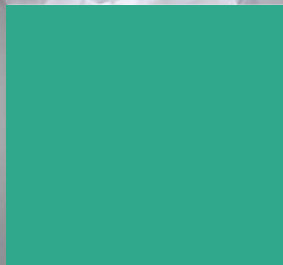


# HANDBOOK FOR PARLIAMENTARIANS

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

**(MEDICRIME Convention, CETS No. 211)**



COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

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**(MEDICRIME Convention, CETS No. 211)**

French edition:

*Manuel à l'usage des parlementaires –  
Convention du Conseil de l'Europe  
sur la contrefaçon des produits  
médicaux et les infractions similaires  
menaçant la santé publique  
(STCE n° 211, Convention MÉDICRIME)*

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# I. The Council of Europe and the Parliamentary Assembly

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The Council of Europe is the continent's oldest political organisation. Founded in 1949, it has 47 member states, representing more than 820 million Europeans, and five observer states (Canada, the Holy See, Japan, Mexico and the United States of America).

The main aims of the Organisation are:

- protecting human rights, parliamentary democracy and the rule of law in all member states;
- developing continent-wide agreements to harmonise member states' social and legal practices;
- promoting awareness of a European identity and greater unity based on shared values that transcend different cultures.

Since the fall of the Berlin Wall, its main purpose has been to act as a political anchor and human rights watchdog for all the democracies in greater Europe; assist them in carrying out and consolidating political, legal and constitutional reform; and facilitate the exchange of good practice in areas such as human rights, local democracy, education, culture and the environment.

The protection of public health has long been a key element of the work carried out by the Council of Europe. Its conventions on bioethics, the safety of blood products and organ transplantation are widely considered as authoritative by regulatory authorities and health-care professionals within and outside Europe. The Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50), serviced by the Council of Europe's European Directorate for the Quality of Medicines & HealthCare (EDQM), provides quality standards for the ingredients and the production of medicines. These standards are binding for 38 signatories in Europe, including the European Union, and are a recognised reference for its 27 observers all around the world, including the World Health Organization (WHO).

The Council of Europe has its permanent headquarters in Strasbourg, France. By statute, it has two constituent organs: the Committee of Ministers composed of the ministers for foreign affairs of the member states, and the Parliamentary Assembly (PACE), comprising delegations from the 47 national parliaments.

The 648 men and women who make up the Council of Europe Parliamentary Assembly (<http://assembly.coe.int>) come together four times a year to debate topical issues and common challenges, request action from Europe's governments and hold those governments accountable for their acts. They speak on behalf of more than 820 million Europeans whom they represent on any subject they choose, and Europe's governments – represented in the Council of Europe by the Committee of Ministers – are obliged to reply to them. They are greater Europe's democratic conscience.

## II. Foreword by the President of the Parliamentary Assembly

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Fake medicines are an outrage. Creating or selling drugs that turn out to be useless – or, worse, directly damaging to our health – can hasten death and prolong or aggravate serious illness. To deliberately cause suffering of this kind for crude profit, especially when the actual root of the problem may never be known, is – literally – a sickening act which strikes at the roots of human decency, saps mutual trust and fundamentally damages society in many ways.

In addition to the harm they cause to human health, counterfeit medicines have an economic cost: they drain resources from already hard-pressed public health systems and add to the burden of global disease. And the bad news is that, as far as we can tell, there are more and more of them.

As parliamentarians, we have a responsibility to do everything we can to protect our citizens by stopping this insidious new form of crime. We can pass laws which oblige genuine medical products to be fully and robustly licensed, throughout the chain of production. We can insist that producing, selling or facilitating “bad medicine” are serious crimes in our countries, with strong penalties that are strictly enforced. We can help each other’s law-enforcement agencies to pursue and bring to justice the perpetrators of these crimes, wherever in the world they may hide.

The Council of Europe’s MEDICRIME Convention – first proposed by the Parliamentary Assembly and signed in Moscow in 2011 after years of negotiation by government experts – is a global instrument which will do all that and more. Filling a gap in international law, it is on course to become the world’s strongest weapon in the fight against the counterfeiting of medical products and similar crimes.



Some 24 states have so far signed the convention – including countries beyond the Council of Europe area, such as Guinea, Israel and Morocco. I welcome the recent ratification by Guinea. This will allow the convention to enter into force on 1 January 2016 and to begin doing its vital work.

This handbook explains the MEDICRIME Convention in simple language, spells out clearly what it does, how it can help and what we as parliamentarians can do to make it a reality.

Its clauses may be dry, but they will save lives. By ensuring it enters into force in your country, and by encouraging its full implementation, you can play an important part in saving those lives.

As President of the Parliamentary Assembly of the Council of Europe, I urge national authorities to ratify this important convention without delay. Health and life cannot wait.

*Anne Brasseur  
President of the Parliamentary Assembly  
of the Council of Europe*

## III. Overview

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*“Counterfeiting of medical products and similar crimes violate the right to life as enshrined in the Convention for the Protection of Human Rights and Fundamental Freedoms, as these criminal and dangerous conducts effectively deny patients the necessary medical treatment and may often be harmful to their health, sometimes even leading to the death of the patient or consumer.”*

Explanatory report to the Council of Europe MEDICRIME Convention<sup>1</sup>

### A. The problem of counterfeiting of medical products and similar crimes

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Counterfeiting medical products threatens the health of individuals and the integrity of health-care systems at the global level. This crucial problem, which requires a co-ordinated international response, is addressed by the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (the MEDICRIME Convention) (CETS No. 211).<sup>2</sup>

The need for action is obvious: US\$75 billion dollars in global value per year in counterfeit medicines for human use;<sup>3</sup> more than US\$250 billion in lost revenue in counterfeiting products in general;<sup>4</sup> untold administrative costs for investigation and prosecution; physical and emotional harm to countless victims; increased long-term economic cost due to a greater global disease burden.

1. Explanatory report to the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health, paragraph 3.
2. Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health, Moscow, 28.X.2011.
3. Interpol, Pharmaceutical Crime Sub-Directorate, “Pharmaceutical Crime and Organised Criminal Groups. An analysis of the involvement of organised criminal groups in pharmaceutical crime since 2008”, 2014.
4. OECD, “The Economic Impact of Counterfeiting”, 1998.

Counterfeiting is a global phenomenon that grows significantly each year, as improved technology in all areas of the supply chain enhances the ability of criminals to manufacture, transport and deliver dangerous counterfeit medical products to customers, while many customers are unaware that they have not paid for the real thing. Fraudulent or deceptive practices and counterfeit medicines have garnered high-profile media attention because of several key cases, causing untold anguish to patients and their families who must worry about the impact of these medicines. This in turn undermines public trust in health authorities and health-care systems, and thus in the integrity of government protection of public health.<sup>5</sup>

In response to the growing market for counterfeit medicines, and the subsequent danger to public security from manufacturing, supplying, trafficking in counterfeits and even providing false documentation of medical products that are made to appear legitimate, the Council of Europe has successfully drawn up the first international, legally binding treaty against the criminal act of counterfeiting medical products and similar crimes involving threats to public health. Opened for signature in Moscow, at a high-level conference on 28 October 2011, following a wide consensus among the member states, to date (October 2015), the MEDICRIME Convention has been signed by 24 states.<sup>6</sup> With five ratifications so far, the convention has the requisite support to enter into force on 1 January 2016.

Law plays an important role in regulating conditions that can lead to injury. But there is little that can be done to prevent harm in circumstances where there is no law. This is why it was so important for this convention to be developed and for the Council of Europe's work against counterfeiting to receive political backing. This support was provided by the Parliamentary Assembly of the Council of Europe (PACE), which adopted a number of recommendations<sup>7</sup> on this subject. PACE challenged the image of counterfeiting as a harmless activity and called upon Council of Europe member states "to improve data collection on the linkage between counterfeited goods and injuries or deaths, in particular as regards products such as pharmaceuticals" and

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5. Interpol, Pharmaceutical Crime Sub-Directorate, *op. cit.*; Explanatory report to the MEDICRIME Convention, paragraph 4.
  6. The text of the convention was corrected in accordance with the Committee of Ministers' decision in September 2012 (1151st meeting of the Ministers' Deputies, 18-19 September 2012).
  7. Recommendation 1673 (2004) on counterfeiting: problems and solutions; Recommendation 1793 (2007) on the need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods; Recommendation 1794 (2007) on the quality of medicines in Europe.

emphasised the need for a Council of Europe convention on the suppression of counterfeiting and trafficking in counterfeit goods, underlining that “traffic in counterfeit goods is a scourge that is growing to epidemic proportions across the wider Europe in both the range and volume of goods involved”.<sup>8</sup>

At the intergovernmental level, the multidisciplinary Ad hoc Group on Counterfeit Medicines, established in 2003, dealt with aspects of public health protection and possibilities for improved co-operation of member states and other stakeholders as regards counterfeit medical products: it carried out a survey to identify the gaps in legislation and administrative procedures<sup>9</sup> and held several seminars and conferences.<sup>10</sup> In 2008, the European Committee on Crime Problems (CDPC) agreed on the importance of combating counterfeit pharmaceutical products and stressed that the Council of Europe’s work could bring much added value to the initiatives of other international and regional organisations in combating the counterfeiting of medicines and other health-care products. It approved the terms of reference of the Group of Specialists on Counterfeit Pharmaceuticals and entrusted an ad hoc committee on counterfeiting of medical products and similar crimes, with the task of preparing a report that could be included in a possible international, legally binding instrument to fight crime concerning counterfeit pharmaceutical products (the final report). The CDPC agreed that the highest priority should be given to criminal law aspects of the problem by strengthening international co-operation in preventing any activity that jeopardises public health. The CDPC stressed the need for the specialist group to take into account existing national legislation of member states in this field as well as other work being carried out at the international level, in particular by the European Union and WHO.

Ultimately these efforts produced a text that emphasises international co-operation among governments and international law-enforcement authorities, and international collaboration among transdisciplinary groups of experts, to refine the understanding of the impact on public health and develop robust

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8. Recommendation 1673 (2004); Recommendation 1793 (2007); Recommendation 1794 (2007).

9. Harper J. and Gellie B. (2006), *Counterfeit Medicines – Survey Report*, Council of Europe Publishing, Strasbourg. The “Harper Report” exposes differences that exist in national legislations concerning criminalising counterfeiting of medical products.

10. Seminar “Counteract the Counterfeiters – limiting the risks of counterfeit medicines to public health in Europe by adequate measures and mechanisms”, Strasbourg, 21-23 September 2005; International Conference “Europe against Counterfeit Medicines”, Moscow, 23-24 October 2006.

models for testing and detecting counterfeit pharmaceuticals and medical devices. It provides a strong message to encourage member states to engage in awareness campaigns to alert the public, health-care professionals and industry stakeholders to the dangers of pharmaceutical and health-care product crimes, with particular emphasis on Internet sales. The resulting MEDICRIME Convention covers legitimate medical products including generic medicines and medical devices, regardless of whether they are protected under intellectual property legislation. To cover offences including illicitly distributed medicines that otherwise are not included in the concept of counterfeiting, the MEDICRIME Convention has introduced the concept of “similar crimes involving threats to public health” (Article 8). Such medicines are legitimately produced for certain markets but fraudulently diverted, often by organised crime elements, out of the legitimate supply chain and from the essential safety and quality controls which maintain their integrity. The MEDICRIME Convention also covers the counterfeiting of veterinary medicines: there is a growing black market in counterfeit veterinary medicines, affecting the lives of pets as well as the quality of food for human consumption in the food chain, and also threatening human health directly if veterinary diseases bypass species barriers.<sup>11</sup> The risk of injury and death from counterfeit medical products and similar crimes is thus comprehensively addressed by the MEDICRIME Convention.

Member states are affected by the threat of these crimes whether they are a state of destination, transit or origin. No member state or any part of the world is exempt from this truly international crime. While it may be global in nature, it has a domestic impact. The extent of counterfeiting of medical products in Council of Europe member states or globally is not easily calculable from the public health perspective, due to the challenges posed by injuries not being directly linked to their cause: victims’ injuries and deaths are usually recorded according to their underlying ailments and do not reflect the impact of counterfeit medical products.

The absence of a cohesive worldwide legal instrument establishing the counterfeiting of medical products and similar acts as crimes under international law has impeded efforts to prevent the entry of counterfeit medicines into the legitimate supply chain. The criminalisation of the counterfeiting of medical products has also been inadequately addressed within many nations.<sup>12</sup> The MEDICRIME Convention represents a first legislative attempt to create a

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11. For example, a falsified poultry vaccine led to the avian flu, thus endangering human health.

12. The Falsified Medicines Directive of the EU is not, in fact, a criminal law instrument.

comprehensive international criminal law instrument to provide for a system to prevent public health threats from criminal activities, support the victims and prevent and detect crimes involving medical products. This is achieved by creating and implementing a workable multi-jurisdictional framework addressing counterfeiting and falsification of medical products and similar crimes involving threats to public health. This convention criminalises counterfeit, falsified and illegally supplied medical products, so that now there is a new juridical basis for criminal enforcement to protect the integrity of the legitimate supply chain for medicines and medical devices.

The MEDICRIME Convention is the first international treaty or agreement specifically establishing the counterfeiting of medical products, falsification of documents and similar acts as international crimes, without regard to the status of similar activities under domestic national laws.<sup>13</sup> Instead of piecemeal attacks under domestic laws that may or may not include criminal penalties along with their potential civil liability for documented impact on public health, the convention seeks to impose legal order over counterfeiting chaos. Never before has international law had the criminal jurisdiction to halt and punish crimes involving medical products that threaten to harm large populations of the general public.

## **B. Introduction and objectives of the handbook**

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This handbook is designed to promote greater awareness among parliamentarians concerning all forms of counterfeiting of medical products and similar crimes. Significantly, this handbook is a vital tool for parliamentarians who wish to encourage member states to sign, ratify and implement the MEDICRIME Convention, the Council of Europe's main instrument to combat the counterfeiting of medical products and similar crimes, with a view to stopping such crimes in order to protect public health.

Driven by the urgency of this public health issue, Council of Europe member states wished to extend their co-operation under the convention to non-member states. This approach can promote a juridical consensus and provide a justification for each state to apply their authority under the auspices of the MEDICRIME Convention, and provide a rationale for them to join existing efforts by the International Criminal Police Organization (ICPO/Interpol), Europol,

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13. For example, with regard to patent and trademark laws. The protection of intellectual property rights lies outside the scope of the MEDICRIME Convention, which is drafted from a human rights and public health perspective.

the World Customs Organization (WCO), the United Nations Office on Drugs and Crime (UNODC) and the WHO Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit (SSFFC) member state mechanism including its Rapid Alert System for surveillance.

Despite their ongoing efforts, international organisations involved in fighting the counterfeiting of medical products currently lack critical enforcement authority to take on this specific problem as a matter of international criminal law. Their programmes operate in separate spheres, sometimes under the auspices of their general powers but without specific legal authority regarding these crimes. The time has come, however, to provide a juridical basis for intervention.

The MEDICRIME Convention therefore represents an important step in the creation of criminal law that will facilitate transnational co-operation to arrest a global problem.

