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Draft Explanatory Report

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Convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health

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Document prepared by the Directorate General of Human Rights and Legal Affairs

Introduction

In recent years, both patent protected and generic medical products have increasingly been targeted by counterfeiters. At the same time, the illicit manufacturing and illicit supplying of medical products have also manifested itself as a serious problem. All these inexpedient and unwanted conducts have in common that they potentially offer high financial gains at relatively low risk for the perpetrators, while posing immense risks to public health.

The fact that counterfeiters make frequent use of the internet to advertise and supply their inherently dangerous products directly to patients and consumers around the world have only aggravated the problem.

Furthermore, the fact that counterfeit medical products have become increasingly difficult to detect without carrying out costly laboratory test means that there is today an omnipresent risk, that counterfeit medical products may inadvertently also enter into the legitimate supply chains for medical products, in the process getting mixed up with legitimate products with potentially disastrous results for the public health.

There is accordingly an urgent need to take decisive repressive and preventive measures against counterfeiting and illicit manufacturing and illicit supplying of medical products in order to protect public health interests. Though counterfeiting and illicit manufacturing and supplying of medical products have already been outlawed at national level in many States, the absence of a dedicated international legal instrument establishing these activities as criminal offences carrying effective, proportionate and dissuasive penal sanctions and providing the basis for efficient international co-operation to combat them has facilitated the cross-border operation of criminals in this field. The purpose of this Convention is to address these shortcomings.

The Council of Europe has long been involved in finding adequate answers to the serious problems posed by counterfeiting of medical products and other threats to public health, in particular through the work of the European Directorate for the Quality of Medicines and Healthcare (EDQM), but also through decisions of the Committee of Ministers, and resolutions adopted by the Parliamentary Assembly.

The Parliamentary Assembly Recommendations 1673 (2004) on “Counterfeiting: problems and solutions”, and 1794 (2007) on “The quality of medicines in Europe”, the declaration of the G8 Summit in St. Petersburg entitled “Combating IPR piracy and counterfeiting” of 16 July 2006, the declaration of the International Conference “Europe against counterfeit medicines” held in Moscow 23 – 24 October 2006 and the conclusions of the High-level Conference of the Ministries of Justice and the Interior on “Improving European Co-operation in the Criminal Justice Field”, Moscow 9 – 10 November 2006, have all highlighted the need for taking decisive action to protect public health from the dangers posed by counterfeiting of medical products and similar crimes.

Despite the many legal and other challenges inherent in such an undertaking, the drafting of an international legal instrument of the Council of Europe aimed at combating the counterfeiting of medical products and similar crimes involving threats to public health was identified as the most expedient approach.

To this end a Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP) was set up by decision of the Committee of Ministers.

The PC-S-CP on 23 April 2008 produced a report on the feasibility of an international legal instrument in the field of counterfeiting of medical products and similar crimes. In all the group (composed of 11 specialists and with participation from the Parliamentary Assembly of the Council of Europe, as well as

a number of Member States' delegations as observers) held a series of six meetings in Strasbourg to prepare the draft Convention. The last meeting, at which a draft text of the Convention was adopted, took place on 2 – 4 February 2009.

Following the adoption of the draft Convention by the PC-S-CP, negotiations were launched in the Ad Hoc Committee on Counterfeiting of Medical products and Similar Crimes Involving Threats to Public Health (PC-ISP) with the participation of all Member States and Observers of the Council of Europe. The PC-ISP held two meetings in Strasbourg, on 2 – 5 June and 1 – 4 September 2009 respectively. .

Preamble

The preamble to the Convention contains references to the most important international legal instruments, guidelines and practical co-operation measures relevant for the combating of counterfeiting of medical products and similar crimes involving threats to public health in the framework of the Council of Europe, the European Union and the World Health Organization of the United Nations (WHO) and the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

The preamble describes the aims of the Convention, namely to contribute to the combating of counterfeiting of medical products and similar crimes involving threats to public health through penal sanctions, preventive measures and protection of victims.

Chapter I – Purposes , principle of non-discrimination, scope, definitions

Article 1 – Purposes

Paragraph 1 deals with the purposes of the Convention, which are to prevent and combat threats to public health by:

a. Providing for the criminalisation of certain acts, namely counterfeiting of medical products and similar crimes, as well as aiding or abetting and attempt;
b. protecting the rights of victims of offences related to the crimes mentioned under a);
c. promoting national and international co-operation against the crimes mentioned under a).

As regards point a., the notion of "similar crimes" is to be understood as acts other than counterfeiting and related acts, cf. Article 5, involving medical products, ingredients, parts and materials, as well as accessories , and constituting a threat to public health.

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Thus the focus of the Convention is on the protection of public health; as it was felt that intellectual property rights are generally adequately protected at both national and international level, the Convention does not cover any issues related to the infringement of intellectual property rights in relation to counterfeiting of medical products, ingredients and components. However, the provisions of the Convention shall obviously be applied without prejudice to any possible criminal prosecution of infringements of intellectual property rights to which an act criminalised under the Convention may also give rise.

The similar crimes covered by this Convention are enumerated in Article 6 (illicit manufacturing or supplying of (non-counterfeit) medical products).

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Regarding point b., the protection of victims is dealt with in Article 17. The standing of victims in criminal investigations and proceedings is covered by Article 18.

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Concerning point c), the promotion of national and international co-operation is regulated in Article 15 (national measures of co-ordination, collaboration and information exchange), Article 16 (preventive measures) and Articles 19 and 19bis (international co-operation in criminal matters and international co-operation on prevention and other administrative measures).

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Paragraph 2 provides for the establishment of a specific monitoring mechanism (Articles 20 – 22) in order to ensure an effective implementation of the Convention.

Article 2 – Principle of non-discrimination

This article prohibits discrimination in Parties' implementation of the Convention and in particular in enjoyment of measures to protect and promote victims' rights. The meaning of discrimination in Article 2 is identical to that given to it under Article 14 ECHR.

The concept of discrimination has been interpreted consistently by the European Court of Human Rights in its case-law concerning Article 14 ECHR. In particular this case-law has made clear that not every distinction or difference of treatment amounts to discrimination. As the Court has stated, for example in the *Abdulaziz, Cabales and Balkandali v. the United Kingdom* judgment, "a difference of treatment is discriminatory if it 'has no objective and reasonable justification', that is, if it does not pursue a 'legitimate aim' or if there is not a 'reasonable relationship of proportionality between the means employed and the aim sought to be realised".

