Council of Europe

THE MEDICRIME CONVENTION

Fighting the falsification of medical products and similar crimes

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

The Medicrime Convention in a few words

Crime linked to the manufacture, distribution and sale of falsified medicines and medical devices,* often called "pharmaceutical crime", is a global scourge that has reached alarming proportions, all the more so as these products are increasingly distributed via the Internet. It poses a serious threat to public health that can only be addressed **through a dedicated international legal instrument**.

Most existing legislation has little deterrent effect. The criminals involved stand to make a substantial profit compared to the penalties they may face and, if indeed they are caught, they are often prosecuted for administrative offences or breaches of regulations, with only minor sanctions.

Milestones:
2010 ➡ Medicrime Convention adopted by the Committee of Ministers of the Council of Europe
2011 ➡ Medicrime Convention opened for signature by the 47 member states of the Council of Europe and the rest of the world
Janvier 2016 ➡ Medicrime Convention enters into force
Février 2017 ➡ Medicrime Convention ratified by 9 states – both members and non-members of the Council of Europe – and signed by 18

The Council of Europe's Convention on the counterfeiting of medical products and similar crimes involving threats to public health** **(CETS No. 211, "the Medicrime Convention")** is the first anti-pharmaceutical crime treaty specifically created to:

- protect public health;
- criminalise and punish all activities related to the falsification of medical products and similar crimes;
- provide a common legal framework allowing international co-operation for the prosecution of these crimes and offences.

* The term "medical device" covers any instrument, apparatus, implement or other article for diagnostic or therapeutic use, from sticking plasters to pacemakers.

** The term "counterfeiting" in the official title of the Convention is meant in the sense of "falsification". For ease of reading, "falsified" or "falsification" will be used throughout this brochure.

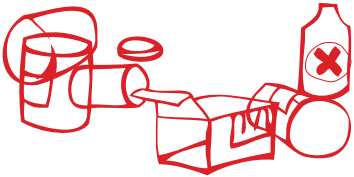
Some explanations...

What are "falsified medical products"?

These are products that pass themselves off as the authentic, authorised medical product, that is, products whose labels or packaging are deliberately misleading as to their contents, identity and/or source.

What are "similar crimes"?

This refers to manufacturing, storing, trafficking and offering for sale medical products that have not been through obligatory, official authorisation procedures. These crimes are just as dangerous as falsification of medical products and pose just as great a threat to public health. For instance, performance-enhancing drugs that do not have licensed indications can be found on the market as a result of these "similar crimes".

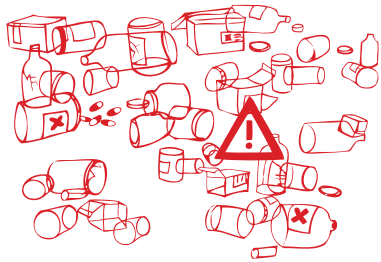


In Europe and elsewhere, the pharmaceutical and medical device industries are closely regulated. The medicinal products manufactured and all starting materials, active ingredients, synthesis intermediates, accessories and packaging articles used must meet high quality standards of the type established by the European Pharmacopoeia. All legitimate manufacturers apply these quality standards and are regularly inspected or audited to ensure compliance, and all medicines and medical devices undergo a stringent battery of tests during their development and manufacture to prove that they are both safe and effective. It is on the basis of the results obtained that the medical products can be launched on the market through regional and national regulatory procedures.

Falsified medical products – silent killers

Both criminal trafficking of falsified medical products and their use can have fatal consequences for public health in general and patients in particular.

- The active ingredients, materials, substances, excipients or packaging materials used in their manufacture can be inappropriate and harmful.
- Even if falsified medicinal products contain the same ingredients as the original product, uniform distribution of those ingredients is never guaranteed. Hence, over- or under-dosing of active ingredients is possible.
- Falsified medical products that do not contain the active ingredient or the part/component as declared or stated on the label are at best useless, and at worst directly damaging to the health of the patients using them.
- The quality of falsified or stolen medical products which are stored under inappropriate conditions may deteriorate. For example, poor storage conditions may lead to the growth of harmful micro-organisms in injectable medicines.
- The availability of falsified medical products on the black market and sometimes even via the legal manufacturing and distribution chains can also undermine people's trust in the public health system and in authentic medical products.