This handbook for parliamentarians falls within the context of the parliamentary dimension of the Council of Europe's will to criminalise the counterfeiting of medical products and similar crimes involving threats to public health. The objectives of this handbook include:

1. Explaining the MEDICRIME Convention's purposes and language in a manner that is accessible to parliamentarians and their constituents across the member states of the Council of Europe and beyond.
2. Encouraging ratification of the convention based on such understanding of the purposes, its impact and the public health protections it intends to provide by making the counterfeiting of medical products and similar acts involving threats to public health crimes under international law.
3. Enabling parliamentarians and their home legislatures to engage in programmes for awareness raising to reassure the law-abiding, general public.
4. Encouraging home nations to proactively co-operate with international law-enforcement efforts.
5. Encouraging international collaboration by experts to develop the benchmarks, analytical methods and related enforcement tools that can recognise counterfeit medical products once such products enter the market, so that evidence will exist when prosecuting the people who profit from the manufacturing, distribution and transport of counterfeit medical products.

The MEDICRIME Convention may be described as both a comprehensive and proactive legal instrument. It contributes to the fight against this global public health threat from a unified, international perspective, encouraging international co-operation by enforcement authorities, while also requiring international collaboration by experts to bolster state-of-the-art methods that can detect counterfeit medical products. Presently, there is inadequate jurisdiction to support efforts among international organisations and treaty-based organisations which take action but suffer from the absence of justification in international criminal law. The convention has an added value that lies in its multidisciplinary approach. It aims to prevent the counterfeiting of medical products by developing international collaboration between a wide variety of specialists in various disciplines, in order to combat the problem at its source using a wide range of tools. International co-operation and collaboration by experts are therefore a linchpin for controlling the traffic and monitoring the long-term effects of these threats to public health, at all stages of the supply chain.

## **C. Role of parliamentarians**

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Parliamentarians can play a vital role in efforts to combat this global phenomenon by:

- promoting signature and ratification of the MEDICRIME Convention;
- encouraging their national legislatures and enforcement administrations to implement the MEDICRIME Convention requirements.

The following are some activities that could be undertaken by parliamentarians.

### **1. Fact-finding**

- initiate relevant parliamentary enquiries.

### **2. Public awareness campaigns**

- formally request their respective governments to hold public hearings that address specific questions about the spread, prevention and public health impact of these crimes;
- engage their respective legislature, enforcement authorities and executive branch in a public awareness campaign offering tools at the local and national levels (this handbook, USB flash drives containing legislative texts and campaign material on the subject).



### **3. Steps towards the ratification of the MEDICRIME Convention**

- strengthen existing domestic legislation;
- organise debates at national level (within their parliaments), and at regional and local levels (in their respective constituencies), regarding methods to prevent and stop these crimes, while respecting respect civil liberties and other human rights;
- initiate open discourse with the general public (articles in the press, social media, public forum events in community centres and schools).

### **4. Implementation of protections to safeguard public health**

- establish a specific follow-up committee (or sub-committee, or parliamentary group) within the national parliament;
- exchange information and expertise with other parliamentarians to stop trafficking in counterfeit, falsified or deliberately sub-standard medicines;
- establish bilateral partnerships at national and international levels (professional associations, non-governmental organisations (NGOs), the European Union, Europol, Interpol, WHO, the United Nations, the Inter-Parliamentary Union (IPU), WCO, UNODC, the Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO), the Permanent Forum on International Pharmaceutical Crime (PFIPC)) and across Council of Europe member States to:
  - contribute to the development of national strategies and programmes aimed at instituting criminal liability for crimes covered by the MEDICRIME Convention;
  - enable their staff to provide technical/legal assistance to states which so request;
  - ensure compliance of national legislation with international commitments in the field, in particular the MEDICRIME Convention;
  - revise and strengthen national legislation, including by establishing a database to register the impact on, and the subsequent needs of, victims of counterfeit medical products, including the ones for veterinary use;
  - adopt legislation that is consistent across European countries and beyond, with a view to achieving greater harmonisation, which will advance enforcement efforts;

- appropriate sufficient funding for resources that combat counterfeiting of medical products, the falsification of documents accompanying medical products and similar crimes;
- establish national data-collection systems to help identify vulnerable groups and the consumers who are likely to fall prey to these medicines and medical devices, and follow-up with higher scrutiny of health care for victims;
- establish confidential and anonymous hotlines and other support services so that anyone can report an incident of medical counterfeiting, falsified documents or similar crimes covered by the convention;
- support increased oversight and quality surveillance for all licensed medicines throughout the world.

The MEDICRIME Convention is very special because it enables states parties to create a follow-up mechanism in order to ensure effective implementation of these provisions. By creating working groups and encouraging international co-operation for enforcement and international collaboration for the definition, surveillance and long-term understanding of the disease burden caused by these crimes, the convention will also inevitably raise the general public's awareness of national law. We urge your participation and welcome your enthusiastic use of this handbook.

## **D. Background**

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The sale and subsequent use of counterfeit medicines and medical devices (and of products from similar crimes involving threats to public health) are ubiquitous. These products are made using components from unregulated sources, resulting in risky medicines and medical devices that present an undisputed danger to life and health.

This global public health problem has profound short and long-term consequences for physical health, psychological development and psychosocial well-being. In addition, the fear of having taken deliberately counterfeit (falsified) medicines causes untold emotional anguish for patients and their loved ones alike, thus undermining public trust in all health care, even when using legitimate products from authorised suppliers. It may be surprising that counterfeit medical products are not yet subject to international criminal law. Even though these products may be illegal in some states, it is not internationally agreed that they are illegal. Hence there is no violation of criminal law, until the MEDICRIME Convention enters into force.

## **A costly threat to the integrity of global public health**

A primary trend in many member countries is the increased use of illicit, so-called “online pharmacies”, operated by both informal networks and organised criminal groups.

Large amounts of money are involved in these types of transnational criminal enterprises: one illicit online pharmacy network, which was dismantled by US authorities in 2011, made US\$55 million during its two years of operations.<sup>14</sup>

A 2008 European Commission working document<sup>15</sup> estimated the costs incurred to the EU from falsified medicines until 2020 as follows: hospitalisations as a consequence of treatment using counterfeit medicines, €1.8-22 billion and avoidable medical treatment at primary health-care doctors, €93 million to 1.1 billion. There is also the unnecessary suffering caused to the patients, which is not quantifiable, but very damaging indeed.

Are law-enforcement authorities’ hands tied by the organised networks that conduct these dangerous activities?

Is there something that governments can do by working together?

## **A global public health problem requires an international solution**

Protecting public health, an offshoot of a government’s duty towards citizens that is derived from the core value of protecting the right to life, has long been a key element of the work carried out by the Council of Europe. Council of Europe conventions are respected for their wide influence that extends “... way beyond its Member States’ perimeter”.<sup>16</sup>

Injury prevention specialists recognise that injury is best controlled by eliminating and/or minimising opportunities for exposure to harm, which can be achieved by creating strategies at national and international levels. Furthermore, the World Health Assembly Executive Board has continuous reporting regarding this problem, and has “decided that a study to increase understanding and knowledge on the links between accessibility and affordability and their

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14. Interpol, Pharmaceutical Crime Sub-Directorate, op. cit.

15. Commission Staff Working Document accompanying document to the proposal for a Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified, 2008.

16. Statement by Mr Ferit Hohxa, Permanent Representative of Albania to the United Nations, on “Cooperation between United Nations and Regional Organizations” 53rd meeting of the 67th General Assembly (Plenary), GA/11326, 12 December 2012, New York.

impact on the emergence of substandard/spurious/false-labelled/falsified/counterfeit medical products (SSFFC) and to recommend strategies to minimise their impact will be included on the next provisional list of activities for consideration by the fourth meeting of the Member State mechanism<sup>17</sup>

Treaties, such as the European Convention on Human Rights (ETS No. 5), the European Convention on Mutual Assistance in Criminal Matters (ETS No. 30) and the Convention on Cybercrime (ETS No. 185), are well-established global benchmarks and have been incorporated into national, European Union and international laws. Council of Europe guidance documents concerning bioethics, safety of blood products and organ transplantation are the source of respected standards, applied by regulatory authorities and health-care professionals worldwide. The Convention on the Elaboration of a European Pharmacopoeia, for example, serviced by the Council of Europe's European Directorate for the Quality of Medicines & HealthCare, provides quality standards for the ingredients and production of medicines. These standards are binding for 37 signatory states in Europe and the European Union, and are a respected reference for its 27 observers all around the world, including WHO. The certification process under the auspices of EDQM is a potential repository for the reporting of counterfeit drugs and medical devices and the testing of their contents.

In light of this juridical context, it is natural for the Council of Europe to lead the international movement to criminalise counterfeit medical products.

The Committee of Ministers of the Council of Europe relied upon the juridical foundations expressed in its preamble when it adopted the MEDICRIME Convention in December 2010. Noting other relevant international legal instruments and programmes, especially within WHO and by the European Union, as well as in the forum of the G8, it was clear that there were no obstacles to having the Council of Europe fill this void in international criminal law.

## **1. Scope of the global health problem posed by counterfeiting**

The EU has acknowledged the need to simultaneously protect consumers and safeguard intellectual assets so that creativity and innovation can continue to be major drivers of growth. Europol's Serious and Organised Crime Threat Assessment (SOCTA) has issued a report describing cases involving commodity

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17. World Health Organization, Report by the Director-General. Agenda item 8, report of the third meeting of the member state mechanism on SSFFC medical products, 68th World Health Assembly A68/33 Provisional agenda item 17.3, 20 March 2015.

counterfeiting in violation of health, safety and food regulations and the sale of sub-standard goods. It has designated this issue as a new priority area in the EU policy cycle 2014-17. Cases are often extremely complex, involving many different jurisdictions, sometimes crossing borders through easily removed websites on the Internet or connecting counterfeiters to unsuspecting buyers via social media. For example, their report cites Peter Gillespie, a chartered accountant and pharmaceutical distributor, who imported 72 000 packs of counterfeit medicinal products, which is more than 2 million doses. Approximately one third of these shipments involved medicines for serious conditions such as prostate cancer, heart problems and schizophrenia.<sup>18</sup>

To combat these operations, in 2014 WHO implemented the Surveillance and Rapid Alert System for SSFFC Medical Products. The system is operational throughout the European region and functions in affiliation with other WHO regional offices. WHO sets forth four basic conditions<sup>19</sup> for individuals, communities and societies to attain optimal levels of safety. But efforts are hampered by the lack of criminal law jurisdiction to enforce protections, and by rapid changes in technology for counterfeiting and anonymous distribution via the Internet.

## 2. Health as a human right: the Council of Europe mission

Rights are not favours or gifts, and society cannot survive without protecting the human right to health, the linchpin right of access to preventive health care and the right to medical treatment, as enshrined in different Council of Europe and international treaties. Thus, protecting the right to health through the proactive enforcement of laws that protect public health is an integral part of fostering the well-being of society as a whole.

Crimes involving medical products are a complex problem that destroys consumer and prescribers' choices through deceptive and criminal acts of third parties. Regulatory models have been developed to promote the implementation

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18. Europol and the Office for Harmonization in the Internal Market, 2015 Situation Report on Counterfeiting in the European Union, at [www.europol.europa.eu/content/2015-situation-report-counterfeiting-european-union](http://www.europol.europa.eu/content/2015-situation-report-counterfeiting-european-union).

19. 1) a climate of social cohesion and peace as well as of equity protecting human rights and freedoms, at a family, local, national or international level 2) the prevention and control of injuries and other consequences or harms caused by accidents; 3) the respect of the values and the physical, material and psychological integrity of the individuals; and 4) the provision of effective preventive, control and rehabilitation measures to ensure the presence of the three previous conditions. Québec WHO Collaborating Centre for Safety Promotion and Injury Prevention, Activity Report January 2002-June 2003, at [www.inspq.qc.ca/pdf/publications/261-ReportOMS2002-2003Eng.pdf](http://www.inspq.qc.ca/pdf/publications/261-ReportOMS2002-2003Eng.pdf).

of safety measures to control known risks of injuries in the workplace, public spaces, the environment and in fixed infrastructures such as health-care delivery systems. Using established knowledge about control systems to implement protection can therefore reduce injury or prevent certain problems. It may be possible, through international collaboration between experts in the fields of health-care, law enforcement and legislation, to construct a model regulatory apparatus that will detect dangerous activities before counterfeit (falsified) and illegally supplied medicines and medical devices enter the supply chain and reach their markets.

### **3. Patient, consumer and victim perspective**

The convention is a unique tool that allows for states to prosecute upon proven evidence of these acts, without requiring the victim to file charges (this role belongs to the state prosecutor; the victim has a standing in criminal procedure). It is very difficult to prove the causal relation between consumption of a drug and damage to health, but the convention determines criminalisation based on the risks, even without harm occurring. The international collaboration provision of the MEDICRIME Convention offers a good start in this respect. There is a range of variables that may influence the level of harm to an individual from a counterfeit medical product, and this convention is the first step towards redress for people who have been harmed and the national health-care systems that pay to provide care for them and which may not have the necessary means.

## **E. National activities among Council of Europe member states**

Alexander Prokopiev, member of the Russian Duma, garnered international attention by discussing, in the Russian press, amendments to the Russian Code of Administrative Offences and the Criminal Code that tighten the controls over pharmaceutical production and introduce criminal penalties for documented harm.<sup>20</sup> Citing weak criminal penalties as a major cause of the mounting crisis in counterfeit products, this member of the Russian Duma would like such acts to be considered crimes that pose a direct threat to the life of individuals. Since producing legitimate medicines nonetheless requires precision technology that is not immune to mistakes, the parliamentarian was quick to note the importance of exonerating legitimate manufacturers in case of unintended errors.

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20. Interview with member of the Duma committee on health, 12 May 2015.

In 2011, the French medicines and health-care products regulatory authority (ANSM) withdrew PIP (Poly Implant Prothese) breast implants from the market. These medical devices contained materials that were unsuitable for humans, and which had not been declared in the product's documentation. Thousands of women in Europe and on other continents suffered health complications, and some of them have sought help through their national health-care systems.<sup>21</sup>

In September 2014, law-enforcement authorities from Austria, Belgium, Cyprus, France, Hungary, Slovakia, Spain and the United Kingdom, supported by Europol, joined in a simultaneous operation to stop the distribution of counterfeit prescription-only medicines in the European Union. Authorities seized several million pills with an estimated value well in excess of €10 million, a large amount of cash and several vehicles, and froze more than €7.5 million in bank accounts and assets. The investigation began in September 2012, thanks to intelligence leads provided by Spanish authorities. Eurojust assisted with the creation of a common strategy, including the establishment of a joint investigation team from Spain, Austria, France and the UK, and which was supported by authorities in Cyprus, Hungary and Slovakia. Over the course of the investigation, more than 300 000 tablets with an estimated value of €2 million were seized in Austria, but authorities believe that amount represents only one fifth of the total transactions in that country. Significant financial transactions relating to the sale of counterfeit and unlicensed medicines were uncovered in both France (payments totalling €9 million over three years) and the UK (more than €12 million in transactions). In Spain, counterfeit goods worth more than €1.5 million were seized and three people were arrested.<sup>22</sup>

Since 2008, Interpol has co-ordinated Pangea, targeting medicines sold illicitly online. Their 2014 campaign led to the removal of more than 19 000 adverts for medicines on social media platforms and the closure of over 10 600 websites. The public health threat and the economic dimensions of this phenomenon cannot be understated.<sup>23</sup>

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21. Kleijssen J. and Keitel S., "The Council of Europe MEDICRIME Convention: protecting the patient from counterfeit/falsified medical products, a pre-requisite for safe healthcare", May 2014, [www.coe.int/fr/web/human-rights-rule-of-law/article-jk-2014-04-03](http://www.coe.int/fr/web/human-rights-rule-of-law/article-jk-2014-04-03).