The list of non-discrimination grounds in Article 2 is identical to that in Article 14 ECHR and the list contained in Protocol No.12 to the ECHR. However, the negotiators wished to include also the non-discrimination grounds of sexual orientation, state of health and disability. "State of health" includes in particular HIV status. The list of non-discrimination grounds is not exhaustive but indicative. It is worth pointing out that the European Court of Human Rights has applied Article 14 to discrimination grounds not explicitly mentioned in that provision (see, for example, as concerns the ground of sexual orientation, the judgment of 21 December 1999 in *Salgueiro da Silva Mouta v. Portugal*). The reference to "or other status" could refer, for example, to members of refugee or immigrant populations.

Article 2 refers to "implementation of the provisions of this Convention by the Parties". These words seek to specify the extent of the prohibition on discrimination. In particular, Article 2 prohibits a victim's being discriminated against in the enjoyment of measures – as provided for in Chapter VI of the Convention – to protect their rights.

Article 3 – Scope

The scope of the Convention is expressly limited to medicines for human and veterinary use as well as medical devices, their ingredients, parts or materials designated to be used in the production of medical products, including accessories designated to be used together with medical devices, as defined in Article 4, irrespective of the status of these products, ingredients, parts, materials and accessories, under intellectual property law.

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After some hesitancy due to the current lack of standardisation as regards medical devices as opposed to the situation regarding medicinal products, the ad hoc committee decided to include "medical devices" under the scope of the Convention, because of the obvious dangers to public health posed by such devices when counterfeited or manufactured or supplied without authorisation or in breach of standards for quality, safety and efficacy. Consequently, the parts, materials and accessories designated for use in the production of, or together with, medical devices have been included.

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The ad hoc committee decided not to include the related but distinct categories of foodstuffs, cosmetics and biocides under the scope of the Convention, however not excluding that these categories of products could eventually become the subject of additional protocols in the future.

Article 4 – Definitions

The article contains several definitions which are used throughout the Convention: "Medical product", "medicinal product", "ingredients", "medical device", "accessory" "parts", "materials", "document related to a medical product", "manufacturing", "counterfeit" and "victim".

The term medical "medical product", cf. letter a., covers both "medicinal products" and "medical devices".

A "medicinal product", as defined in letter b, is to be understood as covering medicines for human and veterinary use. The reason for including medicines for veterinary use under this Convention, is the fact that such medicines may directly or indirectly affect public health in cases where diseases are transmitted from animals to humans, such as the avian flue. The term "medicinal product" also covers an "investigational medicinal product", cf. letter b, iii, which may be a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation, but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.

The definition of medicinal products used in the Convention is inspired by European Union law, in particular Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products and Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

A "medical device", as defined in letter d, shall mean any instrument intended to be used for diagnostic and/or therapeutic purposes. The definition covers a whole range of devices, from relatively simple objects such as spatulas to technically complicated instruments such as incubators or heart-lung machines. The definition used in the Convention is inspired by a number of legal acts of the European Union, in particular Directive 2007/47/EC amending Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, and Directive 93/42/EEC concerning medical devices, as well as Directive 98/8/EC on the placing on the market of biocidal products.

A "medicinal product" is composed of "ingredients", which term is defined in letter c. Likewise; a "medical device" is made of "parts" and "materials", which are defined in letter f. Medical devices may contain "accessories", which term is defined in letter e.

Since counterfeiting of medical products is often done through tampering with the documentation accompanying a medical product, the ad hoc committee found it useful to also introduce a new, all-encompassing definition, namely "document related to a medical product", cf. letter g. This definition is intended to cover all kinds of documents from first test results to the packaging of the final medical product.

Letter h., defining "manufacturing" is split in three parts, one for medicinal products, one for medical devices and one for accessories. The definition of "manufacturing" is based on the current definition used in the framework of cooperation under the World Health Organisation (WHO).

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The term "counterfeit" is defined in letter i. as a "false representation as regards identity and/or source". For the purposes of this Convention, a medical product shall not be considered as counterfeit for the sole reason that it is not authorised and/or legally marketed in a particular State. Likewise, medical products, which are otherwise legal, shall not be considered as counterfeits for the sole reason that they form part of a sub-standard batch or are suffering from quality defects or non-compliance with good manufacturing or good distribution practices, it being understood that such defects and non-compliance are not resulting from an intentional act or omission on the part of the manufacturer. Finally, the ad hoc committee decided to consider an adulterated medical product simply as a counterfeit and hence not introduce "adulterated medical product" as a specific defined term, different from "counterfeit medical product".

The ad hoc committee considered it pertinent to exclude physical or moral persons having incurred purely financial losses resulting from the conducts criminalised under the Convention (i.e. counterfeiting of medical products and illicit manufacture or illicitly supply of medical products) from enjoying the rights of victims under the Convention. Hence, the term "victim" is defined in letter j. as "a natural person having suffered adverse physical or psychological effects as a result of having used counterfeit or illicitly manufactured or illicitly supplied medical products".

Chapter II – Substantive criminal law

Article 5 – Counterfeiting of medical products, ingredients, parts or materials, as well as accessories and related crimes

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This article provides for the criminalisation of certain intentional conducts consisting in the manufacturing of counterfeit medical products, their ingredients, parts or materials as well as accessories (including through adulteration), as well as conducts closely related thereto, such as the counterfeiting of any document related to medical products, ingredients, parts or materials as well as accessories, supplying or offering to supply of counterfeit medical products, ingredients, parts or materials and accessories, the advertising - to the general public or to professionals – with the intention to promote the supply of counterfeit medical products, as well as the trafficking in counterfeit medical products, ingredients, parts, materials and accessories. The term "supplying" is not specifically defined, but understood to cover, in its widest sense, the acts of procuring, selling or offering for free counterfeit medical products, ingredients, parts, materials and accessories.

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As regards the term "trafficking", this term is widely used in international legal instruments in the field of criminal law, 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), in particular the Firearms Protocol, and the Council of Europe Convention on Action against Trafficking in Human Beings (ETS No. 197) (2005) and is not intended to have a different content or scope for the purposes of this Convention.

Paragraph 2 of Article 5 provides for the criminalisation of the possession of a counterfeit medical product, a counterfeit active substance, counterfeit parts and materials as well as counterfeit a accessory with the intention of manufacturing, supplying, offering to supply or trafficking thereof.

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The ad hoc committee, after some discussion, decided not to provide for the criminalisation of the possession of equipment that could be used for counterfeiting or similar crimes, as it would in practice often prove difficult to establish a sufficiently strong link between the mere possession of equipment,

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that could theoretically be used for counterfeiting, and the actual activity of counterfeiting or similar crimes. However, such equipment may of course play an important role as evidence, if that link can indeed be established.

