THE MEDICRIME CONVENTION IN 10 QUESTIONS AND ANSWERS

The Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health







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La Convention MEDICRIME en 10 questions et réponses

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The Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health

Council of Europe

The MEDICRIME Convention in 10 Questions and Answers

Falsified medical products are a danger to public health and can violate the right to life enshrined in the European Convention on Human Rights. They can cause irreparable harm to millions of unsuspecting consumers via legal supply chains and the internet, and undermine public confidence in health-care systems. To stop this, the first step is to criminalise the activities connected with the falsification of medical products. This is the aim of the MEDICRIME Convention (the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health).

Under the convention, which entered into force in January 2016, intentionally manufacturing, supplying, offering to supply and trafficking of falsified medicines is considered a criminal act. This innovative treaty calls for multilateral collaboration across nations, disciplines and sectors, and lays the ground for co-operation with and between international bodies such as INTERPOL, Europol, UNODC, the WCO and WHO, in order to put a stop to this international threat to public health.

Falsifying medical products is a transnational crime which does not recognise boundaries – therefore each new ratification strengthens the convention's power to combat this scourge. Your parliament and your country can only benefit from becoming party to the convention, thus protecting not only your own health but also public health more generally.

This Question and Answer booklet presents ten key issues of relevance to parliamentarians regarding the MEDICRIME Convention:

1. What are the falsification of medical products and similar crimes?
2. Why should my country sign and ratify the MEDICRIME Convention?
3. What is the added value of the MEDICRIME Convention?
4. What will happen when my country ratifies the MEDICRIME Convention?
5. Why a Council of Europe convention?
6. What about intellectual property rights?
7. Couldn't the MEDICRIME Convention have a chilling effect on the generics industry?
8. How will the MEDICRIME Convention improve the prosecution of these crimes?
9. How will the MEDICRIME Convention help protect the victims?
10. How will the MEDICRIME Convention help prevent these crimes in the first place?

The term "counterfeit" used in the MEDICRIME Convention is consistent with the meaning of the term "falsified", which has become the more commonly used term, hence it is used in this booklet for ease of reading.

EDQM: European Directorate for the Quality of Medicines and Healthcare

UNODC: United Nations Office on Drugs and Crime

SPOC: Single Point of Contact

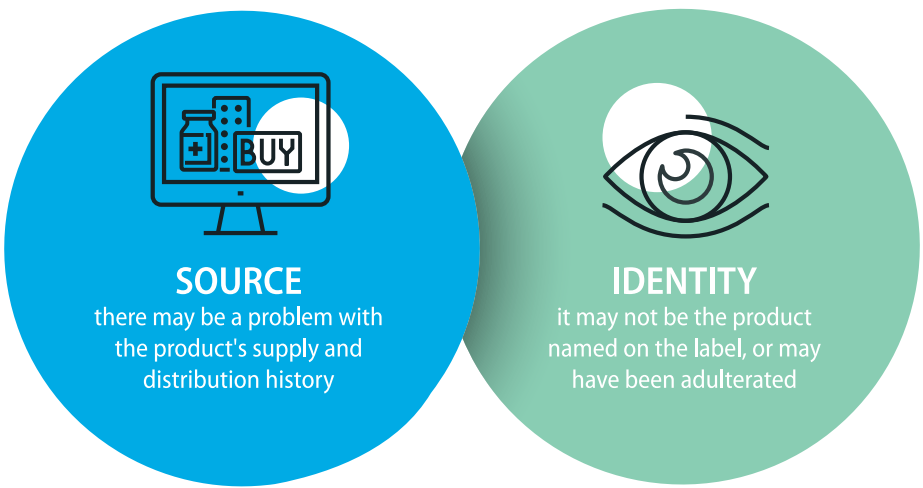
WHO: World Health Organization

WCO: World Customs Organization

1. What are the falsification of medical products and similar crimes?

Falsification of medical products

Under the convention, a falsified medical product (for human or veterinary use) has a deliberately false representation of its source and identity.



Similar crimes

Similar crimes include crimes which do not involve falsified medical products, but rather medicinal products that are intentionally manufactured, supplied or placed on the market without authorisation, or medical devices not in compliance with the conformity requirements, as laid down in the domestic law of the states parties. This would include, for example, manufacturing or supplying medicinal products for hormonal treatment produced without authorisation as means of doping for sports persons and others on the sprawling black market.

This designation was created to provide protection against crimes that fall outside of the regular scheme of the falsification of medical products but pose similar threats to consumers and public health.