22. Eurojust, Press release (2014) "Fake medicines targeted", at <http://www.eurojust.europa.eu/press/PressReleases/Pages/2014/2014-09-01.aspx>.

23. <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea>.

## F. The dearth of international standards

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The MEDICRIME Convention represents a path-breaking first step towards solving these potentially devastating threats to public health throughout Europe and the world.

Due to the globalisation of commerce in general, and the organised cross-border networks for the manufacture, transport and distribution of counterfeit and illicitly supplied medical products, the solution to this global health problem must include a unified governmental response under international law. Without specific language to provide jurisdiction for stopping these activities, current prevention efforts have been piecemeal at best and cannot outstrip the massive influx of illicitly supplied medicines and devices into the public health delivery system unless there is a firm basis for treating acts involving medical products as international crimes.

The 20th session of the UN Commission on Crime Prevention and Criminal Justice (CCPCJ)<sup>24</sup> adopted resolution 20/6 “Countering fraudulent medicines, in particular their trafficking”, due to concern about the involvement of organised crime in the trafficking of fraudulent medicines. Resolution 20/6 highlights the potential utility of the United Nations Convention against Transnational Organized Crime (UNTOC) for which UNODC is the guardian, in re-enforcing international co-operation in the fight against trafficking, under provisions for mutual legal assistance, extradition and the seizing, freezing and forfeiture of the instrumentalities and proceeds of crime. Resolution 20/6 contains nine action points.<sup>25</sup> Paragraph 8 requests that UNODC, in co-operation with other United Nations bodies and international organisations, such as the International Narcotics Control Board (INCB), WHO, the WCO and Interpol, assist member states in capacity building by using the experiences, technical expertise and resources of each organisation in order to create a co-ordinated effort to dismantle organised criminal networks engaged in all stages of distribution and trafficking. It must be recognised, however, that resolutions lack the force of a treaty or convention governing international criminal laws.

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24. Technical Conference of Experts on the Trafficking in Fraudulent Medicines, 14-15 February 2013 in Vienna; Report on the 20th session of the Commission on Crime Prevention and Criminal Justice (CCPCJ); Resolution 20/6: English and French international law enforcement action against fake medicines, The Hague, The Netherlands, 1 September 2014.

25. [www.unodc.org/documents/organized-crime/FM/Resolution\\_20\\_EN.pdf](http://www.unodc.org/documents/organized-crime/FM/Resolution_20_EN.pdf).



Within the European Union, the European Falsified Medicines Directive (FMD), a regulatory instrument, is intended to protect the integrity of authorised medicinal products within the legitimate supply chain. But, FMD is a regulatory approach covering – within the EU – medicinal products for human use, and is not focused on the criminal law perspective. By contrast, the MEDICRIME Convention aims to criminalise acts that interfere with legal medical products for humans and animals, and includes both the trafficking and the criminal acts involved in the distribution of products such as adulterated materials, fraudulent components and falsified documentation to patients and health-care systems.

Although laudable and sometimes fruitful, existing efforts by international organisations have no plain language that defines the counterfeiting and falsification of medicines and medical devices as criminal activity under international law. Unless there is a firm basis for treating the activities discussed in the MEDICRIME Convention as crimes under international law, those existing efforts will be unable to stem the tide of these harmful activities. Bringing criminals to justice, from the standpoint of procedure, because it codifies the juridical concept of the counterfeiting of medical products and similar crimes where there has previously been no international criminal law, and from the point of view of substance, by defining the acts that cause harm, therefore represents a major step towards establishing jurisdiction over these acts as criminal activity under international law.

## **G. The involvement of international organisations in the fight against counterfeiting of medical products and similar crimes**

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Here are some examples of efforts by international organisations that have taken an expansive view of their jurisdiction to tackle the global public health challenge and to prevent and arrest transnational counterfeiting activities that are dangerous to public health but are not considered as “crimes” under current international law.

### **1. WHO Surveillance and Rapid Alert System for SSFFC Medical Products**

WHO found that the manufacturing, distribution and sale of SSFFC medical products is an international issue threatening the health of citizens and public confidence in medicines. WHO Executive Board recommendations for

detailed approaches to pharmacovigilance, though not treaty based and not law, provide a springboard for discussion of detailed methods to protect the integrity of medicines everywhere, because the procedures set forth in their recommendations are the product of international collaboration by experts.<sup>26</sup>

Officially recognising that vigilance is necessary to protect global trust in health-care delivery systems, WHO initiated a project specifically focused on creating a global reporting and alert system for SSFFC products with follow-up. The WHO Surveillance and Rapid Alert System for SSFFC Medical Products provides a form that can be sent to a designated WHO email address to alert the network about the discovery of an SSFFC product. Photographs, laboratory reports, recall notices or other documents can also be sent as attachments. When the Rapid Alert Form is received, the information automatically populates a WHO database. The originator will receive email confirmation and follow-up contact by email or telephone from WHO within 24 hours in cases where adverse reactions in patients are reported, or 72 hours if there are no adverse reactions. The reporting form is available in several languages. Workshops are held to increase member states participation and capacity building for handling, communication and prevention of incidents involving SSFFC products, including development of specialised laboratories for quality assurance and forensic testing. Detailed statistical analysis of reported incidents are conducted by WHO analysts who will publish reports concerning the scope, scale, extent and harm caused by SSFFC products. The success of this programme requires international collaboration among experts from WHO member states and national medicines regulatory authorities (NMRAs) to create an effective global surveillance system and a database of reliable, validated and accurate data. NMRAs play a critical role as the frontline for data collection, submitting information to WHO in order to assist in the development of new strategies to reduce these products.<sup>27</sup> Under the WHO system, NMRAs are trained to report incidents involving SSFFC products through the use of the WHO Rapid Alert Form.

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26. World Health Organization, Executive Board, Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products, November 2014.

27. From 27 to 29 May 2014, WHO offered training for implementing the surveillance and rapid alert system for SSFFC products. Hosted by the Ministry of Health of Turkey and Medicines and Medical Device Agency, 48 experts from 19 countries of the WHO European Region included pharmaceutical inspectorates, pharmacovigilance departments, quality control laboratories and enforcement.

## 2. The World Customs Organization

Established in 1952, the Customs Co-operation Council (now the World Customs Organization) is an independent intergovernmental body whose mission is to enhance the effectiveness and efficiency of customs administrations. WCO represents 179 customs administrations across the globe that collectively process approximately 98% of world trade.<sup>28</sup> As the global centre for customs expertise, the WCO is the only international organisation with competence in customs matters and can rightly call itself the voice of the international customs community. The WCO's governing body – the Council – relies on the competence and skills of a secretariat and a range of technical and advisory committees to accomplish its mission. The secretariat comprises over 100 international officials, technical experts and support staff of various nationalities. As a forum for dialogue and exchange of experiences between national customs delegates, the WCO offers its members a range of conventions and other international instruments, as well as technical assistance and training services provided either directly by the secretariat, or with its participation. The secretariat also actively supports its members in their efforts to modernise and build capacity within their national customs administrations. WCO endeavours to combat fraudulent activities are also recognised internationally. The partnership approach championed by the WCO is one of the keys to building bridges between customs administrations and their partners.

## 3. Interpol's response to counterfeit medicine

According to Interpol, organised criminal networks are attracted to the huge profits made from counterfeit medicines. An Interpol analytical report published in 2014,<sup>29</sup> asserts that counterfeiters operate in networks across national borders using components from different sources and using major routes of global commerce to import, export, manufacture, distribute and sell counterfeit medicines. According to Interpol, global action is vital in order to identify, investigate and prosecute the perpetrators of these activities, even though there is no present international consensus that such actions are a crime under international law.

Despite this void in international criminal law, Interpol is tracking medical counterfeiting and similar crimes in three main ways:

- co-ordinating operations in the field to dismantle transnational criminal networks;

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28. [www.wcoomd.org](http://www.wcoomd.org).

29. Interpol, Pharmaceutical Crime Sub-Directorate, op.cit.

- delivering training and capacity-building programmes for agencies involved in the fight against crimes concerning medical products;
- building partnerships with stakeholders across a variety of sectors.

It should be noted, however, that Interpol is neither a regulatory agency nor a treaty-generating international organisation. Therefore it can track the problem of medical counterfeiting but it cannot deploy its full range of resources and powers as it does to stop activities that are recognised as a crime under international law. The Council of Europe MEDICRIME Convention therefore provides an essential element for arriving at the criminalisation of harmful acts that would otherwise be without redress under international law.

## 4. Europol

The European Union has acknowledged the need to protect consumers and safeguard intellectual assets simultaneously, to ensure that creativity and innovation continue to be major drivers of growth. Europol supports and strengthens action by competent authorities to co-operate mutually in preventing and combating organised crime, terrorism and other forms of serious crime affecting two or more member states. In March 2013, Europol Focal Point “COPY’s”<sup>30</sup> mandate to investigate counterfeit products was expanded to include sub-standard and dangerous goods. Europol’s 2013 SOCTA evaluation identified counterfeit goods violating health, safety and food regulations and sub-standard goods as a recommended priority crime areas in the 2014-17 EU Policy Cycle.

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30. Focal Points are teams formed by specialists and analysts supporting member states’ operations related to specific areas of crime that are included in the 6 April 2009 Council Decision establishing the European Police Office (Europol)“.



## IV. The Council of Europe MEDICRIME Convention

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The MEDICRIME Convention sets forth a path-breaking new approach to tackling the major global public health threat of counterfeiting of medical products and similar crimes.

For the first time in international law, the Council of Europe offers a workable framework for national and international co-operation between the competent legal, health, police and customs authorities, the effective prosecution of crime and the protection of victims. It brings together the field of criminal law, as the mechanism to achieve the specific purpose of protection, and the field of public health as the beneficiary, in a single instrument. Thus the MEDICRIME Convention represents the most advanced and comprehensive instrument at the international level for averting the public health crisis that could arise if counterfeiting of medical products and similar crimes were left unchecked. This convention clearly recognises that international co-operation among states is key to solving this problem in order to protect public health. It aims to achieve this by creating a workable strategy for prevention, detection and response, including prosecution, to these types of crimes all while taking into account the impact on victims.

### **Protecting public health, by combating counterfeiting of medical products and similar crimes**

Existing informal mechanisms do not provide a legal basis to establish counterfeiting of medical products and similar acts as crimes under international law from a public health perspective. The MEDICRIME Convention therefore represents the first time an international treaty defines and criminalises the counterfeiting of medical products that undermines public confidence in the safety, efficacy and quality of medical products and the ability of the state to guarantee a sufficient level of confidence in its health-care system.

Equally important, the convention covers all medical products (Article 3), regardless of whether they are protected under intellectual property rights or are generics. This is because counterfeiters do not discriminate between innovative and generic medical products and counterfeiting of either type constitutes a danger to public health. The convention facilitates international co-operation among legal, law-enforcement and health authorities as well as harmonisation of procedures for detection, inspection, reporting and follow-up in the event of negative health consequences. These measures include but are not limited to product recall, the prohibition of confiscated medicines, active substances, medical devices and their parts and materials, storage of evidence and destruction of dangerous counterfeit materials. Lastly, the convention establishes an international agenda that will make use of existing monitoring mechanisms.

### **No safe havens for criminals**

One major added value of the MEDICRIME Convention, from a practical enforcement perspective, may be its codification of “common language”, which creates transborder pathways for co-operation. This will make it harder for counterfeiters to benefit from “legal gaps” – there will be no safe havens for counterfeiters within the realm of the Council of Europe and the co-operating states also bound by the convention. At the same time, the convention protects the integrity of the larger public health system.

## **A. Purposes of the convention**

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The duty of governments to protect public health is a long-established principle of law. Globalisation has made the transfer of goods and technology easy, but until the advent of the MEDICRIME Convention there was no international criminal law limiting transborder trade in counterfeit medical products and no formalised international co-operation to punish such acts while taking into account the perspective of public health. Despite the threat of harm to the general public, each state was compelled to rely on its own resources and the limited reach of its criminal jurisdiction with uneven consistency and variable results, and with only informal co-operation from foreign enforcement authorities or international policing organisations.

Therefore, the MEDICRIME Convention endeavours:

- to prevent and combat counterfeiting of medical products and similar crimes thereby protecting the rights of consumers to the integrity of

- their medicines and maintaining trust in the health-care system, thus helping governments to fulfil their obligation to protect public health;
- to protect the rights of victims of the counterfeiting of medical products and similar crimes;
  - to provide a basis under international criminal law for national and international co-operation to fight this phenomenon, which, according to Interpol, is sometimes linked to money laundering and organised crime;
  - to promote international collaboration that will produce robust procedures to aid detection, data collection, monitoring, follow-up, reporting and notification to authorities, consumers, stakeholders and the general public;
  - to provide a platform to ensure the uniform criminalisation of dangerous acts across states parties, the co-ordination of law enforcement to detect the crime, report the crime to the relevant enforcement authorities and notify public health officials who in turn can alert the general public in case of emergency; ultimately, this will also prevent illness that inevitably burdens national health-care resources.

## **B. Non-discrimination principle**

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The convention prohibits all types of discrimination when implementing its provisions. The list of grounds for discrimination is based on those listed in Article 14 of the European Convention on Human Rights, and its Protocol No. 12, and also includes other grounds. Specifically, in applying the convention it is prohibited to discriminate against individuals based on sex, race, colour, language, age, religion, political or any other opinion, national or social origin, association with a national minority, property, birth, sexual orientation, state of health, disability or other status.

Protection against discrimination is important when implementing measures to safeguard the rights of victims, because illness and disability in nature does discriminate and refuses to respect international borders. The ever-increasing data on health disparities linked to race, age or sex is poorly understood, but it remains true that the impact of counterfeiting of medical products and similar crimes may differ based on a victim's overall health status, race, age or sex, or whether they have an underlying disability that is unrelated to the counterfeit medical product. It is reasonably foreseeable that specific counterfeit products will have different effects across sub-populations, due to individual variability or genetic differences (such as adverse reactions or



a patient's genetically inherited condition). For example, in 2008, medicines containing contaminated heparin, a blood-thinning medicine essential in the treatment of several life-threatening conditions, were associated with serious injuries and deaths.<sup>31</sup> Many of those who died were also being treated for other medical conditions.

## C. Definitions

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The MEDICRIME Convention uses the term “counterfeit” in the sense of “a false representation as regards identity and/or source” (Article 4.j).<sup>32</sup> Jurisdiction therefore extends beyond the final products that reach end users in the supply chain, to include the active substances and excipients that go into the manufacture of medicines and parts and materials specifically used to create counterfeit medical devices.