Article 6 – Illicit manufacturing or supplying of medical products

Article 6 provides for the criminalisation of illicit manufacture and illicit supply of non-counterfeit medical products which have a potential [serious] risk to public or individual health.

It has been considered necessary to include the intentional illicit manufacturing or illicit supplying of non-counterfeit medical products under "similar crimes", as these acts pose a direct threat to public health. An example of illicit manufacturing or illicit supplying of otherwise legitimate medical products is the sprawling black market for hormonal treatment drugs as means of doping for those athletes, bodybuilders and others, who want to enhance their physical performance artificially. The abuse of such drugs can lead to bodily injury and death, and their uncontrolled circulation constitutes in itself a significant threat to public health.

Article 7 – Aiding or abetting and attempt

The purpose of this article is to establish additional offences relating to aiding or abetting of the offences defined in the Convention and the attempted commission of some.

Paragraph 1 requires Parties to establish as criminal offences aiding or abetting the commission of any of the offences established in accordance with the Convention. Liability arises for aiding or abetting where the person who commits a crime is aided by another person who also intends the crime to be committed.

Paragraph 2 provides for the criminalisation of attempt to commit any of the offences established in accordance with the Convention.

As with all the offences established under the Convention, aiding or abetting and attempt must be intentional.

Article 8 – Jurisdiction

This article lays down various requirements whereby Parties must establish jurisdiction over the offences with which the Convention is concerned.

Paragraph 1 a. is based on the territoriality principle. Each Party is required to punish the offences established under the Convention when they are committed on its territory.

Paragraph 1 b. and c. are based on a variant of the territoriality principle. These sub-paragraphs require each Party to establish jurisdiction over offences committed on ships flying its flag or aircraft registered under its laws. This obligation is already in force in the law of many countries, ships and aircraft being frequently under the jurisdiction of the State in which they are registered. This type of jurisdiction is extremely useful when the ship or aircraft is not located in the country's territory at the time of commission of the crime, as a result of which paragraph 1 a. would not be available as a basis for asserting jurisdiction. In the case of a crime committed on a ship or aircraft outside the territory of the flag or registry Party, it might be that without this rule there would not be any country able to exercise jurisdiction. In addition, if a crime is committed on board a ship or aircraft which is merely passing through the waters or airspace of another State, there may be significant practical

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The formulation "each Party shall take the necessary legislative or other measures, in accordance with its internal legal system, to ensure that the following acts, when committed intentionally, are subject to criminal and/or other measures" makes it clear that a State Party is not obliged to criminalise the conducts described in Article 6, if, because of its internal legal system, the Party prefers to impose sanctions on the perpetrators under administrative law.

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With regard to paragraph 2, on attempt, the expert group felt that treating certain offences, or elements of offences, as attempt gave rise to conceptual difficulties. Moreover, some legal systems limit the offences for which the attempt is punished. For these reasons paragraph 3 permits parties to reserve the right not to criminalise attempt to commit the offences set out in the Convention. This means that any Party making a reservation as to that provision will have no obligation to criminalise attempt at all, or may select the offences or parts of offen ... [1]

impediments to the latter State's exercising its jurisdiction and it is therefore useful for the Registry State to also have jurisdiction.

Paragraph 1 d. is based on the nationality principle. The nationality theory is most frequently applied by countries with a civil-law tradition. Under it, nationals of a country are obliged to comply with its law even when they are outside its territory. Under sub-paragraph d, if one of its nationals commits an offence abroad, a Party is obliged to be able to prosecute him/her. The ad hoc committee considered that this was a particularly important provision in the context of the fight against the promotion and sale of counterfeit medical products via the internet. Indeed, certain States under whose jurisdiction internet websites used to deal in counterfeit medical products fall either do not have the will or the necessary resources to successfully carry out investigations or lack the appropriate legal framework.

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Paragraph 1 e. applies to persons having their habitual residence in the territory of the Party. It provides that States Parties shall establish jurisdiction to investigate acts committed abroad by persons habitually residing in their territories, hereby contributing to the efficient punishment of counterfeiting of medical products and similar crimes.

Paragraph 2 enables these cases to be tried even where they are not criminalised in the State in which the offence was committed (i.e. where the internet website advertising and/or supplying counterfeit medical products is registered).

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Paragraph 2 represents an important element of added value in this Convention, and a major step forward in the fight against counterfeiting of medical products and similar crimes. The provision eliminates, in relation to the offences laid down in Article 5, paragraph 1, sub-paragraphs a, to c, in conjunction with Article 11, paragraphs a, e, and f, of the Convention, the usual rule of dual criminality where acts must be criminal offences in the place where they are performed. Paragraph 2 further prohibits the subordination of the initiation of proceedings in the state of nationality or of habitual residence to the condition of a denunciation form the authorities of the state in which the offence took place. Its aim is to combat the phenomenon of promoting and supplying counterfeit medical products via the internet. Paragraph 2 enables these cases to be tried even where they are not criminalised in the State in which the offence was committed.

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Paragraph 3 is linked to the nationality of the victim and identifies particular interests of national victims to the general interests of the State. Hence, according to paragraph 3, if a national or a person having habitual residence is a victim of an offence abroad, the Party shall establish jurisdiction in order to start proceedings.

Paragraph 4 concerns the principle of *aut dedere aut judicare* (extradite or prosecute). Jurisdiction established on the basis of paragraph 2 is necessary to ensure that Parties that refuse to extradite a national have the legal ability to undertake investigations and proceedings domestically instead, if asked to do so by the Party that requested extradition under the terms of the relevant international instruments.

Paragraph 5 allows for the Parties to declare reservations with regard to the application of paragraph 1, sub-paragraphs d and e, and paragraphs 2, 3, and 4, of Article 8.

In certain cases of counterfeiting of medical products and similar crimes, it may happen that more than one Party has jurisdiction over some or all of the participants in an offence. For example, a counterfeit medical product may be manufactured in one country, then trafficked and sold in another. In order to avoid duplication of procedures and unnecessary inconvenience for witnesses or to otherwise facilitate the efficiency or fairness of proceedings, the affected Parties are, in accordance with paragraph 6, required to consult in order to determine the proper venue for prosecution. In some cases it will be most effective for them to choose a single venue for prosecution; in others it may be best for one

country to prosecute some alleged perpetrators, while one or more other countries prosecute others. Either method is permitted under this paragraph. Finally, the obligation to consult is not absolute; consultation is to take place "where appropriate". Thus, for example, if one of the Parties knows that consultation is not necessary (e.g. it has received confirmation that the other Party is not planning to take action), or if a Party is of the view that consultation may impair its investigation or proceeding, it may delay or decline consultation.