Real cases of falsification covered by the Medicrime Convention

Case 1: falsification of a medicine

- In 2014, vials of an anti-cancer monoclonal antibody (a very expensive, high-tech medicine) were stolen from a number of Italian hospitals. The vials, some of which had been tampered with, were then reintroduced into the official distribution chain via a parallel import circuit. This fake circuit was set up by a European-wide trafficking ring.

Cas 2 : fraudulent medical devices

- In 2010, it was established that a French manufacturer had deliberately produced substandard breast implants and sold them on the international market. Quality auditors, the regulatory authorities, doctors and patients were misled by fraudulent information provided in certificates of analysis and manufacturing dossiers for the implants which were authorised and widely used before their true nature was discovered and they were withdrawn from the market.

Case 3: sale of an illegal medicine, a "similar crime"

- Online pharmacies run by fraudulent operators continue to sell pseudo-slimming drugs containing the amphetamine-like appetite suppressant sibutramine which has been banned worldwide since 2010.

The **Medicrime Convention makes it possible to investigate these different crimes and bring the individuals and groups that perpetrate them to justice**. By fostering co-ordination of an international network involving all the stakeholders (health authorities, the judiciary and law enforcement agencies (police and customs), or medicines control laboratories), the Convention also allows rapid and efficient sharing of information on how these crimes and offences are dealt with worldwide.

When the authorities conduct an investigation into a suspected falsified medical product, it is not unusual for 10 (and sometimes even more) states to co-operate as foreseen in the Convention, ranging from the country in which the falsified medical product was manufactured and the source of the traffic, to those involved in its storage, shipment and distribution and those hosting the online sales websites or illicit financial transactions.

The Medicrime Convention explained

Common definitions and legal framework

The Medicrime Convention provides a set of **common and legally-binding definitions** for the falsification of medical products and similar crimes, to be transposed into the national legislation of signatory parties. The definitions stress the threat to public health posed by these criminal activities and provide a common legal framework for their prosecution.

The Convention covers legitimate medical products, from both generic and innovator medicines to starting materials, active ingredients, excipients and indeed extends to any other materials or accessories used in the manufacture and packaging of medical products and devices, all of which are considered to be equally at risk of falsification and similar crimes.

The Medicrime Convention establishes the following as criminal offences

- the intentional manufacturing of falsified medical products, active substances, excipients, parts, materials and accessories, and their adulteration (Article 5);
- supplying, or offering to supply, including trafficking, counterfeit medical products, active substances, excipients, parts, materials and accessories (Article 6). The term "supplying" is understood to cover the acts of brokering, procuring, selling, donating or offering these products for free, as well as promoting (including through advertising) them;
- falsification of documents (Article 7), with the aim of misleading the reader by claiming that the medical product, active substance, excipient, part, material or accessory for which the information is provided is not false;
- similar crimes (Article 8): the manufacture or supply of medicinal products without authorisation or sale of medical devices that do not comply with conformity requirements, where they exist;
- aiding or abetting falsification (Article 9).

The Medicrime Convention in practice

Objectives

With the ultimate aim of public health protection, the Medicrime Convention:

- **reinforces co-operation between health authorities, law enforcement agencies, customs services and the judiciary on the national and international scale**. To consolidate the fight against medical product falsification and similar crimes, the Convention introduces "single points of contact" (SPOCs) as a means of fostering transborder co-operation amongst these authorities and agencies ensuring that the Convention is enforced;
- **encourages communication and the exchange of information and data** (by overcoming existing legal obstacles) not only between the health authorities and official bodies at both national and international level, but also between the public and private sectors;

- **establishes all activities related to the falsification of medical products as criminal offences**. Any individuals or companies manufacturing and distributing falsified products are now considered to be criminals looking to make a fast profit with complete disregard for the health and lives of patients and are to be brought to justice;
- **officially recognises as victims of a crime** individuals who have suffered physical or psychological damage through the use of a falsified medical product.

What does the European Directorate for the Quality of Medicines & HealthCare (EDQM) do to combat falsification of medical products and similar crimes?

The EDQM has developed a global strategy against falsification of medical products and similar crimes that works through risk management and prevention initiatives and encourages member states and other stakeholders to work closely together, in Europe and beyond.