> *"Counterfeit medicines … constitute a big and valuable market. Every year, the turnover runs into the billions, making the traffickers rich at the expense of the sick. This new type of crime has now overtaken drug trafficking in terms of quantities and offers criminals an undeniable advantage: the punishment is less severe"*
>
> *Jan Kleijssen, Director, Information Society and Action against Crime Directorate of the Council of Europe*

Every country is vulnerable



2. Why should my country sign and ratify the MEDICRIME Convention?

Global crime requires a global coalition

Every country is vulnerable to the falsification of medical products – regardless of how tightly it controls its borders – because of the fragmented nature of these crimes. Despite the rapid advances of sensor technologies in customs, there may be nothing illegal about shipping empty, printed boxes or assembling different elements that have each been produced in other countries. These isolated acts may take place undetected by the safeguards of individual countries. Without any check upon such activity via criminal enforcement, these products may find their way into the legal supply chains.

A common legal framework for prosecution

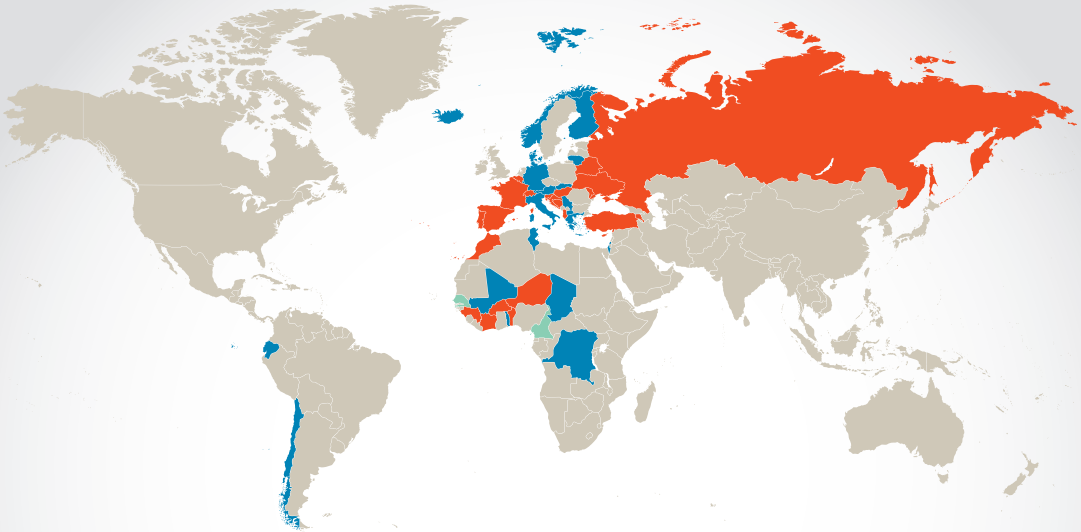
The MEDICRIME Convention is the first treaty to define a set of common and legally-binding definitions for the falsification of medical products and similar crimes and which requires states parties to transpose these definitions into their national legislation, thus creating a uniform legislation between countries which facilitates prosecution of these crimes.

Shared strength, expertise and communication channels

Detection of these crimes is often hindered by a lack of communication between health authorities, customs, police, judiciary and the private sector. To resolve this issue, the MEDICRIME Convention promotes co-operation at national and at international level, training and information exchange.

To put this into practice, the Council of Europe has created an online training course in co-operation with the European Programme for Human Rights Education for Legal Professionals (HELP). The course aims to enhance the capacities of legal professionals to apply the MEDICRIME Convention by studying cases connected with the falsification of medical products from Spanish and international courts. This innovative course helps legal professionals better understand the issues relevant to proper prosecution of the falsification of medical products and similar crimes.

Signatures and ratifications



November 2026

States which have ratified the Convention

Signatures of states of the Convention

States invited to accede to the Convention

Since the Convention was opened for signature in Moscow on 28 October 2011, 23 states have ratified it:

Ukraine	20 August 2012
Spain	5 August 2013
Hungary	9 January 2014
Republic of Moldova	14 August 2014
Guinea	24 September 2015
Armenia	5 February 2016
Albania	6 June 2016
Belgium	1 August 2016
France	21 September 2016
Burkina Faso	27 July 2017
Türkiye	21 September 2017
Russian Federation	20 March 2018
Benin	29 May 2018
Switzerland	25 October 2018
Portugal	18 December 2018
Croatia	20 September 2019
Bosnia and Herzegovina	18 September 2020
Belarus	28 September 2020
Niger	10 March 2022
Morocco	19 April 2022
Slovenia	3 May 2022
Ivory Coast	20 July 2023
Cyprus	5 September 2023

22 states have signed but not yet ratified the Convention:

Austria	28 October 2011
Finland	28 October 2011
Germany	28 October 2011
Iceland	28 October 2011
Israel	28 October 2011
Italy	28 October 2011
Liechtenstein	4 November 2011
Luxembourg	22 December 2011
Denmark	12 January 2012
Serbia	2 October 2019
Ecuador	7 May 2021
Mali	29 June 2021
North Macedonia	9 September 2021
Lithuania	21 April 2022
Greece	18 May 2022
Togo	16 January 2023
Norway	12 April 2023
Congo	05 June 2023
Slovak Republic	24 October 2023
Tunisia	7 February 2024
Chad	11 September 2024
Chile	27 November 2024

3. What is the added value of the MEDICRIME Convention?

A focus on public health

Until now, efforts to curb the falsification of medical products have focused mainly on intellectual property rights. The Council of Europe's MEDICRIME Convention puts individuals at the heart of its mission and focuses specifically on fighting the falsification of medical products and its threat to public health. In light of this, the convention also specifically calls for the protection of victims.