The bases of jurisdiction set out in paragraph 1 are not exclusive. Paragraph 7 of this article permits Parties to establish other types of criminal jurisdiction according to their domestic law. Thus, in matters of the counterfeiting of medical products and similar crimes, some States exercise criminal jurisdiction whatever the place of the offence or nationality of the perpetrator.

Article 9 – Corporate liability

Article 9 is consistent with the current legal trend towards recognising corporate liability. The ad hoc committee is of the opinion that due to the gravity of offences in the area of pharmaceutical crime, it is appropriate to include corporate liability in the Convention. The intention is to make commercial companies, associations and similar legal entities ("legal persons") liable for criminal actions performed on their behalf by anyone in a leading position in them. Article 13 also contemplates liability where someone in a leading position fails to supervise or check on an employee or agent of the entity, thus enabling them to commit any of the offences established in the Convention.

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Under paragraph 1, four conditions need to be met for liability to attach. First, one of the offences described in the Convention must have been committed. Second, the offence must have been committed for the entity's benefit. Third, a person in a leading position must have committed the offence (including aiding and abetting). The term "person who has a leading position" refers to someone who is organisationally senior, such as a director. Fourth, the person in a leading position must have acted on the basis of one of his or her powers (whether to represent the entity or take decisions or perform supervision), demonstrating that that person acted under his or her authority to incur liability of the entity. In short, paragraph 1 requires Parties to be able to impose liability on legal entities solely for offences committed by such persons in leading positions.

In addition, paragraph 2 requires Parties to be able to impose liability on a legal entity ("legal person") where the crime is committed not by the leading person described in paragraph 1 but by another person acting on the entity's authority, i.e. one of its employees or agents acting within their powers. The conditions that must be fulfilled before liability can attach are: 1) the offence was committed by an employee or agent of the legal entity; 2) the offence was committed for the entity's benefit; and 3) commission of the offence was made possible by the leading person's failure to supervise the employee or agent. In this context failure to supervise should be interpreted to include not taking appropriate and reasonable steps to prevent employees or agents from engaging in criminal activities on the entity's behalf. Such appropriate and reasonable steps could be determined by various factors, such as the type of business, its size, and the rules and good practices in force.

Liability under this article may be criminal, civil or administrative. It is open to each Party to provide, according to its legal principles, for any or all of these forms of liability as long as the requirements of Article 14 paragraph 2 are met, namely that the sanction or measure be "effective, proportionate and dissuasive" and include monetary sanctions.

Paragraph 4 makes it clear that corporate liability does not exclude individual liability. In a particular case there may be liability at several levels simultaneously – for example, liability of one of the legal entity's organs, liability of the legal entity as a whole and individual liability in connection with one or other.

Article 10 – Sanctions and measures

This article is closely linked to Articles 5 and 6, which define the various offences that should be made punishable under criminal law. In accordance with the obligations imposed by those articles, Article 10 requires Parties to match their action to the seriousness of the offences and lay down criminal penalties which are "effective, proportionate and dissuasive". In the case of an individual committing the offence, Parties must provide for prison sentences that can give rise to extradition. It should be noted that, under Article 2 of the European Convention on Extradition (ETS No. 24), extradition is to be granted in respect of offences punishable under the laws of the requesting and requested Parties by deprivation of liberty or under a detention order for a maximum period of at least one year or by a more severe penalty.

Legal entities whose liability is to be established under Article 9 are also to be liable to sanctions that are "effective, proportionate and dissuasive", which may be criminal, administrative or civil in character. Paragraph 2 requires Parties to provide for the possibility of imposing monetary sanctions on legal persons.

In addition, paragraph 2 provides for other measures which may be taken in respect of legal persons, with particular examples given: exclusion from entitlement to public benefits or aid; temporary or permanent disqualification from the practice of commercial activities; placing under judicial supervision; or a judicial winding-up order. The list of measures is not mandatory or exhaustive and Parties are free to envisage other measures.

Paragraph 3 requires Parties to ensure that measures concerning seizure and confiscation of certain documents, goods and the proceeds derived from offences can be taken. This paragraph has to be read in the light of the Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime (ETS No. 141) as well as the Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime and on the Financing of Terrorism (ETS No. 198), which are based on the idea that confiscating the proceeds of crime is an effective anti-crime weapon. As all of the offences related to the counterfeiting of medical products and similar crimes are undertaken for financial profit, measures depriving offenders of assets linked to or resulting from the offence are clearly needed in this field as well.

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Paragraph 3 a. provides for the destruction of medical products resulting from the offences established under Articles 5 and 6. This has been deemed necessary by the ad hoc committee in order to protect the public health.

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Paragraph 3 b provides for the seizure and confiscation of goods documents and other instrumentalities used to commit the offences established under the Convention as well as proceeds of the offences or assets ("property") whose value corresponds to such proceeds.

Paragraph 3 c provides for closure of any establishment used to carry out any of the offences established in the Convention. This measure is identical to Article 23 paragraph 4 of the Council of Europe Convention on Action against Trafficking in Human Beings and Article 27 paragraph 3 b of the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse. Alternatively, the provision also allows the perpetrator to be banned, temporarily or permanently, from carrying on the commercial or professional activity in connection with which the offence was committed. The latter measure includes the possibility to withdraw licences in cases where the perpetrators have abused the confidence placed in them in their professional capacities (primarily, but not exclusively, health care professionals) or are holding authorisation to manufacture and supply medical products. The ad hoc committee considered it necessary to introduce such measures in order to ensure public confidence in the health profession and medical products.

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The Convention does not contain definitions of the terms “confiscation”, “instrumentalities”, “proceeds” and “property”. However, Article 1 of the Laundering Convention provides definitions for these terms which may be used for the purposes of this Convention. By “confiscation” is meant a penalty or measure, ordered by a court following proceedings in relation to a criminal offence or criminal offences, resulting in final deprivation of property. “Instrumentalities” covers the whole range of things which may be used, or intended for use, in any manner, wholly or in part, to commit the criminal offences. “Proceeds” means any economic advantage or financial saving from a criminal offence. It may consist of any “property” (see the interpretation of that term below). The wording of the paragraph takes into account that there may be differences of national law as regards the type of property which can be confiscated after an offence. It can be possible to confiscate items which are (direct) proceeds of the offence or other property of the offender which, though not directly acquired through the offence, is equivalent in value to its direct proceeds (“substitute assets”). “Property” must therefore be interpreted, in this context, as any property, corporeal or incorporeal, movable or immovable, and legal documents or instruments evidencing title to or interest in such property. It should be noted that Parties are not bound to provide for criminal-law confiscation of substitute assets since the words “or otherwise deprive” allow “civil” confiscation.