The term “medical product” is used in the convention to include both medicines (medicinal products)<sup>33</sup> and medical devices.

“Medicinal product” is defined (Article 4.b) as:

- i. any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;
- ii. any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;”

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31. FDA, Postmarket Drug Safety Information for Patients and Providers (2015), Information on Heparin, at [www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM112597](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM112597).

32. This definition is similar in wording and has the same meaning as the EU Falsified Medicines Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, at [http://ec.europa.eu/health/files/eudralex/vol-1/dir\\_2011\\_62/dir\\_2011\\_62\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf). The EU Directive refers to the term as falsified whereas the MEDICRIME Convention refers to the term as counterfeit. As both have the same meaning they are used in this handbook interchangeably, but the term counterfeit is preferred.

33. The term medicinal product is the same as used in the EU Directive 2004/27, for human use and Directive 2004/28 for veterinary use, but the convention combines these to provide a single medicinal product definition. It also adds investigational medicinal products under this combined heading but does not define this latter term. The term investigational medicinal product is, however, defined in EU Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001.

The terms “active substance” and “excipient”, which are components of the finished dosage medicinal product, are defined separately.<sup>34</sup>

Article 4.e states that “medical device” shall mean “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:

- i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
- ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- iii. investigation, replacement or modification of the anatomy or of a physiological process;
- iv. control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”.

The terms “parts and materials” and “accessories” are used in relation to medical devices and are also separately defined.<sup>35</sup>

The very broad term “document”, as defined in Article 4.h, covers “any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labelling instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof”.

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34. “Excipient” means any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medical product for human or veterinary use and essential for the integrity of the finished product. “Active substance” means any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product. (Articles 4.c and 4.d).

35. “Parts and materials” mean all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof, (Article 4.g). For example, this could be a screw or mechanical joint specifically designated for a hip replacement. “Accessory” means an article which, whilst not being a medical device, is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of a medical device intended by the manufacturer of the medical device. For example, this could be software used to run a medical device.

The legislatively developed term “trafficking” is not defined in the convention, but is used in a manner that is consistent with UN texts.<sup>36</sup>

Article 4.k reaffirms the important duty of a state to protect the public health of its citizens, stating “the term ‘victim’ shall mean 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”. Victims have, among others (see Articles 19 and 20 of this convention), the right to access to information relevant to their case and which is necessary for the protection of their health, but the convention respects existing national laws and procedural criminal rules, as well as national laws governing civil liability for such acts.

A major argument favouring ratification is that medicinal products which are unhealthy for animals may have an impact on the health and well-being of humans. Animals in the food chain must be healthy in order to ensure protection of people in daily life. Article 4 uses the phrase “preventing disease in humans or animals” and covers “medicines for human and veterinary use”. The rationale for including medicines for veterinary use under this convention is that deliberately compromised medicines may directly affect public health through the food chain, and indirectly where disease is transmitted from animals to humans as a consequence of inefficacious veterinary medicines. The drafters of the convention have had the forethought to include non-human consumption of medicines in the scope of their definitions, ensuring a comprehensive system so that no subsequent international treaty or convention is required to target the presence of counterfeit medicines in the food chain.

### **Criminalisation of counterfeiting and related acts**

The MEDICRIME Convention obliges parties to establish as criminal offences the intentional commission of the acts defined in Articles 5 to 8:

- manufacturing of counterfeit medical products;
- supplying, offering to supply (including brokering), and trafficking in counterfeit medical products;
- falsification of documents;

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36. Such as the United Nations Single Convention on Narcotic Drugs (1961), the United Nations Convention on Psychotropic Substances (1971), the United Nations Convention Against Transnational Organized Crime and its Protocols (2000), the United Nations Firearms Protocol, and the Council of Europe Convention on Action against Trafficking in Human Beings (CETS No. 197, 2005).

- similar crimes involving threats to public health, in so far as such activity is not covered by Articles 5, 6 and 7. These include, in particular:
  - “a. the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:
    - i. medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or
    - ii. medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;
  - b. the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.”

Examples of offences covered by Articles 5, 6 and 7 are outlined below to illustrate the breadth of risk for patients, and the profit that can be made by white-collar criminals, as well as by organised crime. They also illustrate that, increasingly, lifesaving medicines rather than “lifestyle” medicines are being counterfeited and trafficked. Of particular relevance to the offences described in the MEDICRIME Convention is the reality that each instance is likely to involve two or three of the offences established in Articles 5, 6 and 7, and possibly in some cases, Article 8.

Italian organised criminal elements are suspected to have been involved in the 2014 theft, counterfeiting and trafficking of Herceptin<sup>®</sup>,<sup>37</sup> a medicine for the treatment of cancer. Once stolen, the medicines were channelled through an authorised Italian wholesaler to fictitious wholesalers in Hungary, Romania, Latvia and Italy. They were then tampered with and falsified, so much so that in some cases no active ingredient remained. The counterfeit Herceptin<sup>®</sup> was then put on the market in other countries (Austria, Finland, Germany, Sweden and the UK) for dispensing to patients. This was a very lucrative crime as one vial costs, for example, over £400 in the UK.

Avastin<sup>®</sup>, a high-priced medicine used for the treatment of cancer, was trafficked by Richard Taylor from Europe to the US, and sold directly by Montana Health Care Solutions and Rocky Ventures to US medical clinics. This involved both the diverted authentic as well as counterfeit versions of Avastin<sup>®</sup>. Some of the Avastin<sup>®</sup> did not contain any active substance, to the detriment of the

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37. IRACM (2014), “Herceptin traffic in Europe: Organized crime at the heart of the investigation”, at [www.iracm.com/en/2014/05/europe-herceptin-traffic-organized-crime-at-the-heart-of-the-investigation/](http://www.iracm.com/en/2014/05/europe-herceptin-traffic-organized-crime-at-the-heart-of-the-investigation/).

cancer patients. Richard Taylor was finally sentenced to 18 months in prison and a fine of US\$800 000.<sup>38</sup>

Other lifesaving medicines that have been counterfeited and trafficked<sup>39</sup> include Truvada®, Viread®, Combivir® and Viramune®, all indicated for the treatment of HIV. Counterfeit versions of these treatments have been found on the markets of several European countries since 2009. The trade in counterfeit lifesaving medicines, such as Casodex® for the treatment of prostate cancer, Zyprexa® for the treatment of psychosis and Plavix® for the treatment of cardiovascular disease, was the subject of a multi-state investigation centred on the UK, which began in 2007.<sup>40</sup>

Adulteration with different active substances is common in the illegal manufacturing industry and supply market, due to the use of the same machinery to make various products involving the use of different active substances. This has been common in the production of counterfeit erectile dysfunction medicines where multiple active ingredients have been found during analysis.<sup>41</sup> In 2012, over 100 patients of a Pakistani medical clinic were reported to have died as a result of the adulteration of Isotab®, a cardiac medication, with pyrimethamine which is used for the treatment of malaria. The resulting product contained over 14 times the recommended dosage of pyrimethamine for malarial patients.<sup>42</sup>

Veterinary medicinal products are equally vulnerable. Questions were raised in one UK prosecution<sup>43</sup> as to the impact of counterfeit veterinary medicines on the global epidemic of antibiotic resistance. Counterfeit anti-inflammatories, pain medication, sedatives and antibiotics, with a value of £6 million, were sold by a couple living in France, and operating from Belgium and the UK, to 4 000 customers in the farming and veterinary professions up to 2011. The products had been imported from Asia.

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38. Roth J. (2013), "Counterfeit Drugs: Prosecuting the Profiteers, Protecting the Public Health", FDA Voice, At <http://blogs.fda.gov/fdavoices/index.php/tag/misbranded/>.

39. Partnership for SafeMedicines.org, "Counterfeit HIV Medication: Profitable for Criminals but Dangerous for Patients", at [www.safemedicines.org/counterfeit-hiv-medication-profitable-for-criminals-but-dangerous-for-patients.html](http://www.safemedicines.org/counterfeit-hiv-medication-profitable-for-criminals-but-dangerous-for-patients.html).

40. Jessop N. (2012) "Stepping up the fight against counterfeits", PharmTech.com, 24 (3), at [www.pharmtech.com/stepping-fight-against-counterfeits](http://www.pharmtech.com/stepping-fight-against-counterfeits).

41. Campbell N., et al. (2013), "Adulteration of purported herbal and natural sexual performance enhancement dietary supplements with synthetic phosphodiesterase type 5 inhibitors", *J Sex Med*, 10(7), 184209, PubMed.gov. at [www.ncbi.nlm.nih.gov/pubmed/23634714](http://www.ncbi.nlm.nih.gov/pubmed/23634714).

42. Khan S.M. (2012), "Medicine adulterated with large amounts of anti-malarial: Sharif", *The Express Tribune*, at <http://tribune.com.pk/story/330278/medicine-adulterated-with-large-amounts-of-anti-malarial-sharif/>.

43. McKenna M. (2011), "Are counterfeit drugs driving antibiotic resistance?", *Wired*, at [www.wired.com/2011/08/counterfeit-driving-resistance/](http://www.wired.com/2011/08/counterfeit-driving-resistance/).

Medical devices are also vulnerable to being counterfeited. The recent PIP breast implant scandal<sup>44</sup> affecting many European countries resulted in industrial-grade silicone being used in human-grade implants.

## **D. Preventive measures**

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A good reporting system is one of the best approaches to combating the counterfeiting of medical products and similar crimes, because it can collect data and alert officials to potential problems before harm occurs. Article 18 of the MEDICRIME Convention offers preventive measures that attack this global health problem in several important ways.

It requires measures for the establishment of quality and safety requirements for medical products as well as a safe distribution system and measures to prevent the illegal supply of counterfeit medical products. The 28 member states of the EU that are members of the Council of Europe already have this type of regulatory system established under the directives covering medical products, as described in this convention, but some non-EU member states may not. By establishing regulation and good practice standards there will be a safer and a more guaranteed system of medical product supply within and among all states bound by the MEDICRIME Convention.

Article 18 also includes provisions for training all authorities involved and for awareness-raising campaigns aimed at populations affected by the counterfeiting of medical products and similar crimes.<sup>45</sup> Without these measures, it would be easier for offenders to commit the crimes described in Articles 5 to 8 of this convention without the fear of sanction and thus contribute to the detriment of public health.

### **1. Specialised prevention authorities and co-ordinating bodies**

#### **Reporting suspected counterfeit medical products, falsification of documents or similar crimes**

Health professionals are key players in the process of detecting and reporting suspected counterfeit medical products, but they do not have the authority

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44. Jones B. (2012), "Breast implant scandal: What went wrong?", CNN, at <http://edition.cnn.com/2012/01/27/world/europe/pip-breast-implant-scandal-explained/index.html>.

45. The Interpol co-ordinated "Operation Pangea" includes this concept in order to raise awareness among the consuming public, at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm322492.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm322492.htm); at <http://interpolnoticeremoval.com/tag/mpcpc/>.

to act independently. Article 17 of the convention calls on states to ensure that their legislatures create enforcement networks with partners among all types of competent authorities, including health authorities, customs and police, so they may exchange information and co-operate in accordance with domestic law. Article 17 also encourages these competent authorities to co-operate with industry and trade sectors on risk management in regards to the counterfeiting of medical products and similar crimes involving threats to public health. The text therefore opens the way for a highly sophisticated national infrastructure which allows public health officials and others to work together in order to detect, report, measure and counteract counterfeiting and similar crimes.

Consequently, the MEDICRIME Convention creates an opportunity for states to support the work of global health policy makers, such as the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Rapid Alert Scheme<sup>46</sup> and the WHO<sup>47</sup> strategic approach to this global health problem as outlined in guidelines from the Executive Board of WHO, which reports to the World Health Assembly (WHA).<sup>48,49</sup> There is no need

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46. PIC/S (2015), Procedure for handling rapid alerts and recalls arising from quality defects (PI 013-3) at [www.picscheme.org/publication.php?id=17](http://www.picscheme.org/publication.php?id=17).

47. In November 2014, the WHO Executive Board determined that its in-house monitoring mechanism should review procedures to detect, report and follow up SFFC issues using the WHO Rapid Alert System which is designed to offer patients and consumers a validated basis to develop collaboration strategies for reducing the incidence of SFFC products, by identifying the vulnerabilities in supply chains, measuring the harm caused and facilitating the more efficient exchange of information between countries. WHO Executive Board guidelines are consistent with the international collaboration provisions of the MEDICRIME Convention.

48. WHO guidelines, "it is advisable to have the sample, if possible, attached to a report form on the suspected SFFC medical products containing as much pertinent data as possible, including but not limited to: identification and description of the problem, contact details for the person or entity reporting the problem, product name (International Non-proprietary Name and brand name, if any), batch, manufacturing date, expiry date, manufacturer or marketing authorization holder (hereinafter MAH), location/source where the product was acquired (online, authorized or unauthorized establishment), and description of any adverse events due to the use".

49. It should be noted that both PIC/S and WHO's Member State Mechanism (MSM) on SFFC concern medical products, but do not include medical devices, parts, materials or accessories, and are focused on the protection of health through recording effects of medical products adversely affecting health. The MEDICRIME Convention's focus is different in that it uses criminal law to address offending behaviours in relation to medical products, active substances, excipients, parts, materials and accessories.

to re-invent the wheel to convey information about these offences.<sup>50</sup> WHO activities already in place<sup>51</sup> can serve to rebut potential arguments against ratification such as “we don’t have the money and infrastructure to set up data collection to combat such crimes”: rather, states or the Committee of the Parties can tailor the existing system to meet specific needs.

## **2. Protective measures and assistance to victims**

The MEDICRIME Convention does not alter existing methods of recovering damages using civil liability. Instead, Article 19 of the convention reaffirms victims’ right to compensation from the perpetrators, while also granting them the opportunity for assistance in their recovery process and requiring that they have access to information about their case, when necessary for the protection of their health. Ratifying states also undertake to promote the role of such rights in their national legislatures.

Article 20 ensures, among other rights, that victims have standing to complain at criminal proceedings, in a manner consistent with the procedural rules of domestic law, and to have access to the information regarding their complaint, possible charges, the general progress of the investigation or proceedings, and their role therein as well as the outcome of their cases. This is a key provision because, while not expressly being provided for by the convention, it may enable victims to obtain additional information on the harm that has been done to them as relevant to their health (Article 19). At the same time, the provision of the right of victims to access information promotes institutional accountability and governmental transparency.

## **3. Measures aimed at the general public: outreach and awareness to prevent counterfeiting**

Communication with the general public is an essential tool for preventing crime, however this is often neglected when estimating the costs for any programme targeting criminal activity.

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50. WHO’s SSFFC includes sub-standard products which are not included in the MEDICRIME Convention, as sub-standard is a breach of good manufacturing practice standards and not an intentional activity to counterfeit a medical product or a similar crime. Substandard products are not counterfeit, unless made intentionally sub-standard under Article 5 of the convention.

51. WHO recommendations for health authorities to detect and deal with actions, activities and behaviours that result in substandard/spurious/falsely-labelled/falsified/counterfeit medical products IV.1.2. Testing in quality-control laboratories.



And yet outreach to the public is one of the least expensive approaches to crime prevention, with the added value that it reassures the public that states have taken a proactive interest in protecting their right to health by defending the integrity of health care.