A history of international co-operation

The Council of Europe is a leader in legal and pharmaceutical co-operation, with a well-established network in Europe and beyond, and decades of experience creating international policy. The European Directorate for the Quality of Medicines and Healthcare (EDQM) of the Council of Europe, established in 1964, protects public health by issuing quality standards for safe medicines which are recognised as a scientific benchmark worldwide.

Cross-cutting strategies

Signing and ratifying the convention allows countries to participate in a global coalition that employs cross-sector co-operation between health professionals, law-enforcement and the judiciary, thus overcoming the silo mentality that often hinders individual actors who try to stop these crimes.

Open to all

No single country can battle the falsification of medical products alone because this crime does not respect borders. Falsified medical products and similar crimes constitute a global threat. Even if the convention was made in Europe, it is not meant for Europe only; it is also open to states that are not members of the Council of Europe. To date, 16 states have ratified the convention, including three non-member states, and an additional 16 states have signed it, including four non-member states. The Convention entered into force on 1 January 2016. The fight against falsified medicines grows stronger with each new ratification.

From signatures to co-operation



4. What will happen when my country ratifies the MEDICRIME Convention?

The MEDICRIME Convention provides states parties with:

- access to legal expertise to transpose the provisions of the Convention into national law;
- training for the legal professions to help them understand the nature of the falsification of medical products and similar crimes;
- a framework for national and international co-operation across the different sectors of the public administration (police, customs, health and judicial authorities);
- participation in the Committee of the Parties – the Convention's monitoring body – which includes representatives from each state party and is tasked with overseeing the implementation and guiding international cross-sectoral collaboration.

The MEDICRIME Convention

Criminal-law penalties, international prevention and victim-protection measures

Setting up contact points within national judicial, health and law enforcement authorities to ensure transborder co-operation



Framework for international co-operation and co-ordination at national level

Setting up a Committee of the Parties to monitor implementation

5. Why a Council of Europe Convention?

Shouldn't WHO or the EU be dealing with this?

MEDICRIME unites actors from across the globe under a legally-binding treaty that defines the falsification of medical products as a criminal offense. WHO has a reporting and alert system, and the EU has adopted a Falsified Medicines Directive. Both organisations are vital partners, but neither can tackle the falsification of medical products via criminal law.

Isn't it easier to wait until the EU ratifies?

EU ratification is a long and complex process that may take years or even decades.

The Council of Europe MEDICRIME Convention is already in place and becomes more powerful with each new ratification. Joining the Convention now allows your country to take immediate, concrete action to curb the falsification of medical products in your country and around the world.

> *"I urge national authorities to ratify this important convention without delay. Health and life cannot wait."*
>
> *Ms Anne Brasseur, former President of the Assembly*

6. What about intellectual property rights?

A people-centred approach

The protection of intellectual property rights (IPR) lies outside the scope of the MEDICRIME Convention, which is drafted from a human rights and public health perspective. It permits all states parties to the Convention to put the health of their inhabitants first.

Let states set their policies

The MEDICRIME Convention does not hinder IPR holders from seeking legal recourse via the specific legislation applying to IPR. However, violations of the rights of owners of patents, brands and trademarks of medical products which are authorised by a competent authority for placement on the market are not covered by the MEDICRIME Convention.

> *As the Explanatory Report to the Convention notes: "the focus of the Convention is on the protection of public health; as it was felt that intellectual property rights are generally adequately protected at both national and international level, the Convention does not cover any issues related to the infringement of intellectual property rights in relation to the counterfeiting of medical products, active substances, excipients, parts and materials."*

7. Couldn't the MEDICRIME Convention have a chilling effect on the generics industry?

Generics are not targeted…

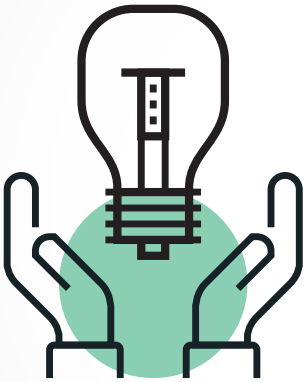
The MEDICRIME Convention does not prevent approval or market access for generic medicines that are authorised by a competent regulatory authority, provided that their quality, safety and efficacy have been independently verified by the appropriate competent regulatory authorities.