Article 11 – Aggravating circumstances

Article 11 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 penalty for offences established in this Convention. These circumstances must not already form part of the constituent elements of the offence. This principle applies to cases where the aggravating circumstances already form part of the constituent elements of the offence in the national law of the State Party.

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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 internal law” is intended to reflect the fact that the various legal systems in Europe have different approaches to aggravating circumstances and permits Parties to retain some of their fundamental legal concepts.

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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 medicinal product 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 State Parties to assess the causal link between the conducts criminalised under the Convention and any death or injury sustained as a result thereof.

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The second aggravating circumstance (b) is where the offence was committed by persons abusing the confidence placed in them in their professional capacity or holding authorisation to manufacture and supply medical products, ingredients, parts, materials and accessories. These categories of persons are in the first line obviously health professionals, but the application of the aggravating circumstance is not restricted to health professionals.

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The third aggravating circumstance (c) is where the offences of advertising and supplying are committed through the use of large scale distribution, including information technology systems. The ad hoc committee found that the use of the internet for the advertising and supplying in counterfeit medical products and the illicit supply of medical products is one of the most worrying and serious aspects of counterfeiting of medical products and similar crimes today. Given the immense outreach provided by the internet, counterfeit and 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

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increasingly difficult to get at the criminals behind various internet sites, offering cheap (i.e. mostly counterfeit) medicines or other medical products.

The fourth aggravating circumstance (d) is where the offence was committed by several persons acting together. This indicates a collective act committed by more than one person.

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 line 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".

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The sixth aggravating circumstance (f) is where the perpetrator has previously been convicted of offences of the same nature as those established under the Convention. By including this, the ad hoc committee wanted to signal 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.

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Article 12 – Previous convictions

Counterfeiting of medical products and similar crimes are more often than not perpetrated transnationally by criminal organisations or by individual persons, some of whom may have been tried and convicted in more than one country. At domestic level, many legal systems provide for a different, often harsher, penalty where someone has previous convictions. In general, only conviction by a 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 because of a degree of suspicion of decisions by foreign courts.

Such arguments have less force today in that internationalisation of criminal-law standards – as a pendent to internationalisation of crime – is tending to harmonise different countries' law. In addition, in the space of a few decades, countries have adopted instruments such as the ECHR whose implementation has helped build a solid foundation of common guarantees that inspire greater confidence in the justice systems of all the participating States.

The principle of international recidivism is established in a number of international legal instruments. Under Article 36(2)(iii) of the *New York Convention of 30 March 1961 on Narcotic Drugs*, 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 counterfeiting of currency.

The fact remains that at international level there is no standard concept of recidivism and the law of some countries does 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 Article 3 of the EU Council Framework Decision 2008/675/JHA of 24 July 2008 on taking account of

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convictions in the member States of the European Union in the course of new criminal proceedings, firstly established in a general way – without limitation to specific offences – the obligation of taking into account a previous conviction handed down in another (Member) State.

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Therefore Article 12 provides for the possibility to take into account final sentences passed by another Party in assessing a sentence. To comply with the provision Parties may provide 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 in setting the sentence, courts should take those convictions into account. This possibility should also include the principle that the offender should not be treated less favourably than he would have been treated if the previous conviction had been a national conviction.

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 (ETS No. 30), a Party's judicial authorities may request from another Party extracts from and information relating to judicial records, if needed in a criminal matter.

Chapter III – Investigations, prosecution and procedural law

Article 13 – Initiation and continuation of proceedings

Article 13 is designed to enable the public authorities to prosecute offences established in accordance with the Convention ex officio, without a victim having to file a complaint. The purpose of this provision is to facilitate prosecution, in particular by ensuring that criminal proceedings may continue regardless of pressure or threats by the perpetrators of offences towards victims.

Article 14 – Criminal investigations

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The article provides for the specialised criminal investigation and combating of counterfeiting of medical products and similar crimes by persons, units or services of the competent national authorities of State Parties.

Paragraph 2 provides for State Parties to ensure the effective investigation and prosecution of offences established under the Convention in accordance with the fundamental principles of their national law. The notion of "fundamental principles of national law" should be understood as also encompassing basic human rights, including those provided under ECHR Article 6.

"Effective investigation" is further defined as asset investigations, covert operations, controlled delivery and other special investigative techniques such as electronic and other forms of surveillance as well as infiltration operations. As indicated by the wording "where appropriate", Parties are not legally obliged to apply any or all of these investigative techniques.

The ad hoc committee underlines that "controlled delivery" is one of the most important investigative tools available to authorities in the area of counterfeiting of medical products and similar crimes. The measure of "controlled delivery" is already foreseen by a number of international legal instruments in the field of criminal law, in particular the United Nations Convention Against Transnational Organised Crime and the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

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As regards “infiltration operations”, the jurisprudence of the European Court of Human Rights has been taken into account by the ad hoc committee. In the leading case of *Ramanauskas v. Lithuania* decided by the Grand Chamber of the Court ob 5 February 2008, the Court found that the use of special investigative methods – in particular, undercover techniques – cannot in itself infringe the right to a fair trial. The essential element that distinguishes permissible from impermissible infiltration, is the influence exerted by the officers on the applicant (the defendant of the criminal case), i.e., whether the officers involved in the operation acted in an essentially passive manner or whether they exerted such an influence on the applicant that it amounted to an incitement to commit the crime for which the latter was convicted. Furthermore, such “infiltration operations” must be in accordance with the law, necessary in a democratic society and based on concrete evidence of a criminal activity.

Chapter IV – Collaborating authorities and information exchange

Article 15 – National measures of co-ordination, collaboration and information exchange

Article 15 provides for the co-ordination, collaboration and information exchange between the competent authorities involved at national level in combating and preventing counterfeiting of medical products and similar crimes. In addition, paragraph 1 provides for the facilitation of assistance to be provided by the relevant commercial and industrial sectors to the competent authorities as regards risk management.