Priorities

- promoting the **Medicrime Convention** to encourage countries to make best use of the global framework it provides for harmonising national criminal law and legal instruments for the prosecution of pharmaceutical crimes on a global scale;
- transferring know-how and proven practices between national health and law enforcement agencies (police and customs) **through tailored training programmes** (since 2007); the aim is to foster efficient co-operation and networking amongst these public services;
- co-ordinating existing resources and expertise in European member states for the physicochemical and biological analysis of falsified medical products, via the **network of official medicines control laboratories (OMCL)**.

Ongoing projects

- the **single points of contact (SPOC) network**: SPOCs within the different competent authorities form a network in each member state; at international level, these SPOCs are represented by a "national SPOC" to encourage co-operation amongst member states;
- the "**Know-X**" database, created by the EDQM, which collates details (from health authorities, the police and testing laboratories) on falsified medicine cases and is intended for governments as an aid to decision making for risk prevention and management;
- support for inspection authorities in their conformity assessment of **mass serialisation systems for medicines**, to prevent falsified medical products from entering the legal supply chain. For example, from 2019 onwards, in the European Union (EU), each authentic medicine pack will bear a unique medicine identifier guaranteeing its integrity from one end of the supply chain to the other. Secure databases will allow distributers, wholesalers and pharmacists to verify the authenticity of a medicine.

A little bit more about the EDQM…

The EDQM and the Council of Europe

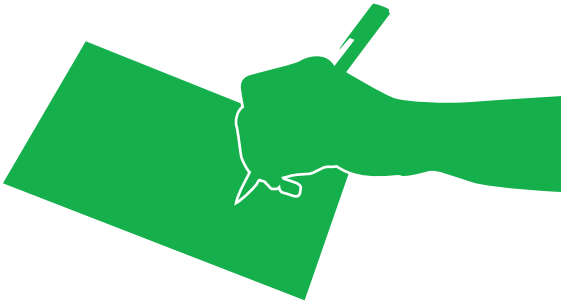
The EDQM contributes to the basic human right of access to good quality medicines and health care, and promotes and protects human and animal health by:

- establishing and providing official standards for the manufacture and quality control of medicines in all the signatory states of the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50) and beyond;
- granting certificates of suitability which verify the compliance of pharmaceutical substances with European Pharmacopoeia standards and carrying out inspections of manufacturers of these substances;
- co-ordinating a network of Official Medicines Control Laboratories (OMCLs) to collaborate and pool expertise and to effectively use limited resources with the aim of achieving effective public quality control of medicines in Europe and beyond;
- proposing ethical, safety and quality standards for blood transfusions (collection, preparation, storage, distribution and appropriate use of blood components) and organ, tissue and cell transplantation;
- working with national, European and international organisations in efforts to combat counterfeiting/falsification of medical products and similar crimes;
- providing policies and model approaches for the safe use of medicines, including guidelines on pharmaceutical care;
- establishing standards for cosmetics and food contact materials and co-ordinating the public control of cosmetics.

The Medicrime Convention and criminal law: role of the Council of Europe

The Council of Europe has played an active role in crime prevention since 1958 and, more recently, has helped its member states apply the Medicrime Convention in the field of criminal law.

Its European Committee on Crime Problems (CDPC), which has representation from all Council of Europe member states, identifies priorities for intergovernmental legal cooperation, makes proposals to the Committee of Ministers on activities in the fields of criminal law and procedure, criminology and penology and implements these activities. The CDPC establishes conventions, agreements, recommendations and reports. It also organises criminological research conferences and other criminology meetings, including Conferences of Directors of Prison and Probation Services.



For all further information about the Medicrime Convention:
www.coe.int/medicrime

Council of Europe
Avenue de l'Europe
F-67075 Strasbourg Cedex
Tel. +33 (0)3 88 41 20 00 – Fax + 33 (0)3 88 41 27 81
www.coe.int

European Directorate for Quality of Medicines & Healthcare (EDQM)
7 allée Kastner, CS30026,
F-67081 Strasbourg
Tel. + 33 (0)3 88 41 30 30 – Fax + 33 (0)3 88 41 27 71
www.edqm.eu

Prems 057117 – PRDD-17-12

ENG

www.coe.int

The Council of Europe is the continent's leading human rights organisation. It comprises 47 member states, 28 of which are members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law. The European Court of Human Rights oversees the implementation of the Convention in the member states.