The MEDICRIME Convention encourages the participation of the private sector and civil society, including the media. The media clearly have an important role to play in educating the general public and in realistically addressing the issue through documentaries and television films on the risks posed by the counterfeiting of medical products and similar crimes. Other players active in the field include NGOs and the voluntary sector, also covered by the term “civil society”, whose work must be acknowledged and built upon. States are invited to encourage these secondary projects and programmes aimed at preventing counterfeiting of medical products and similar crimes.

The convention invites states to adopt a range of measures, within national and local plans, using a multidisciplinary approach to prevention, along with efficient co-ordination across jurisdictions.

Some possible approaches include:

- co-ordination between the education and health sectors, law-enforcement and licencing authorities;
- establishing infrastructure for the detection of counterfeit medicines, with a view to enacting criminal laws against counterfeiting in each country;
- establishing mechanisms for data collection, in collaboration with civil society, for detecting and evaluating the crimes covered by the convention, with due respect for the requirements of personal data protection;
- encouraging co-operation between competent state authorities, civil society and the criminal prosecution apparatus to curb this danger to public health.

## **E. Interventions**

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Concerned countries already participate on an ad hoc basis in several key international programmes set up by Interpol<sup>52</sup> and Europol, but the absence of a juridical basis for enforcement undermines the ability to fully exploit these

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52. Interpol operations on pharmaceutical crime at [www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Mamba](http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Mamba).

resources. The MEDICRIME Convention fills this void. It provides a legal basis for successful programmes that prevent, stop and punish offences established under the MEDICRIME Convention.

Article 22 of the MEDICRIME Convention promotes international collaboration among states to organise surveillance measures for the quality and integrity of medical products in commerce, and to co-operate on protecting and providing assistance to victims. To do so, the convention obliges states parties to designate national contact points (without prejudice to the internal reporting systems of the parties) for the exchange of information. Thus, monitoring occurs at two levels: at the national level, by encouraging laws that are consistent across ratifying nations, and at the international level, through sharing information.

## **1. International co-operation in criminal matters**

The MEDICRIME Convention offers an important example of a practical approach to intervention because it allows for subsequent extradition treaties regarding the offences established in the convention. Article 21, paragraph 2, obliges states to “co-operate to the widest extent possible in pursuance of the relevant applicable international, regional and bilateral treaties on extradition and mutual legal assistance in criminal matters concerning the offences established in accordance with this Convention”. This effort can provide a legal basis for the efforts already undertaken by states in conjunction with other organisations, such as Interpol, Europol and WHO. This provision also offers a new opportunity to harmonise existing treaties and conventions regarding extradition, in the event that a transnational offence is committed and causes harm in one country but is not, until the ratification of the MEDICRIME Convention, illegal in the perpetrator’s home state.

## **2. International co-operation on prevention and other administrative measures**

Although criminal law is invaluable as a tool to punish perpetrators and their agents, other administrative measures (particularly, of a preventive nature) are necessary in order to counter the risks posed by counterfeiting of medical products and similar crimes. It is important to use both types of measures.

Article 18 of the MEDICRIME Convention promotes consistency across infrastructures, by encouraging governments to, among other requirements for ensuring safety and quality in the manufacturing and distribution of medical

products, engage in a campaign informing the general public about the crimes covered by the convention and the competent authorities which fight these offences.

As stated in Article 22, paragraph 2, “the Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health”. For example, by encouraging international co-operation among states,<sup>53</sup> it should become easier, at all stages in the supply chain, for national authorities to prevent, trap and arrest perpetrators of offences established by states under the MEDICRIME Convention.<sup>54</sup> Because illegitimate copies of medicines do not have quality, safety and efficacy guarantees from competent authorities, the prevention portions of the MEDICRIME Convention that facilitate international collaboration and the creation of robust systems to detect and report counterfeit medical products are important for protecting public health.

The MEDICRIME Convention will enable enforcement agencies, police, customs and health regulatory authorities to build on and benefit from communication, collection of samples for verification, risk evaluation by competent authorities and the health sector and a communication strategy for disseminating the information to the public. WHO, for example, accepts reports received in-person, by post mail, telephone or email. Reports and samples sent to WHO are then systematically recorded and communicated to stakeholders including enforcement, public health officials and the general public. Reporting at the international level involves contacting national focal points. According to WHO, follow-up after appropriate investigation by competent authorities may

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53. Council of Europe Ad hoc Group on Counterfeit Medicines (2007), “A model for a network of Single Points of Contact (SPOCs) to combat counterfeit medical products”, EDQM, at [www.edqm.eu/medias/fichiers/Model\\_for\\_a\\_Network\\_and\\_Single\\_Points\\_of\\_Contacts\\_SPOCs.pdf](http://www.edqm.eu/medias/fichiers/Model_for_a_Network_and_Single_Points_of_Contacts_SPOCs.pdf).

54. Relevant precedent exists such as the WHO Executive Committee guidelines, which are not law, but which provide a useful starting point: “A. ... 1. Establish and convene an MSM working group comprised of experts from Member States to: (i) draft recommendations to strengthen NRRAs in their prevention, detection and response to SSFFC medical products, including on criteria for risk classification and assessment prioritization of cases of SSFFC medical products; (ii) develop training material for NRRAs in hard and soft copy, multilingual, virtual and face to face formats focused on the prevention, detection and response to SSFFC medical products. B. Create a focal point network for the exchange of information and consultation at large among Member States and establish an on-going virtual exchange forum”.

include the recall and destruction of hazardous medicines,<sup>55</sup> while sharing information with counterparts in other states and with patients or their families.

Non-EU member states of the Council of Europe and other states considering the implementation of the convention could choose to seek guidance from the EU directives on human and veterinary medicines, clinical trials and medical devices, or from the WHO Executive Board guidelines as a basis for international co-operation by specialised bodies for implementing the inspections along the distribution chain, noting compliance history and best practices for prevention. For example, WHO collects data about: (a) verification of current good manufacturing and distribution practices in the supply chain from starting materials to finished dosage medical product; (b) verification of the origin and destination for each transfer of possession; (c) post marketing surveillance and co-ordination with regulatory agencies; (d) identification and investigation of activities and behaviours that result in SSFFC medical products; (e) collection of samples for verification, or analysis and (f) recalls of SSFFC medical products.<sup>56</sup> By increasing prevention through international co-operation, the MEDICRIME Convention can provide a legal basis to existing efforts under WHO guidelines and open communication channels with health professionals, patients and consumers.<sup>57</sup>

## **F. Criminalisation of acts**

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The MEDICRIME Convention obliges parties to establish as offences, when committed intentionally, the manufacturing, supplying, offering to supply and trafficking of counterfeit medical products, active substances, excipients, parts, materials or accessories, the falsification of documents and other similar crimes involving threats to public health.

The convention does not target unintended breaches of good practices by manufacturers authorised to manufacture or distribute medical products, where such authorisation is required by domestic law. As noted by Jan Kleijssen

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55. WHO's Member State Mechanism (MSM) has described such medicines, which do not include medical devices, parts, materials or accessories, as SSFFC (Substandard/spurious/falsely-labelled/falsified/counterfeit) rather than as counterfeit or falsified. At [http://apps.who.int/gb/SSFFC/pdf\\_files/WG1b/A\\_MSM\\_WG1\\_2-en.pdf](http://apps.who.int/gb/SSFFC/pdf_files/WG1b/A_MSM_WG1_2-en.pdf).

56. World Health Organization, Executive Board, Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products, November 2014.

57. [http://apps.who.int/gb/ebwha/pdf\\_files/EB136/B136\\_29-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB136/B136_29-en.pdf).

and Susanne Keitel: “The Convention does not criminalise honest medicine manufacturers.”<sup>58</sup>

### **Similar crimes involving threats to public health**

Global trafficking has made it necessary for the MEDICRIME Convention to take an expansive view of “threats to public health,” and obliges the parties to take the necessary legislative and other measures to also establish similar crimes (as mentioned above) as offences under its domestic law, when they are committed intentionally.

These crimes, committed throughout the world,<sup>59</sup> affect a wide range of medicinal products, including those indicated for blood pressure, cancer, sedatives, antidepressants, hormone replacement therapies and cholesterol, but also medical devices, such as needles, condoms and dental equipment, including X-Ray machines.<sup>60,61</sup>

Wherever authentic medical products have been diverted from their intended market, as in the offences envisaged by Article 8, they often also involve the trafficking of counterfeit medical products as envisaged by Articles 5 and 6, as well as the use of falsified documentation as envisaged by Article 7 of the convention.

## **1. General overview**

Due to the fact that many counterfeit medical products are manufactured in a first country for marketing in one or more state(s) and then diverted from the state of intended destination to a third state, detection and prosecution may be challenging. By specifically targeting the manufacture, trafficking and sale of medical products outside the scope of regulatory systems, the MEDICRIME Convention may stop threats to public health that undermine public confidence in the system. It is difficult for states to co-operate on

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58. Kleijssen J. and Keitel S., “The Council of Europe MEDICRIME Convention: protecting the patient from counterfeit/falsified medical products – a pre-requisite for safe healthcare”, May 2014.

59. Singh J. (2008), “Phase out the Fakes”, *Medicaldevice-network.com*. at [www.medicaldevice-network.com/features/feature1811/](http://www.medicaldevice-network.com/features/feature1811/).

60. MHRA Press release (2015), “UK leads the way with £15.8 million seizure in global operation targeting counterfeit and unlicensed medicines and devices”, at [www.gov.uk/government/news/uk-leads-the-way-with-158-million-seizure-in-global-operation-targeting-counterfeit-and-unlicensed-medicines-and-devices](http://www.gov.uk/government/news/uk-leads-the-way-with-158-million-seizure-in-global-operation-targeting-counterfeit-and-unlicensed-medicines-and-devices).

61. Interpol (2015) Operation Pangea VIII, at [www.interpol.int/en/Crime-areas/Pharmaceutical-crime/Partnerships](http://www.interpol.int/en/Crime-areas/Pharmaceutical-crime/Partnerships).

matters such as extradition and mutual legal assistance because national laws regarding the definition and punishment of the type of offences covered by the MEDICRIME Convention vary between states. Extradition for offences, as established under the convention, may be impossible unless the states are parties to the MEDICRIME Convention.

Throughout the substantive criminal law chapter of the MEDICRIME Convention, parties undertake to establish as offences in their domestic laws each act targeted by the various provisions. There is limited scope for each state or the European Union, at the time of signature or when depositing its instrument of ratification, to declare to the Secretary General of the Council of Europe a reservation where that is provided for, such as in Articles 5.1, 6 and 7 as regards excipients, parts and materials, and for 5.2 as regards excipients. Reservations may also be entered in the same circumstances in Article 9.2 as regards Articles 7 and 8 and, in Articles 10.1.d and 10.2 as regards jurisdiction. These possible reservations notwithstanding, the list of prohibited acts and consequent offences applies equally to all cited medical products.

As regards Articles 5 to 7 of the MEDICRIME Convention, it should be noted that the mere possession of counterfeit medical products, active substances, excipients, parts, materials and accessories or falsified documents is not specifically criminalised under the convention. However, possession of such items with an intent to commit any of the criminal acts set out in Articles 5 and 6 could be considered – when not included in the concept of “keeping in stock” related to “trafficking” of Article 6 – as an attempt under Article 9.

The MEDICRIME Convention does not specifically require criminalising the possession of equipment that could be used to commit the criminal acts set out in Articles 5, 6 and 7, since it would in practice often prove difficult to establish a sufficiently strong link between the mere possession of equipment that could theoretically be used for such criminal activity and the actual activities of counterfeiting, supplying and trafficking in counterfeits, as well as the falsification of documents. However, such equipment may, of course, play an important role as evidence, if that link can be established. Finally, possession of equipment could also be considered as an attempt (under Article 9), if a criminal intention can be demonstrated.

## 2. Key provisions

Articles 5 to 8 of the MEDICRIME Convention list intentional conduct that is considered to be so inherently dangerous to public health that those articles

apply even without actual physical or psychological damage to victims. As the right to life is protected by Article 2 of the European Convention on Human Rights, it follows that public health is a protected collective right. The manufacturing of counterfeit medical products creates a health risk, but until these products are consumed or used they are unlikely to cause actual harm. For this reason alone it would be futile to suggest that actual harm needs to be proven when an offender manufactures a counterfeit medical product or falsifies or uses a falsified document.<sup>62</sup> That risk comes to fruition when the patient consumes the finished dosage form of a medicinal product or is treated with the medical device. Too often, due to delayed detection of harm or to another underlying medical condition, it can be difficult to prove a nexus of actual harm in many cases.<sup>63</sup> Although “adulteration” has not been specifically defined in Article 4 of this convention, the concept of adulteration involves reducing the quality of a product by changing its ingredients at the manufacturing stage. Supplying, offering to supply or trafficking in adulterated medical products are defined as criminal offences in the convention. People who are agents of a corporation engaging in such illegal activity are also criminals under this convention.

Significantly, the criminal law in the MEDICRIME Convention punishes people who are not in possession of the illegal goods in question, but who provide a link in the distribution chain, under Article 6, for supplying or offering “to supply, or trafficking ...counterfeit medical products, active substances, excipients, parts, materials and accessories”. The terms “supplying” and “offering to supply” are not specifically defined, but were intended by the drafters to include brokering, procuring, selling, donating or offering for free as well as promoting these products through advertising. Note that “offering to supply”<sup>64</sup> is a separate criminal act distinguished from an “attempt to supply”,

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62. Interpol, Pharmaceutical Crime Sub-Directorate, op. cit. Actual harm would not have occurred to the patients in the medical clinic if the medicinal product adulterated with Pyrimethamine had not been dispensed to patients, but the threat existed once the product had been manufactured. Having been dispensed, over 100 patients died. It took significant investigation to determine which medicinal product actually caused the deaths as more than one was initially suspected as being the cause.

63. The case of dinitrophenol (DNP) weight loss product is an example where the post mortem can show that the death was consistent with the actions of 2,4-dinitrophenol, but a death from an Erectile Dysfunction (ED) medicine would present itself as a cardiac event and might not be connected with the ED medication unless prompted by external information. NHS choices (2013), “Warning issued over deadly DNP ‘diet drug’”, at [www.nhs.uk/news/2013/09September/Pages/Warnings-issued-over-deadly-DNP-diet-drug.aspx](http://www.nhs.uk/news/2013/09September/Pages/Warnings-issued-over-deadly-DNP-diet-drug.aspx).

64. Offering to supply can often be found on online auction sites.

under Article 9. A person may thus engage in the criminal act of making an “offer to supply” without actually having those products in their possession. This conduct differs from “attempt to supply”, when the supplier does possess counterfeit medical products, but does not complete the criminalised act.

MEDICRIME Convention Article 7 on the falsification of documents covers the act of producing a false document from scratch, as well as unlawfully amending or changing a document with regard to its content or its appearance so that a person reading the document is deceived into believing that the medical product, active substance, excipient, part, material or accessory which the document accompanies is legitimate,<sup>65</sup> and not counterfeit or the subject of a criminal conduct as described in Article 8, paragraph *a*.