The ad hoc committee found that the wide range of authorities involved in the fight against counterfeiting of medical products and similar crimes, from law enforcement to health, usually requires a strengthening of the existing frameworks for co-operation. Thus Article 15 does not in any way oblige Parties to introduce new bodies tasked with co-ordination and information exchange in the field of counterfeiting of medical products and similar crimes.

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Chapter V – Measures for prevention

Article 16 – Preventive measures

Paragraph 1 of this article provides for the introduction, at national level, of norms on the manufacturing and supply of medical products, ingredients and components. These norms shall, in particular, but not exclusively, address standards for quality, safety and efficacy, authorisations and certificates, as well as the supervision of all professional activities within the distribution chain for medical products, ingredients, parts, materials and accessories.

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Paragraph 2 provides for the establishment of co-operation with the pharmaceutical and medical device sectors with a view to introducing adequate track and trace systems on medical products, ingredients, parts, materials and accessories. The wording “as appropriate and where applicable” is intended to leave a certain margin of appreciation to the Parties as regards the implementation of this provision.

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As further preventive measures, paragraph 3 requires Parties to provide training of health care professionals, providers, police, customs and relevant regulatory authorities in order to better prevent an combat the counterfeiting of medical products and similar crimes; to promote awareness raising campaigns with the involvement of relevant non-governmental organisations and the media; to supervise all professional activities within the distribution chain of medical products, as well as to

develop agreements with Internet Service Providers and Domain Registrars to facilitate actions against websites involved in the promotion and selling of counterfeit medical products.

The actions enumerated in paragraphs 1 - 3 are not to be considered as an exhaustive list.

Chapter VI – Measures for protection

Article 17 – Protection of victims

Article 17 provides for the protection of the rights and interests of victims, in particular by requiring Parties to ensure that victims are given access to information relevant for their case and necessary to protect their health; that victims are assisted in their physical, psychological and social recovery, and that victims are provided with the right to compensation under the internal law of the Parties. As regards the right to compensation, the ad hoc committee noted that in a number of Member States of the Council of Europe national victim funds are already in existence. However, this provision does not oblige Parties to establish such funds.

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Article 18 – The standing of victims in criminal investigations and proceedings

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This article contains a non-exhaustive list of procedures designed to victims of crimes established under this Convention during investigations and proceedings. These general measures of protection apply at all stages of the criminal proceedings, both during the investigations (whether they are carried out by a police service or a judicial authority) and during criminal trial proceedings.

First of all, the article sets out the right of victims to be informed of developments in the investigations and proceedings in which they are involved. In this respect, the provision provides that victims should be informed of their rights and of the services at their disposal and, unless they do not wish to receive such information, the follow-up given to their complaint, the charges, the general progress of the investigations or proceedings, and their role as well as the outcome of their cases.

The article goes on to list a number of procedural rules designed to implement the general principles set out in Article 18: the possibility, for victims, of being heard, of supplying evidence, choosing the means of having their views, needs and concerns presented, directly or through an intermediary, and of being protected against any risk of retaliation.

Paragraph 2 also covers administrative proceedings, since procedures for compensating victims are of this type in some States. More generally, there are also situations in which protective measures, even in the context of criminal proceedings, may be delegated to the administrative authorities.

Paragraph 3 provides for access, free of charge, where warranted, to legal aid for victims of counterfeiting of medical products or similar crimes. Judicial and administrative procedures are often highly complex and victims therefore need the assistance of legal counsel to be able to assert their rights satisfactorily. This provision does not afford victims an automatic right to free legal aid. The conditions under which such aid is granted must be determined by each Party to the Convention when the victim is entitled to be a party to the criminal proceedings.

In addition to Article 18 paragraph 3, dealing with status of victims as parties to criminal proceedings, the States Parties must take account of Article 6 ECHR. Even though Article 6, paragraph 3.c. ECHR provides for the free assistance of an officially assigned defence counsel only in the case of persons charged with criminal offences, the case law of the European Court of Human Rights (*Airey v. Ireland* judgement, 9 October 1979) also, in certain circumstances, recognises the right to free assistance from an officially assigned defence counsel in civil proceedings, under Article 6, paragraph 1 ECHR, which is interpreted as enshrining the right of access to a court for the purposes of obtaining a

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decision concerning civil rights and obligations (*Golder v. United Kingdom* judgment, 21 February 1975). The Court took the view that effective access to a court might necessitate the free assistance of a lawyer. For instance, the Court considered that it was necessary to ascertain whether it would be effective for the person in question to appear in court without the assistance of counsel, i.e. whether he could argue his case adequately and satisfactorily. To this end, the Court took account of the complexity of the proceedings and the passions involved – which might be incompatible with the degree of objectivity needed in order to plead in court – so as to determine whether the person in question was in a position to argue his own case effectively and held that, if not, he should be able to obtain free assistance from an officially assigned defence counsel. Thus, even in the absence of legislation affording access to an officially assigned defence counsel in civil cases, it is up to the court to assess whether, in the interests of justice, a destitute party unable to afford a lawyer's fees must be provided with legal assistance.

Paragraph 4 provides for the possibility for various organisations to support victims. The reference to conditions provided for by internal law highlights the fact that it is up to the States to make provision for assistance or support, but that they are free to do so in accordance with the rules laid down in their national systems, for example by requiring certification or approval of the organisations, foundations, associations and other bodies concerned.

Chapter VII – International co-operation

Article 19 – International co-operation in criminal matters

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The article sets out the general principles that should govern international co-operation in criminal matters.
Paragraph 1 obliges Parties to co-operate, on the basis of relevant international and national law, to the widest extent possible for the purpose of investigations or proceedings of crimes established under the Convention, including for the purpose of carrying out seizure and confiscation measures.

Paragraph 2 is based on Article 11, paragraphs 2 and 3, of the Framework Decision of 15 March 2001 of the Council of the European Union on the standing of victims in criminal proceedings. It is designed to make it easier for victims to file a complaint by enabling them to lodge it with the competent authorities of the State of residence. A similar provision is also found in Article 38, paragraph 2 of the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse (ETS No. 201) of 25 October 2007.

Paragraph 3 authorises a Party that makes mutual assistance in criminal matters or extradition conditional on the existence of a treaty to consider the Convention as the legal basis for judicial co-operation with a Party with which it has not concluded such a treaty. This provision, which serves no purpose between Council of Europe Member States because of the existence of the European Conventions on Extradition and Mutual Legal Assistance in Criminal Matters, dating from 1957 and 1959 respectively, and the Protocols to them, is of interest because of the possibility provided to third States to accede to the Convention (cf. Article 26).