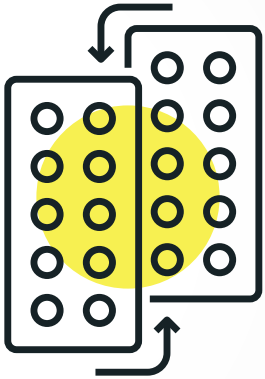
…and will be better protected under the MEDICRIME Convention

The threat to the integrity of generic drugs is identical, if not greater because generic drugs are legally licensed but theoretically less expensive versions of brand-name drugs. Their lower price makes them more accessible to patients in the general public. Unfortunately, they are at greater risk of being copied because they are popular. Thus, countries covered by the MEDICRIME Convention are actually safeguarding the public's access to safe generic medicines.

The Convention "concerns medical products … whether they are generic or not" (Article 3 – Scope)

Intellectual property and the generics industry





8. How will the MEDICRIME Convention improve the prosecution of these crimes?

Officially recognise these acts as crimes

The MEDICRIME Convention provides a legal basis for prosecution by obliging the states parties to criminalise:

1

the **manufacturing** of falsified medical products including veterinary medicines;

2

supplying, offering to supply and trafficking in falsified medical products;



4

the **falsification** of documents.

3

the **unauthorised manufacturing** or **supplying** of medicinal products and the **placing on the market** of medical devices which do not comply with conformity requirements.

Co-operation and exchange of information

Article 17 of the Convention emphasises national measures of co-operation and information exchange, which could be inspired by the model of "Single Point of Contact" (SPOC) developed by the EDQM. This system makes information and data obtained by the health authorities, customs, police and other competent authorities available to each other for co-operation purposes, including use as evidence for prosecution of criminals. In the SPOC network, national contact points are appointed which are responsible for transmitting and receiving information which can be used when contacting the general public, alerting distributors or to support the prosecution of criminals.

The reporting mechanism is both a deterrent to criminals and a source of evidence for demonstrating the falsification of medical products.

Article 14 provides for the possibility to take into account final sentences passed by another state party in the determination of a sentence. Previous convictions in another state party to the Convention for the same offense could therefore open the way to hand down a heavier sentence to an offender.

Protecting the victims



9. How will the MEDICRIME Convention help protect the victims?

Until now, many countries based their prosecution of the falsification of medical products on IPR laws, which excluded the possibility to prosecute based on harm to victims of falsified medicine. MEDICRIME's focus on public health means that any person who has been exposed to the danger of falsified medicines can bring criminal charges. Defining these acts as crimes allows for victims to take legal action against perpetrators.

The rights of victims are enshrined in article 19 of the MEDICRIME Convention.

> ***Article 19 – Protection of victims***
>
> *Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims, in particular by:*
>
> *a ensuring that victims have access to information relevant to their case and which is necessary for the protection of their health;*
>
> *b assisting victims in their physical, psychological and social recovery;*

The MEDICRIME Convention requires states parties to ensure that proceeds derived from offences included in the Convention can be seized and confiscated. These can, for example, be used to contribute to a national victim fund.

> ***Article 12 –Sanctions and measures***
>
> *3 Each Party shall take the necessary legislative and other measures to:*
>
> *a permit seizure and confiscation of:*
>
> *ii proceeds of these offences, or property whose value corresponds to such proceeds;*

Stronger together



10. How will the MEDICRIME Convention help prevent these crimes in the first place?

Communication facilitates early detection

Training helps professionals in the justice, health and law enforcement fields to better identify and put a stop to the falsification of medical products.

Designating a national contact point provides a clear framework for international communication that can detect criminal activity early on and can share essential strategies for alerting the public to dangers.

Raise the stakes

The falsification of medical products and similar crimes are now statistically more significant than drug trafficking and yet less severely punished if and when caught. By clearly defining these acts as criminal offenses, states can increase the prosecution of these crimes, which may make these activities less appealing to criminal groups.

Stronger together

The Convention is a game-changer, because ratification by many nations ensures a unified approach that protects public health.

Falsified medical products are a danger to public health and can violate the right to life enshrined in the European Convention on Human Rights. They can cause irreparable harm to millions of unsuspecting consumers via legal supply chains and the internet, and undermine public confidence in health-care systems. To stop this, the first step is to criminalise the activities connected with the falsification of medical products. This is the aim of the MEDICRIME Convention.

This booklet presents 10 key issues of relevance to parliamentarians regarding the MEDICRIME Convention in an easily-understandable format. It puts forth arguments in favour of signing, ratifying and implementing the MEDICRIME Convention and is aimed at promoting greater awareness of the public health threat posed by falsified medical products.

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The Council of Europe is the continent's leading human rights organisation. It comprises 46 member states, including all 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.

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