MEDICRIME Convention Article 8 on similar crimes involving threats to public health includes certain offences that are considered to be similar to counterfeiting of medical products, as they pose an equally serious threat to public health, but are nevertheless clearly distinct from that conduct by the fact that the medical products subject to Article 8, paragraph *a*, are not counterfeited. In fact, these products are intentionally manufactured, kept in stock for supply, imported, exported, supplied, offered for supply, or placed on the market without authorisation (medicines) or without being in compliance with the conformity requirements (medical devices) as laid down in the domestic law of the parties.

An example of the offences set out in Article 8, paragraph *a*, is the well-attested existence of a sprawling black market for medicines for hormonal treatment produced without authorisation – which are used for doping for athletes and by others who want to artificially enhance their physical performance.<sup>66</sup> The abuse of these unauthorised medicines can lead to bodily injury and death, and their uncontrolled circulation constitutes in itself a significant threat to public health. Another example is the otherwise legitimate manufacturing of a medicine, which criminals then divert through the black market with a view

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65. Herceptin®, a medicinal product used in the treatment of cancer, was stolen in Italy and was placed on markets in Austria, Finland, Germany, Sweden and the UK. Other countries were involved in the distribution chain of this diversion and counterfeiting and the perpetrators used falsified documentation to get the product onto the market in other countries. Palmer E. (2014), “EMA warns Herceptin vials stolen in Italy spreading through EU”, FiercePharma at [www.fiercepharma.com/story/ema-warns-herceptin-vials-stolen-italy-spreading-through-eu/2014-04-16](http://www.fiercepharma.com/story/ema-warns-herceptin-vials-stolen-italy-spreading-through-eu/2014-04-16).

66. IFPMA, “2 Fields 1 Goal, Protecting the integrity of science and sport” at [www.ifpma.org/ethics/doping-in-sport.html](http://www.ifpma.org/ethics/doping-in-sport.html).



to unauthorised supplying. It is a fact that legitimate anabolic steroids used for medical purposes are also sold on the black market to athletes and other people who wish to enhance their physical performance.<sup>67</sup>

In addition to the offences enumerated in Article 8.a, Article 8.b obliges parties to establish as an offence “the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party”. This provision is intended to target the intentional abuse of original documents for criminal purposes related to the acts set out in Article 8. a, for example, to cover up the fact that a medicine has been manufactured without authorisation by pairing the unauthorised product with original documents intended for another – authorised – medicine. The commercial use of documents outside the legal medical product supply chain without criminal intent, such as the legitimate selling and/or buying of waste papers (such as unused packaging) for recycling purposes is obviously not covered by the provision.

### 3. Integration with existing procedural law

The Council of Europe already has a wide set of standards in relation to judicial co-operation in criminal matters. For example, the European Convention on Extradition (ETS No. 24) and its protocols (ETS Nos. 86 and 98), the European Convention on Mutual Assistance in Criminal Matters (ETS No. 30) and its protocols (ETS Nos. 99 and 182), and the Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime and on the Financing of Terrorism (CETS No. 198) constitute transversal instruments that can be applied to many different offences.

In Article 17 the convention sets forth several principles to govern international co-operation:

- the parties shall remove obstacles to the rapid circulation of information and evidence and co-operate in order to prevent or stop activities criminalised by the convention;
- the parties shall enable international co-operation for enforcement actions;

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67. “Brian Wainstein fights extradition on steroid charges”, 2013, Steroid.com at [www.steroid.com/blog/Brian-Wainstein-Fights-Extradition-on-Steroid-Charges.php](http://www.steroid.com/blog/Brian-Wainstein-Fights-Extradition-on-Steroid-Charges.php). Brian Wainstein had been prosecuted in Ireland and convicted and sentenced to two years’ imprisonment for the 2003 distribution of anabolic steroids, at <http://juicedmuscle.com/jmblog/content/genxll-axio-syntrop-biogen-and-their-offspring>.

- the parties shall promote international collaboration to refine the state of the art of detection.

In sum, the MEDICRIME Convention therefore clearly addresses the present lacunae in public health protection and quality control of medicines and fills an important void in the realm of international criminal law. The practical effect of these criminal law provisions, not written into the text of the document, is that ratification of the MEDICRIME Convention also offers states a modicum of control over transnational corporations that can leapfrog across jurisdictions in search of favourable laws and economic conditions. Thus, regulation in states that have agreed to multi-jurisdictional protections against offences in accordance with the MEDICRIME Convention may provide another important tool to check egregious conduct by bad actors in those nations.

## **G. Jurisdictional requirements for initiating proceedings and punishing offences**

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Article 10 of the MEDICRIME Convention facilitates international co-operation for enforcement against this global threat to public health by taking a broad view of the jurisdiction of parties under this convention. It does this in two ways: first it establishes in Article 10, paragraphs 1, 2 and 3, a broad view of situations where a state party can exert its jurisdiction in relation to offences established under this convention (basis of jurisdiction: territoriality principle, nationality principle, passive personality principle, persons having their habitual residence in the territory of the party, *aut dedere, aut judicare* (extradite or prosecute)). Secondly, Article 10, paragraph 5, establishes a concrete system of co-operation between parties (“where more than one Party claims jurisdiction over an alleged offence established in accordance with this Convention, the Parties concerned shall consult, where appropriate, with a view to determining the most appropriate jurisdiction for prosecution”). Article 10 requires parties to expand their legislative reach, if necessary, in order to comply with these terms.

The MEDICRIME Convention uses plain language that respects long-established principles of international law:

- the territoriality principle: each party is required to punish offences committed on its territory, as well as on ships flying its flag or aircraft registered under its laws;
- the nationality principle: each party is required to punish offences committed by its nationals abroad;

- the passive personality principle: each party is required to punish offences committed against its nationals abroad;
- the principle of attachment of the perpetrator or victim to the state where the person concerned has his/her habitual residence;
- the principle of *aut dedere, aut judicare*.

However, according to Article 10, paragraph 4, each state or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, the jurisdiction rules laid down in Article 10, paragraph 1.d (offence committed abroad by its national or a person habitually residing in its territory), and paragraph 2 of this article (offence committed abroad when the victim is a national or a person habitually residing in the territory of the party).

This means that, if a state already has extraterritorial criminal law provisions, those provisions may apply to offences established in the MEDICRIME Convention: there is no need for new provisions.

The convention does provide for jurisdiction over any offence established in accordance with the MEDICRIME Convention when an alleged offender is present in the territory of one party and cannot be extradited to another party because of his or her nationality. The convention preserves the right of each state party to preserve its jurisdiction over criminal acts in its own territory under its domestic law.

States parties undertake to introduce legislation to conform to these provisions, thereby promoting harmonisation of domestic laws in the field. The MEDICRIME Convention lists circumstances whereby the parties agree to establish jurisdiction over and punish criminal acts such as:

“Article 5 – Manufacturing of counterfeits

1. Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.”

The same language has been accepted in subsequent articles: Article 6 – Supplying, offering to supply and trafficking in counterfeits; Article 7 – Falsification of documents; Article 8 – Similar crimes involving threats to public health.

## **H. Corporate liability**

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Significantly, the MEDICRIME Convention holds accountable with corporate liability – in accordance with the domestic law of the parties – legal persons, such as corporations, that engage in offences established in accordance with the MEDICRIME Convention. This is an important provision because it extends the scope of the substantive criminal law provisions contained in the convention beyond the activities of people into the realm of organised activities and organised crime when committed by legal persons. The states parties also commit to fill the void in their existing domestic laws so that such offences established in accordance with the convention cannot be committed by corporations within their jurisdiction. Subject to the legal principles of the party, the liability of a legal person may be criminal, civil or administrative. The convention obliges the states parties to introduce into their domestic law corporate liability for offences established in accordance with the MEDICRIME Convention. Therefore, this provision promotes harmonisation and consistency among all parties to the convention and indirectly generates a rationale for consistent provisions regarding criminalisation of offences established in accordance with the convention worldwide.

## **I. Sanctions**

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The convention obliges the parties to introduce “effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions”, taking account of the seriousness of the offence. In the case of individuals committing an offence, these sanctions may entail deprivation of liberty and even extradition. Legal persons are also subject to effective, proportionate and dissuasive sanctions, including criminal and non-criminal monetary sanctions, and may be subject to other measures, such as temporary or permanent disqualification from exercising commercial activity, placement under judicial supervision, or a judicial winding-up order.

Additionally, the MEDICRIME Convention requires parties to ensure that measures can be taken concerning the seizure and confiscation of certain documents, goods and the proceeds derived from offences. In addition, the convention allows for the destruction of medical products that have been produced as a result of an offence established under the convention.

## J. Aggravating circumstances

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Article 13 requires parties to ensure that certain circumstances (mentioned in letters *a* to *f*) may be taken into consideration as aggravating circumstances in the determination of the sanction for offences established in this convention.

By the use of the phrase “may be taken into consideration”, the ad hoc committee highlights that the convention places an obligation on parties to ensure that these aggravating circumstances are available for judges to consider when sentencing offenders, although there is no obligation on judges to apply them. The reference to “in conformity with the relevant provisions of national law” is intended to reflect the fact that the various legal systems in Europe have different approaches to aggravating circumstances and therefore the convention permits parties to retain their fundamental legal concepts.

The first aggravating circumstance (*a*), is where the offence caused the death of, or damage to the physical or mental health of, the victim. Given the inherent difficulties in linking the consumption of a medicine or the use of a medical device directly with the occurrence of a death, the ad hoc committee considered that in such cases, it should be up to the national courts of the states parties to assess the causal link between acts criminalised under the convention and any death or injury sustained as a result thereof.

The second aggravating circumstance (*b*), is where the offence was committed by persons abusing the confidence placed in them in their professional capacity. This category of persons obviously includes health-care professionals, but the application of the aggravating circumstance is not restricted to them.

The third aggravating circumstance (*c*), is where the offence was committed by persons abusing the confidence placed in them as manufacturers or suppliers.

The fourth aggravating circumstance (*d*), is where the offences of supplying and offering to supply are committed through the use of large-scale distribution, including through information technology systems. The use of information systems, including the Internet, for supplying counterfeit medicines and the supply (and offering to supply thereof) without authorisation is one of the most worrying and serious aspects of counterfeiting of medical products and similar crimes today. Given the immense reach of the Internet, counterfeit, and hence dangerous, medical products are now being spread all over the world at an alarming rate. At the same time, due to problems of jurisdiction, it has become increasingly difficult to apprehend the criminals behind various

Internet sites, offering cheap (and therefore mostly counterfeit) medicines or other medical products.

The fifth aggravating circumstance (e) is where the offence involved a criminal organisation. The convention does not define “criminal organisation”. In applying this provision, however, parties may take their cue from other international instruments which define the concept. For example, Article 2(a) of the United Nations Convention against Transnational Organized Crime defines “organised criminal group” as “a structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offences established in accordance with this Convention, in order to obtain, directly or indirectly, a financial or other material benefit”. Recommendation Rec(2001)11 of the Committee of Ministers to member states concerning guiding principles on the fight against organised crime and the EU Council Framework Decision 2008/841/JHA of 24 October 2008 on the fight against organised crime give very similar definitions of “organised criminal group” and “criminal organisation”.

The sixth aggravating circumstance (f), applies when the perpetrator has previously been convicted of offences of the same nature as those established under the convention. By including this provision, the convention signals the need to make a concerted effort to combat recidivism in the low risk/high gain area of counterfeiting of medical products and similar crimes.

## **K. International recidivism**

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Counterfeiting of medical products and similar crimes are more often than not perpetrated transnationally by criminal organisations or by individuals, some of whom may have been tried and convicted in more than one country. At the domestic level, many legal systems provide for a different, often harsher, penalty where someone has previous convictions. In general, only conviction by a that same national court counts as a previous conviction. Traditionally, previous convictions by foreign courts were not taken into account on the grounds that criminal law is a national matter and that there can be differences of national law, and also because of a degree of suspicion of decisions by foreign courts.

Such arguments have less force today in that the internationalisation of criminal law standards, in response to the internationalisation of crime, has prompted the harmonisation of different countries’ laws. In addition, in the space of a few decades, countries have adopted instruments such as the European

Convention on Human Rights, whose implementation has helped build a solid foundation of common guarantees that inspire greater confidence in the justice systems of all the participating states.

On the basis of these considerations, the principle of international recidivism has been established in a number of international legal instruments. Under Article 36, paragraph 2 (iii) of the Single Convention on Narcotic Drugs of 30 March 1961, for example, foreign convictions have to be taken into account for the purpose of establishing recidivism, subject to each party's constitutional provisions, legal system and national law. Under Article 1 of the Council Framework Decision of 6 December 2001 amending Framework Decision 2000/383/JHA on increasing protection by criminal penalties and other sanctions against counterfeiting in connection with the introduction of the Euro, European Union member states must recognise as establishing habitual criminality final decisions handed down in another member state for the counterfeiting of currency.

The fact remains that at the international level there is no standard concept of recidivism and the laws of some countries do not have the concept at all. The fact that foreign convictions are not always brought to the courts' notice for sentencing purposes is an additional practical difficulty. However, in the framework of the European Union, Article 3 of the Council Framework Decision 2008/675/JHA of 24 July 2008 on taking account of convictions in the Member States of the European Union in the course of new criminal proceedings has established in a general way – without limitation to specific offences – the obligation of taking into account a previous conviction handed down in another (EU member) state.

Therefore Article 14 of the MEDICRIME Convention provides for the possibility to take into account final sentences passed by another party in the determination of a sentence. To comply with the provision, parties may establish in their domestic law that previous convictions by foreign courts are to result in a harsher penalty. They may also provide that, under their general powers to assess the individual's circumstances when setting the sentence, courts should take those convictions into account. This possibility must also include the principle that the offender should not be treated less favourably than if the previous conviction had been a national one.

This provision does not place any positive obligation on courts or prosecution services to take steps to find out whether persons being prosecuted have received final sentences from another party's courts. It should nevertheless be

noted that, under Article 13 of the European Convention on Mutual Assistance in Criminal Matters, a party's judicial authorities may request from another party extracts from and information relating to judicial records, if needed in a criminal matter. In the framework of the European Union, the issues related to the exchange of information contained in criminal records between member states are regulated in two legal acts, namely Council Decision 2005/876/JHA of 21 November 2005 on the exchange of information extracted from the criminal record and Council Framework Decision 2009/315/JHA of 26 February 2009 on the organisation and content of the exchange of information extracted from the criminal record between member States.

## **L. Follow-up mechanism – Committee of the Parties**

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### **1. Composition**

The convention provides for a follow-up mechanism to ensure its effective implementation in the form of the Committee of the Parties. This mechanism is based on a balanced composition of representatives of states parties to the convention, plus representatives of the Parliamentary Assembly of the Council of Europe, the CDPC and other relevant Council of Europe intergovernmental or scientific committees, "in order to contribute to a multisectoral and multi-disciplinary approach" (Article 24.1). Representatives of international bodies, of relevant official bodies of the parties or of civil society may be appointed to the Committee of the Parties as observers (Articles 24.3, 24.4 and 24.5).

### **2. Functions**

The Committee of the Parties shall monitor the implementation of the convention. In addition to the traditional follow-up competences, the Committee of the Parties has three main functions:

- to facilitate the effective use and implementation of the convention, including the identification of any problems;
- to express an opinion on any question concerning the application of the convention, including by making specific recommendations to the parties in this respect;
- to facilitate the collection, analysis and sharing of information, experience and good practice between states to reinforce their capacities and improve their policies in this field.