Article 19bis – International co-operation on prevention and other administrative measures

This provision obliges Parties to co-operate on protecting and providing assistance to victims, cf. paragraph 1 of the article.

According to paragraph 2, the Parties shall designate national contact points for receiving requests for information and/or co-operation outside the scope of international co-operation in criminal matters . The contact points shall be established without prejudice to the internal reporting systems of Parties.

Paragraph 3 of the article obliges Parties to endeavour to include preventing and combating the counterfeiting of medical products and similar crimes involving threats to public health in development assistance programmes benefiting third States. Many Council of Europe Member States carry out such programmes, which cover such varied areas as the restoration or consolidation of the rule of law, the development of judicial institutions, combating crime, and technical assistance with the implementation of international conventions. Some of these programmes may be implemented in countries faced with substantial problems caused by the activities criminalised under the Convention. In this context, it seems appropriate that such programmes should take account of and duly incorporate issues relating to the prevention and punishment of this form of crime.

Chapter VIII – Monitoring mechanism

Chapter VIII of the Convention contains provisions which aim at ensuring the effective implementation of the Convention by the Parties. The monitoring system foreseen by the Convention is based essentially on a body, the Committee of the Parties, composed of representatives of the Parties to the Convention, including representatives of Parties that may accede to the Convention under Articles 25 and 26.

Article 20 – Committee of the Parties

Article 20 provides for the setting up of a committee under the Convention, the Committee of the Parties, which is a body with the composition described above, responsible for a number of Convention-based follow-up tasks.

The Committee of the Parties will be convened the first time by the Secretary General of the Council of Europe, within a year of the entry into force of the Convention by virtue of the 10th ratification. It will then meet at the request of a third of the Parties or of the Secretary General of the Council of Europe.

It should be stressed that the ad hoc committee intended to allow the Convention to come into force quickly while deferring the introduction of the monitoring mechanism until such time as the Convention was ratified by a sufficient number of States for it to operate under satisfactory conditions, with a sufficient number of representative States Parties to ensure its credibility.

The setting up of this body will ensure equal participation of all the Parties in the decision-making process and in the Convention monitoring procedure and will also strengthen co-operation between the Parties to ensure proper and effective implementation of the Convention.

The Committee of the Parties must adopt rules of procedure establishing the way in which the monitoring system of the Convention operates, on the understanding that its rules of procedure must be drafted in such a way that the Parties to the Convention, including the European Community, are effectively monitored.

Article 21 – Other representatives

Article 21 contains an important message concerning the participation of bodies other than the Parties themselves in the Convention monitoring mechanism in order to ensure a genuinely multidisciplinary approach. It refers, firstly, to the Parliamentary Assembly, and the European Committee on Crime

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First of all, it obliges the Parties to co-operate widely with one another and in particular to reduce, as far as possible, the obstacles to the rapid circulation of information and evidence. ¶
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Article 19 makes it clear that the obligation to co-operate is general in scope: it covers preventing and combating counterfeiting of medical products and similar crimes and providing assistance to victims (a), and investigations or procedures concerning criminal offences established in accordance with the Convention (b).¶
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Paragraph 2 requires the Parties to designate a national contact point responsible at the international level for the receiving or sending of requests for information and/or co-operation in investigations. ¶
¶
Paragraph 3 is based on Article 11, paragraphs 2 and 3, of the Council of the European Union Framework Decision of 15 March 2001 on the standing of victims in criminal proceedings. It is designed to make it easier for victims to file a complaint by enabling them to lodge it with the competent authorities of the State of residence. A similar provision is to be found in Article 38, paragraph 2 of the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse (ETS No. 201) of 25 October 2007.¶
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These authorities may then either initiate proceedings if their law permits, or pass on the complaint to the authorities of the State in which the offence was committed, in accordance with the relevant provisions of the co-operation instruments applicable to the States in question.¶
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Paragraph 4 authorises a Party that makes mutual assistance in criminal matters or extradition conditional on the existence of a treaty to consider the Convention as the legal basis for judicial co-operation with a Party with which it has no ... [2]

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Problems (CDPC), the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), the Commission of the European Pharmacopoeia, the European Directorate for the Quality of Medicines and Healthcare (EDQM) and its Advisory Group of the General Network of Official Medicines Control Laboratories (GeON) – which are listed in the article and, secondly, more unspecified, to other relevant intergovernmental committees of the Council of Europe.

The importance afforded to involving representatives of civil society in the work of the Committee of the Parties is undoubtedly one of the main strengths of the monitoring system provided for by the negotiators. The possibility of admitting representatives of non-governmental organisations and other bodies actively involved in preventing and combating counterfeiting of medical products and similar crimes was considered to be an important issue, if monitoring of the application of the Convention was to be truly effective.

Article 22 – Functions of the Committee of the Parties

When drafting this provision, the ad hoc committee wanted to base itself on the similar provision of the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse (CETS. No. 201), creating as simple and flexible a mechanism as possible, centred on a Committee of the Parties with a broader role in the Council of Europe's legal work on combating the counterfeiting of medical products and similar crimes. The Committee of the Parties is thus destined to serve as a centre for the collection, analysis and sharing of information, experiences and good practice between States to improve their policies in this field using a multisectoral and multidisciplinary approach .

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With respect to the Convention, the Committee of the Parties has the traditional follow-up competencies and:

a. plays a role in the effective implementation of the Convention, by making proposals to facilitate or improve the effective use and implementation of the Convention, including the identification of any problems and the effects of any declarations made under the Convention;

b. plays a general advisory role in respect of the Convention by expressing an opinion on any question concerning the application of the Convention, including by making specific recommendations to Parties in this respect;

c. serves as a clearing house and facilitates the exchange of information on significant legal, policy or technological developments in relation to the application of the provisions of the Convention.

Paragraph 5 states that the European Committee on Crime Problems (CDPC) should be kept periodically informed of the activities mentioned in paragraphs 1, 2 and 3 of Article 22.

Chapter IX – Relationship with other international instruments

Article 23 – Relationship with other international instruments

Article 23 deals with the relationship between the Convention and other international instruments.

In accordance with the 1969 Vienna Convention on the Law of Treaties, Article 23 seeks to ensure that the Convention harmoniously coexists with other treaties – whether multilateral or bilateral – or instruments dealing with matters which the Convention also covers. Article 23, paragraph 1 aims at ensuring that this Convention does not prejudice the rights and obligations derived from other international instruments to which the Parties to this Convention are also Parties or will become Parties, and which contain provisions on matters governed by this Convention.

