE Member States. Any state wishing to sign and ratify the Convention is welcome to do so (Article 28.1), recognising that the world is facing a global problem as a result of such crimes. Apart from the seventeen CoE Member States that have signed the MEDICRIME Convention so far, Israel and Morocco have also signed the Convention while the Republic of Guinea ratified the MEDICRIME Convention on 24 September 2015, initiating the procedure for its entering into force on 1 January 2016. Belarus has also been invited by the CoE's Committee of Ministers to sign this Convention. To date, five countries have ratified the Convention: Ukraine (2012), Spain (2013), Hungary (2014), Moldova (2014) and Guinea (2015). Undeniably, more countries are needed to sign and ratify the MEDICRIME convention in order for it to be effective internationally.

Conclusion

The MEDICRIME Convention offers a valuable tool for combating the counterfeiting of medical products from the standpoint of protecting health. Through the harmonisation of criminal provisions, the Convention lays the foundation for efficient and effective national and international co-operation among all competent authorities involved, namely judicial, health and law enforcement authorities, protecting, above all, the most vulnerable people, patients.

The counterfeiting of medical products and similar crimes are crimes that ultimately could kill or at the very least make people ill or not treat their illnesses. It is a universal problem that demands strong responses: the MEDICRIME Convention can provide them.

* A rogatory letter is a formal request from a court to a foreign court for some type of judicial assistance.