## **M. Relationship with other international instruments**

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The terms of the MEDICRIME Convention do not affect the rights and obligations arising from the provisions of other multilateral or bilateral treaties, or instruments on matters governed by this convention. The parties may conclude bilateral or multilateral agreements and any other international instruments on the matters dealt with in the convention, provided they do not derogate from the convention.

## **N. Amendments to the convention**

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The parties may propose amendments to the provisions of the convention. Proposed amendments must be communicated to all Council of Europe member states, all signatories, all parties, the European Union and any state invited to sign or accede to the convention. The CDPC will draft an opinion on the proposed amendment, which will then be submitted to the Committee of Ministers. After considering the proposal and opinion, the Committee of Ministers must consult all parties and obtain unanimous acceptance before deciding whether to adopt the amendment.

## **O. Final clauses**

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The convention is open for signature by the member states of the Council of Europe, the non-member states which have participated in its elaboration (Israel) or enjoy observer status with the Council of Europe (Holy See, Japan, Mexico, the United States of America and Canada) and the European Union. The Committee of Ministers may invite any non-member state of the Council of Europe to accede to the convention after having obtained the unanimous agreement of the other states/European Union having expressed their consent to be bound by this convention. When appropriate, the parties to the convention may specify the territory or territories to which it will apply.

# V. Postface

## by the Deputy Secretary General of the Council of Europe

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In recent years, occurrences of counterfeiting of medical products and similar crimes have increased worldwide. These crimes endanger public health, and affect patients and their confidence in the legal marketplace.

Even more profitable than drug trafficking, this new form of crime has an undeniable advantage for criminals: they go largely unpunished or receive only mild sanctions. Even when states take strict measures to regulate the production and distribution of medical products and devices, these measures often prove insufficient, especially when criminal networks find gaps in national legislations allowing them to make substantial profits at the expense of people's lives and health. The MEDICRIME Convention was drafted to protect vulnerable patients and their right to safe access to medicines of appropriate quality, and to fight against organised crime. As the first and only international treaty dealing with this problem, the convention aims at prosecuting the counterfeiting of medical products and similar crimes, protecting the rights of victims and promoting national and international co-operation.

Organised criminal groups use the Internet to sell counterfeited medical products globally, and their profits fund other activities linked to organised crime. No state is spared this scourge. It is therefore essential that countries around the world urgently address this problem. Concerned by this global challenge, the Committee of Ministers agreed that this convention should be universal.

The large number of states that have expressed their willingness to be bound by the MEDICRIME Convention shows that more and more governments recognise the severity of the problem. The convention provides a clear legal basis for harmonising provisions and good practices in this field. It lays the foundation for national and international co-operation between legal, law-enforcement and health authorities, in particular through multidisciplinary co-operation within the networks of focal points established by the convention among competent authorities.

The number of victims grows every day. The MEDICRIME Convention, along with all measures taken by the Council of Europe and other international organisations, has a large impact on all states' efforts to eradicate these criminal networks that endanger public health.

Therefore, I welcome this handbook, which I am sure will prove extremely useful for parliamentarians when promoting the MEDICRIME Convention.

*Gabriella Battaini-Dragoni  
Deputy Secretary General  
of the Council of Europe*

# Appendix I

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## **Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes (MEDICRIME Convention)<sup>68</sup>**

*Council of Europe Treaty Series – No. 211*

Moscow, 28.X.2011

### **Preamble**

The member States of the Council of Europe and the other signatories to this Convention,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members;

Noting that the counterfeiting of medical products and similar crimes by their very nature seriously endanger public health;

Recalling the Action Plan adopted at the Third Summit of Heads of State and Government of the Council of Europe (Warsaw, 16-17 May 2005), which recommends the development of measures to strengthen the security of European citizens;

Bearing in mind the Universal Declaration of Human Rights, proclaimed by the United Nations General Assembly on 10 December 1948, the Convention for the Protection of Human Rights and Fundamental Freedoms (1950, ETS No. 5), the European Social Charter (1961, ETS No. 35), the Convention on the Elaboration of a European Pharmacopoeia (1964, ETS No. 50) and its Protocol (1989, ETS No. 134), the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997, ETS No. 164) and the Additional Protocols thereto (1998, ETS No. 168, 2002, ETS No.186, 2005, CETS No. 195, 2008, CETS No. 203) and the Convention on Cybercrime (2001, ETS No. 185);

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68. Text corrected in accordance with the Committee of Ministers' decision (1151st meeting of the Ministers' Deputies, 18-19 September 2012).

Also bearing in mind the other relevant work of the Council of Europe, particularly the decisions of the Committee of Ministers and work of the Parliamentary Assembly, notably Resolution AP(2001)2 concerning the pharmacist's role in the framework of health security, the replies adopted by the Committee of Ministers on 6 April 2005 and on 26 September 2007, concerning respectively, Parliamentary Assembly Recommendations 1673 (2004) on "Counterfeiting: problems and solutions" and 1794 (2007) on the "Quality of medicines in Europe", as well as relevant programmes conducted by the Council of Europe;

Having due regard to other relevant international legal instruments and programmes, conducted notably by the World Health Organisation, in particular the work of the group IMPACT, and by the European Union, as well as in the forum of the G8;

Determined to contribute effectively to the attainment of the common goal of combating crime involving counterfeiting of medical products and similar crimes involving threats to public health, by introducing notably new offences and penal sanctions relative to these offences;

Considering that the purpose of this Convention is to prevent and combat threats to public health, giving effect to the provisions of the Convention concerning substantive criminal law should be carried out taking into account its purpose and the principle of proportionality;

Considering that this Convention does not seek to address issues concerning intellectual property rights;

Taking into account the need to prepare a comprehensive international instrument which is centred on the aspects linked to prevention, protection of victims and criminal law in combating all forms of counterfeiting of medical products and similar crimes involving threats to public health, and which sets up a specific follow-up mechanism;

Recognising that, to efficiently combat the global threat posed by the counterfeiting of medical products and similar crimes, close international co-operation between Council of Europe member States and non-member States alike should be encouraged,

Have agreed as follows:

## **Chapter I – Object and purpose, principle of non-discrimination, scope, definitions**

### **Article 1 – Object and purpose**

- 1 The purpose of this Convention is to prevent and combat threats to public health by:
  - a providing for the criminalisation of certain acts;
  - b protecting the rights of victims of the offences established under this Convention;
  - c promoting national and international co-operation.
- 2 In order to ensure effective implementation of its provisions by the Parties, this Convention sets up a specific follow-up mechanism.

### **Article 2 – Principle of non-discrimination**

The implementation of the provisions of this Convention by the Parties, in particular the enjoyment of measures to protect the rights of victims, shall be secured without discrimination on any ground such as sex, race, colour, language, age, religion, political or any other opinion, national or social origin, association with a national minority, property, birth, sexual orientation, state of health, disability or other status.

### **Article 3 – Scope**

This Convention concerns medical products whether they are protected under intellectual property rights or not, or whether they are generic or not, including accessories designated to be used together with medical devices, as well as the active substances, excipients, parts and materials designated to be used in the production of medical products.

### **Article 4 – Definitions**

For the purposes of this Convention:

- a the term “medical product” shall mean medicinal products and medical devices;

- b the term “medicinal product” shall mean medicines for human and veterinary use, which may be:
  - i any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals;
  - ii any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;
  - iii an investigational medicinal product;
- c the term “active substance” shall mean any substance or mixture of substances that is designated to be used in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of the medicinal product;
- d the term “excipient” shall mean any substance that is not an active substance or a finished medicinal product, but is part of the composition of a medicinal product for human or veterinary use and essential for the integrity of the finished product;
- e the term “medical device” shall mean any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software, designated by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, designated by the manufacturer to be used for human beings for the purpose of:
  - i diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - ii diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
  - iii investigation, replacement or modification of the anatomy or of a physiological process;
  - iv control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

- f the term “accessory” shall mean an article which whilst not being a medical device is designated specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by the manufacturer of the medical device;
- g the terms “parts” and “materials” shall mean all parts and materials constructed and designated to be used for medical devices and that are essential for the integrity thereof;
- h the term “document” shall mean any document related to a medical product, an active substance, an excipient, a part, a material or an accessory, including the packaging, labeling, instructions for use, certificate of origin or any other certificate accompanying it, or otherwise directly associated with the manufacturing and/or distribution thereof;
- i the term “manufacturing” shall mean:
  - i as regards a medicinal product, any part of the process of producing the medicinal product, or an active substance or an excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;
  - ii as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;
  - iii as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state;
- j the term “counterfeit” shall mean a false representation as regards identity and/or source;
- k the term “victim” shall mean 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.



## **Chapter II – Substantive criminal law**

### **Article 5 – Manufacturing of counterfeits**

- 1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories.
- 2 As regards medicinal products and, as appropriate, medical devices, active substances and excipients, paragraph 1 shall also apply to any adulteration thereof.
- 3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials, and paragraph 2, as regards excipients.

### **Article 6 – Supplying, offering to supply, and trafficking in counterfeits**

- 1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories.
- 2 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards excipients, parts and materials.

### **Article 7 – Falsification of documents**

- 1 Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law the making of false documents or the act of tampering with documents, when committed intentionally.

- 2 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 1, as regards documents related to excipients, parts and materials.

### **Article 8 – Similar crimes involving threats to public health**

Each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally, in so far as such an activity is not covered by Articles 5, 6 and 7:

- a the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of:
  - i medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or
  - ii medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party;
- b the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.

### **Article 9 – Aiding or abetting and attempt**

- 1 Each Party shall take the necessary legislative and other measures to establish as offences when committed intentionally, aiding or abetting the commission of any of the offences established in accordance with this Convention.
- 2 Each Party shall take the necessary legislative and other measures to establish as an offence the intentional attempt to commit any of the offences established in accordance with this Convention.
- 3 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or

approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, paragraph 2 to offences established in accordance with Articles 7 and 8.

## **Article 10 – Jurisdiction**

- 1 Each Party shall take the necessary legislative and other measures to establish jurisdiction over any offence established in accordance with this Convention, when the offence is committed:
  - a in its territory; or
  - b on board a ship flying the flag of that Party; or
  - c on board an aircraft registered under the laws of that Party;  
or
  - d by one of its nationals or by a person habitually residing in its territory.
- 2 Each Party shall take the necessary legislative and other measures to establish jurisdiction over any offence established in accordance with this Convention, when the victim of the offence is one of its nationals or a person habitually resident in its territory.
- 3 Each Party shall take the necessary legislative and other measures to establish jurisdiction over any offence established in accordance with this Convention, when the alleged offender is present in its territory and cannot be extradited to another Party because of his or her nationality.
- 4 Each State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply, or to apply only in specific cases or conditions, the jurisdiction rules laid down in paragraph 1, sub-paragraph d, and paragraph 2 of this article.
- 5 Where more than one Party claims jurisdiction over an alleged offence established in accordance with this Convention, the Parties concerned shall consult, where appropriate, with a view to determining the most appropriate jurisdiction for prosecution.

- 6 Without prejudice to the general rules of international law, this Convention shall not exclude any criminal jurisdiction exercised by a Party in accordance with its domestic law.

### **Article 11 – Corporate liability**

- 1 Each Party shall take the necessary legislative and other measures to ensure that legal persons can be held liable for offences established in accordance with this Convention, when committed for their benefit by any natural person, acting either individually or as part of an organ of the legal person, who has a leading position within it based on:
- a a power of representation of the legal person;
  - b an authority to take decisions on behalf of the legal person;
  - c an authority to exercise control within the legal person.
- 2 Apart from the cases provided for in paragraph 1, each Party shall take the necessary legislative and other measures to ensure that a legal person can be held liable where the lack of supervision or control by a natural person referred to in paragraph 1 has made possible the commission of an offence established in accordance with this Convention for the benefit of that legal person by a natural person acting under its authority.
- 3 Subject to the legal principles of the Party, the liability of a legal person may be criminal, civil or administrative.
- 4 Such liability shall be without prejudice to the criminal liability of the natural persons who have committed the offence.

### **Article 12 – Sanctions and measures**

- 1 Each Party shall take the necessary legislative and other measures to ensure that the offences established in accordance with this Convention are punishable by effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, taking account of their seriousness. These sanctions shall include, for offences established in accordance with Articles 5 and 6, when committed by natural persons, penalties involving deprivation of liberty that may give rise to extradition.

- 2 Each Party shall take the necessary legislative and other measures to ensure that legal persons held liable in accordance with Article 11 are subject to effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, and may include other measures, such as:
  - a temporary or permanent disqualification from exercising commercial activity;
  - b placing under judicial supervision;
  - c a judicial winding-up order.
- 3 Each Party shall take the necessary legislative and other measures to:
  - a permit seizure and confiscation of:
    - i medical products, active substances, excipients, parts, materials and accessories, as well as goods, documents and other instrumentalities used to commit the offences established in accordance with this Convention or to facilitate their commission;
    - ii proceeds of these offences, or property whose value corresponds to such proceeds;
  - b permit the destruction of confiscated medical products, active substances, excipients, parts, materials and accessories that are the subject of an offence established under this Convention;
  - c take any other appropriate measures in response to an offence, in order to prevent future offences.

### **Article 13 – Aggravating circumstances**

Each Party shall take the necessary legislative and other measures to ensure that the following circumstances, in so far as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of domestic law, be taken into consideration as aggravating circumstances in determining the sanctions in relation to the offences established in accordance with this Convention:

- a the offence caused the death of, or damage to the physical or mental health of, the victim;

- b the offence was committed by persons abusing the confidence placed in them in their capacity as professionals;
- c the offence was committed by persons abusing the confidence placed in them as manufacturers as well as suppliers;
- d the offences of supplying and offering to supply were committed having resort to means of large scale distribution, such as information systems, including the Internet;
- e the offence was committed in the framework of a criminal organisation;
- f the perpetrator has previously been convicted of offences of the same nature.

### **Article 14 – Previous convictions**

Each Party shall take the necessary legislative and other measures to provide for the possibility to take into account final sentences passed by another Party in relation to the offences of the same nature when determining the sanctions.

## **Chapter III – Investigation, prosecution and procedural law**

### **Article 15 – Initiation and continuation of proceedings**

Each Party shall take the necessary legislative and other measures to ensure that investigations or prosecution of offences established in accordance with this Convention should not be subordinate to a complaint and that the proceedings may continue even if the complaint is withdrawn.

### **Article 16 – Criminal investigations**

- 1 Each Party shall take the necessary measures to ensure that persons, units or services in charge of criminal investigations are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health or that persons are trained for this purpose, including financial investigations. Such units or services shall have adequate resources.
- 2 Each Party shall take the necessary legislative and other measures, in conformity with the principles of its domestic law, to ensure effective criminal investigation and prosecution of offences established in

accordance with this Convention, allowing, where appropriate, for the possibility for its competent authorities of carrying out financial investigations, of covert operations, controlled delivery and other special investigative techniques.