Article 23, paragraph 2 states positively that Parties may conclude bilateral or multilateral agreements – or any other legal instrument – relating to the matters which the Convention governs. However, the wording makes clear that Parties are not allowed to conclude any agreement which derogates from this Convention.

Following the signature of a Memorandum of Understanding between the Council of Europe and the European Union on 23 May 2007 the CDPC took note that "legal co-operation should be further developed between the Council of Europe and the European Union with a view to ensuring coherence between Community and European Union law and the standards of Council of Europe conventions. This does not prevent Community and European Union law from adopting more far-reaching rules."

Chapter X – Amendments to the Convention

Article 24 – Amendments

Amendments to the provisions of the Convention may be proposed by the Parties. They must be communicated to all Council of Europe member States, to any signatory, to any Party, to the European Community and to any State invited to sign or accede to the Convention.

The Committee of the Parties, composed in accordance with Article 20, will prepare an opinion on the proposed amendment, which will be submitted to the Committee of Ministers. After considering the proposed amendment and the opinion submitted by the Committee of the Parties, the Committee of Ministers can adopt the amendment. Before deciding on the amendment, the Committee of Ministers shall consult and obtain the unanimous consent of all Parties. Such a requirement recognises that all Parties to the Convention should be able to participate in the decision-making process concerning amendments and are on an equal footing.

Chapter XI – Final clauses

With some exceptions, Articles 25 to 31 are essentially based on the Model Final Clauses for Conventions and Agreements concluded within the Council of Europe, which the Committee of Ministers approved at the Deputies' 315th meeting, in February 1980.

Article 25 – Signature and entry into force

The Convention is open for signature by Council of Europe member States, the European Community and States not members of the Council of Europe which took part in drawing it up (xx,yy,zz). Once the Convention enters into force, in accordance with paragraph 3, other non-member States may be invited to accede to the Convention in accordance with Article 26, paragraph 1.

Article 25 paragraph 3 sets the number of ratifications, acceptances or approvals required for the Convention's entry into force at five. This number is not very high in order not to delay unnecessarily the entry into force of the Convention but reflects nevertheless the belief that a minimum group of States is needed to successfully set about addressing the major challenge of combating counterfeiting of medical products and similar crimes. Of the five states which will make the Convention enter into force, at least three must be Council of Europe members.

Article 26 – Accession to the Convention

After consulting the Parties and obtaining their unanimous consent, the Committee of Ministers may invite any State not a Council of Europe member which did not participate in drawing up the Convention to accede to it. This decision requires the two-thirds majority provided for in Article 20.d of the Statute of the Council of Europe and the unanimous vote of the Parties to the Convention having the right to sit on the Committee of Ministers.

Article 27 – Territorial application

Article 27, paragraph 1 specifies the territories to which the Convention applies. Here it should be pointed out that it would be incompatible with the object and purpose of the Convention for States Parties to exclude parts of their territory from application of the Convention without valid reason (such as the existence of different legal systems applying in matters dealt with in the Convention).

Article 27, paragraph 2 is concerned with extension of application of the Convention to territories for whose international relations the Parties are responsible or on whose behalf they are authorised to give undertakings.

Article 28 – Reservations

Article 28 specifies that the Parties may make use of the reservations expressly authorised by the Convention. No other reservation may be made. The negotiators wish to underline the fact that reservations can be withdrawn at any moment.

Article 29 – Friendly settlement

Article 29 provides that the European Committee on Crime Problems (CDPC) shall follow the application of the Convention and facilitate the solution of all disputes related thereto between the Parties.

Article 30 – Denunciation

Article 30 allows any Party to denounce the Convention.

Article 31 – Notification

Article 31 lists the notifications that, as the depositary of the Convention, the Secretary General of the Council of Europe is required to make, and designates the recipients of these notifications (States and the European Community).

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With regard to paragraph 2, on attempt, the expert group felt that treating certain offences, or elements of offences, as attempt gave rise to conceptual difficulties. Moreover, some legal systems limit the offences for which the attempt is punished. For these reasons paragraph 3 permits parties to reserve the right not to criminalise attempt to commit the offences set out in the Convention. This means that any Party making a reservation as to that provision will have no obligation to criminalise attempt at all, or may select the offences or parts of offences to which it will attach criminal sanctions in relation to attempt. The reservation aims at enabling the widest possible ratification of the Convention while permitting Parties to preserve some of their fundamental legal concepts.

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Article 19 sets out the general principles that should govern international co-operation.

First of all, it obliges the Parties to co-operate widely with one another and in particular to reduce, as far as possible, the obstacles to the rapid circulation of information and evidence.

Article 19 makes it clear that the obligation to co-operate is general in scope: it covers preventing and combating counterfeiting of medical products and similar crimes and providing assistance to victims (a), and investigations or procedures concerning criminal offences established in accordance with the Convention (b).

Paragraph 2 requires the Parties to designate a national contact point responsible at the international level for the receiving or sending of requests for information and/or co-operation in investigations.

Paragraph 3 is based on Article 11, paragraphs 2 and 3, of the Council of the European Union Framework Decision of 15 March 2001 on the standing of victims in criminal proceedings. It is designed to make it easier for victims to file a complaint by enabling them to lodge it with the competent authorities of the State of residence. A similar provision is to be found in Article 38, paragraph 2 of the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse (ETS No. 201) of 25 October 2007.

These authorities may then either initiate proceedings if their law permits, or pass on the complaint to the authorities of the State in which the offence was committed, in accordance with the relevant provisions of the co-operation instruments applicable to the States in question.

Paragraph 4 authorises a Party that makes mutual assistance in criminal matters or extradition conditional on the existence of a treaty to consider the Convention as the legal basis for judicial co-operation with a Party with which it has not concluded such a treaty. This provision, which serves no purpose between Council of Europe member States because of the existence of the *European* Conventions on Extradition and on Mutual Assistance in Criminal Matters, dating from 1957 and 1959 respectively, and the Protocols to them, is of interest because of the possibility provided to third States to accede to the Convention (cf. Article 46).

Lastly, under paragraph 5, the Parties must endeavour to include preventing and combating the counterfeiting of medical products and similar crimes in development assistance programmes benefiting third States. Many Council of Europe Member

States carry out such programmes, which cover such varied areas as the restoration or consolidation of the rule of law, the development of judicial institutions, combating crime, and technical assistance with the implementation of international conventions. Some of these programmes may be carried out in countries faced with substantial problems caused by the counterfeiting of medical products and similar crimes. It seems appropriate, in this context, that action programmes should take account of and duly incorporate issues relating to the prevention and punishment of this form of crime.