## **Chapter IV – Co-operation of authorities and information exchange**

### **Article 17 – National measures of co-operation and information exchange**

- 1 Each Party shall take the necessary legislative and other measures to ensure that representatives of health authorities, customs, police and other competent authorities exchange information and co-operate in accordance with domestic law in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health.
- 2 Each Party shall endeavour to ensure co-operation between its competent authorities and the commercial and industrial sectors as regards risk management of counterfeit medical products and similar crimes involving threats to public health.
- 3 With due respect for the requirements of the protection of personal data, each Party shall take the necessary legislative and other measures to set up or strengthen mechanisms for:
  - a receiving and collecting information and data, including through contact points, at national or local levels and in collaboration with private sector and civil society, for the purpose of preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health;
  - b making available the information and data obtained by the health authorities, customs, police and other competent authorities for the co-operation between them.
- 4 Each Party shall take the necessary measures to ensure that persons, units or services in charge of co-operation and information exchange are trained for this purpose. Such units or services shall have adequate resources.

## **Chapter V – Measures for prevention**

### **Article 18 – Preventive measures**

- 1 Each Party shall take the necessary legislative and other measures to establish the quality and safety requirements of medical products.
- 2 Each Party shall take the necessary legislative and other measures to ensure the safe distribution of medical products.
- 3 With the aim of preventing counterfeiting of medical products, active substances, excipients, parts, materials and accessories, each Party shall take the necessary measures to provide, inter alia, for:
  - a training of healthcare professionals, providers, police and customs authorities, as well as relevant regulatory authorities;
  - b the promotion of awareness-raising campaigns addressed to the general public providing information about counterfeit medical products;
  - c the prevention of illegal supplying of counterfeit medical products, active substances, excipients, parts, materials and accessories.

## **Chapter VI – Measures for protection**

### **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;
- c providing, in its domestic law, for the right of victims to compensation from the perpetrators.



## Article 20 – The standing of victims in criminal investigations and proceedings

- 1 Each Party shall take the necessary legislative and other measures to protect the rights and interests of victims at all stages of criminal investigations and proceedings, in particular by:
  - a informing them of their rights and the services at their disposal and, unless they do not wish to receive such information, the follow-up given to their complaint, the possible charges, the general progress of the investigation or proceedings, and their role therein as well as the outcome of their cases;
  - b enabling them, in a manner consistent with the procedural rules of domestic law, to be heard, to supply evidence and to choose the means of having their views, needs and concerns presented, directly or through an intermediary, and considered;
  - c providing them with appropriate support services so that their rights and interests are duly presented and taken into account;
  - d providing effective measures for their safety, as well as that of their families and witnesses on their behalf, from intimidation and retaliation.
- 2 Each Party shall ensure that victims have access, as from their first contact with the competent authorities, to information on relevant judicial and administrative proceedings.
- 3 Each Party shall ensure that victims have access, provided free of charge where warranted, to legal aid when it is possible for them to have the status of parties to criminal proceedings.
- 4 Each Party shall take the necessary legislative and other measures to ensure that victims of an offence established in accordance with this Convention committed in the territory of a Party other than the one where they reside can make a complaint before the competent authorities of their State of residence.
- 5 Each Party shall provide, by means of legislative or other measures, in accordance with the conditions provided for by its domestic law, the possibility for groups, foundations, associations or governmental or non-governmental organisations, to assist and/or support the

victims with their consent during criminal proceedings concerning the offences established in accordance with this Convention.

## **Chapter VII – International co-operation**

### **Article 21 – International co-operation in criminal matters**

- 1 The Parties shall co-operate with each other, in accordance with the provisions of this Convention and in pursuance of relevant applicable international and regional instruments and arrangements agreed on the basis of uniform or reciprocal legislation and their domestic law, to the widest extent possible, for the purpose of investigations or proceedings concerning the offences established in accordance with this Convention, including seizure and confiscation.
- 2 The Parties shall co-operate to the widest extent possible in pursuance of the relevant applicable international, regional and bilateral treaties on extradition and mutual legal assistance in criminal matters concerning the offences established in accordance with this Convention.
- 3 If a Party that makes extradition or mutual legal assistance in criminal matters conditional on the existence of a treaty receives a request for extradition or legal assistance in criminal matters from a Party with which it has no such a treaty, it may, acting in full compliance with its obligations under international law and subject to the conditions provided for by the domestic law of the requested Party, consider this Convention as the legal basis for extradition or mutual legal assistance in criminal matters in respect of the offences established in accordance with this Convention.

### **Article 22 – International co-operation on prevention and other administrative measures**

- 1 The Parties shall co-operate on protecting and providing assistance to victims.
- 2 The Parties shall, without prejudice to their internal reporting systems, designate a national contact point which shall be responsible for transmitting and receiving requests for information and/or co-operation in connection with the fight against counterfeiting of medical products and similar crimes involving threats to public health.

- 3 Each Party shall endeavour to integrate, where appropriate, prevention and combating of the counterfeiting of medical products and similar crimes involving threats to public health into assistance or development programmes provided for the benefit of third States.

## **Chapter VIII – Follow-up mechanism**

### **Article 23 – Committee of the Parties**

- 1 The Committee of the Parties shall be composed of representatives of the Parties to the Convention.
- 2 The Committee of the Parties shall be convened by the Secretary General of the Council of Europe. Its first meeting shall be held within a period of one year following the entry into force of this Convention for the tenth signatory having ratified it. It shall subsequently meet whenever at least one third of the Parties or the Secretary General so requests.
- 3 The Committee of the Parties shall adopt its own rules of procedure.
- 4 The Committee of the Parties shall be assisted by the Secretariat of the Council of Europe in carrying out its functions.
- 5 A contracting Party which is not a member of the Council of Europe shall contribute to the financing of the Committee of the Parties in a manner to be decided by the Committee of Ministers upon consultation of that Party.

### **Article 24 – Other representatives**

- 1 The Parliamentary Assembly of the Council of Europe, the European Committee on Crime Problems (CDPC), as well as other relevant Council of Europe intergovernmental or scientific committees, shall each appoint a representative to the Committee of the Parties in order to contribute to a multisectoral and multidisciplinary approach.
- 2 The Committee of Ministers may invite other Council of Europe bodies to appoint a representative to the Committee of the Parties after consulting them.

- 3 Representatives of relevant international bodies may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.
- 4 Representatives of relevant official bodies of the Parties may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.
- 5 Representatives of civil society, and in particular non-governmental organisations, may be admitted as observers to the Committee of the Parties following the procedure established by the relevant rules of the Council of Europe.
- 6 In the appointment of representatives under paragraphs 2 to 5, a balanced representation of the different sectors and disciplines shall be ensured.
- 7 Representatives appointed under paragraphs 1 to 5 above shall participate in meetings of the Committee of the Parties without the right to vote.

### **Article 25 – Functions of the Committee of the Parties**

- 1 The Committee of the Parties shall monitor the implementation of this Convention. The rules of procedure of the Committee of the Parties shall determine the procedure for evaluating the implementation of this Convention, using a multisectoral and multidisciplinary approach.
- 2 The Committee of the Parties shall also facilitate the collection, analysis and exchange of information, experience and good practice between States to improve their capacity to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health. The Committee may avail itself of the expertise of other relevant Council of Europe committees and bodies.
- 3 Furthermore, the Committee of the Parties shall, where appropriate:
  - a facilitate the effective use and implementation of this Convention, including the identification of any problems and the effects of any declaration or reservation made under this Convention;

- b express an opinion on any question concerning the application of this Convention and facilitate the exchange of information on significant legal, policy or technological developments;
  - c make specific recommendations to Parties concerning the implementation of this Convention.
- 4 The European Committee on Crime Problems (CDPC) shall be kept periodically informed regarding the activities mentioned in paragraphs 1, 2 and 3 of this article.

## **Chapter IX – Relationship with other international instruments**

### **Article 26 – Relationship with other international instruments**

- 1 This Convention shall not affect the rights and obligations arising from the provisions of other international instruments to which Parties to the present Convention are Parties or shall become Parties and which contain provisions on matters governed by this Convention.
- 2 The Parties to the Convention may conclude bilateral or multilateral agreements with one another on the matters dealt with in this Convention, for purposes of supplementing or strengthening its provisions or facilitating the application of the principles embodied in it.

## **Chapter X – Amendments to the Convention**

### **Article 27 – Amendments**

- 1 Any proposal for an amendment to this Convention presented by a Party shall be communicated to the Secretary General of the Council of Europe and forwarded by him or her to the Parties, the member States of the Council of Europe, non-member States having participated in the elaboration of this Convention or enjoying observer status with the Council of Europe, the European Union, and any State having been invited to sign this Convention.
- 2 Any amendment proposed by a Party shall be communicated to the European Committee on Crime Problems (CDPC) and other relevant

Council of Europe intergovernmental or scientific committees, which shall submit to the Committee of the Parties their opinions on that proposed amendment.

- 3 The Committee of Ministers, having considered the proposed amendment and the opinion submitted by the Committee of the Parties, may adopt the amendment.
- 4 The text of any amendment adopted by the Committee of Ministers in accordance with paragraph 3 of this article shall be forwarded to the Parties for acceptance.
- 5 Any amendment adopted in accordance with paragraph 3 of this article shall enter into force on the first day of the month following the expiration of a period of one month after the date on which all Parties have informed the Secretary General that they have accepted it.

## **Chapter XI – Final clauses**

### **Article 28 – Signature and entry into force**

- 1 This Convention shall be open for signature by the member States of the Council of Europe, the European Union and the non-member States which have participated in its elaboration or enjoy observer status with the Council of Europe. It shall also be open for signature by any other non-member State of the Council of Europe upon invitation by the Committee of Ministers. The decision to invite a non-member State to sign the Convention shall be taken by the majority provided for in Article 20.d of the Statute of the Council of Europe, and by unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers. This decision shall be taken after having obtained the unanimous agreement of the other States/European Union having expressed their consent to be bound by this Convention.
- 2 This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.
- 3 This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the

date on which five signatories, including at least three member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of the preceding paragraph.

- 4 In respect of any State or the European Union, which subsequently expresses its consent to be bound by the Convention, it shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

### **Article 29 – Territorial application**

- 1 Any State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply.
- 2 Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.
- 3 Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

### **Article 30 – Reservations**

- 1 No reservation may be made in respect of any provision of this Convention, with the exception of the reservations expressly established.

- 2 Each Party which has made a reservation may, at any time, withdraw it entirely or partially by a notification addressed to the Secretary General of the Council of Europe. The withdrawal shall take effect from the date of the receipt of such notification by the Secretary General.

### **Article 31 – Friendly settlement**

The Committee of the Parties will follow in close co-operation with the European Committee on Crime Problems (CDPC) and other relevant Council of Europe intergovernmental or scientific committees the application of this Convention and facilitate, when necessary, the friendly settlement of all difficulties related to its application.

### **Article 32 – Denunciation**

- 1 Any Party may, at any time, denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.
- 2 Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

### **Article 33 – Notification**

The Secretary General of the Council of Europe shall notify the Parties, the member States of the Council of Europe, the non-member States having participated in the elaboration of this Convention or enjoying observer status with the Council of Europe, the European Union, and any State having been invited to sign this Convention in accordance with the provisions of Article 28, of:

- a any signature;
- b the deposit of any instrument of ratification, acceptance or approval;
- c any date of entry into force of this Convention in accordance with Article 28;
- d any amendment adopted in accordance with Article 27 and the date on which such an amendment enters into force;



- e any reservation made under Articles 5, 6, 7, 9 and 10 and any withdrawal of a reservation made in accordance with Article 30;
- f any denunciation made in pursuance of the provisions of Article 32;
- g any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done in Moscow, this 28th day of October 2011, in English and in French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Convention or enjoy observer status with the Council of Europe, to the European Union and to any State invited to sign this Convention.

# Appendix II

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## Table of signatures and ratifications of the MEDICRIME Convention (CETS No. 211)

Treaty open for signature by the member States, the non-member States which have participated in its elaboration and by the European Union, and for accession by other non-member States

### Opening for signature

Place: Moscow  
Date: 28.10.2011

### Entry into force

Conditions: 5 Ratifications  
including at least 3 member States  
of the Council of Europe  
Date: 1/1/2016

Status as of 13/11/2015

### Member States of the Council of Europe

States	Signature	Ratification
Albania		
Andorra		
Armenia	20/09/2012	
Austria	28/10/2011	
Azerbaijan		
Belgium	24/07/2012	
Bosnia and Herzegovina		
Bulgaria		
Croatia	03/09/2015	
Cyprus	28/10/2011	
Czech Republic		
Denmark	12/01/2012	
Estonia		
Finland	28/10/2011	

States	Signature	Ratification
France	28/10/2011	
Georgia		
Germany	28/10/2011	
Greece		
Hungary	26/09/2013	09/01/2014
Iceland	28/10/2011	
Ireland		
Italy	28/10/2011	
Latvia		
Liechtenstein	04/11/2011	
Lithuania		
Luxembourg	22/12/2011	
Malta		
Moldova	20/09/2012	14/08/2014
Monaco		
Montenegro		
Netherlands		
Norway		
Poland		
Portugal	28/10/2011	
Romania		
Russia	28/10/2011	
San Marino		
Serbia		
Slovakia		
Slovenia		
Spain	08/10/2012	05/08/2013
Sweden		
Switzerland	28/10/2011	
The former Yugoslav Republic of Macedonia		

States	Signature	Ratification
Turkey	29/06/2012	
Ukraine	28/10/2011	20/08/2012
United Kingdom		

### Non-member States of the Council of Europe

States	Signature	Ratification
Belarus		
Burkina Faso		
Canada		
Guinea	10/10/2012	24/09/2015
Holy See		
Israel	28/10/2011	
Japan		
Mexico		
Morocco	13/12/2012	
United States of America		

### International Organisations

Organisations	Signature	Ratification
European Union		

Total number of signatures not followed by ratifications:	19
Total number of ratifications/accessions:	5

Fake medicines are an outrage. Creating or selling drugs that turn out to be useless – or, worse, directly damaging to our health – can hasten death and prolong or aggravate serious illness.

As parliamentarians, we have a responsibility to do everything we can to protect our citizens by stopping this insidious new form of crime. We can pass laws which oblige genuine medical products to be fully and robustly licensed, throughout the chain of production. We can insist that producing, selling or facilitating “bad medicine” are serious crimes in our countries, with strong penalties that are strictly enforced. We can help each other’s law-enforcement agencies to pursue and bring to justice the perpetrators of these crimes, wherever in the world they may hide.

The Council of Europe’s MEDICRIME Convention – first proposed by the Parliamentary Assembly and signed in Moscow in 2011 after years of negotiation by government experts – is a global instrument which will do all that and more. Filling a gap in international law, it is on course to become the world’s strongest weapon in the fight against the counterfeiting of medical products and similar crimes.

As President of the Parliamentary Assembly of the Council of Europe, I urge national authorities to ratify this important convention without delay. Health and life cannot wait.

**Anne Brasseur**

**President of the Parliamentary Assembly of the Council of Europe**

**[www.assembly.coe.int](http://www.assembly.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. The Parliamentary Assembly, consisting of representatives from the 47 national parliaments, provides a forum for debate and proposals on Europe’s social and political issues. Many Council of Europe conventions originate from the Assembly, including the European Convention on Human Rights.

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