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

Explanatory Report

1. The Committee of Ministers of the Council of Europe took note of this Explanatory Report at its 1101st meeting held at its Deputies' level, on 8 December 2010.

2. The text of this Explanatory Report does not constitute an instrument providing an authoritative interpretation of the Convention, although it might be of such a nature as to facilitate the application of the provisions contained therein.

Introduction

3. Counterfeiting of medical products and similar crimes violate the right to life as enshrined in the European Convention on 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.

4. In addition to the risk to the health of individuals, the confidence of the general public in health authorities and healthcare systems as such is in risk of being undermined by the circulation on the market of counterfeit and dangerous medical products. 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 enter into the legal supply chains for medical products, in the process getting mixed up with legitimate products with potentially disastrous results for public health.

5. Despite the fact that measures at both national and international levels have been taken to curb this problem, both patent protected and generic medical products, as well as the active substances, excipients, parts and materials of which they are made, have increasingly been targeted by counterfeiters. In parallel, the manufacturing and supply of medical products without authorisation or without the products being in compliance with conformity requirements have also become a serious problem.

6. The reason for the strong growth of this type of crime is clearly the relatively low risk of detection and prosecution compared with the potential high financial gains. Using the internet to advertise and supply their inherently dangerous products directly to patients and consumers around the world has proven to be a safe and easy modus operandi for the criminals involved and has given them a global reach. The result is a serious threat to public health of truly global proportions.

7. There is accordingly an urgent need to take decisive repressive and preventive measures against the counterfeiting of medical products and similar crimes in order to protect the lives of individual patients/consumers and public health in general. Though counterfeiting and the unauthorised manufacturing and supply of medicinal products as well as the placing on the market of medical devices that are not in compliance with conformity requirements 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.

8. The Council of Europe has long been involved in finding adequate answers to the serious problems posed by the 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.

9. 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 on 23 and 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 and 10 November 2006, have all highlighted the need for taking decisive action to protect public health from the dangers posed by the counterfeiting of medical products and similar crimes.

10. 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.

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

12. The PC-S-CP on 23 April 2008 produced a report on the key elements to be included in an international legal instrument in the field of counterfeiting of medical products and similar crimes. In all the group (composed of eleven specialists and with participation from the Parliamentary Assembly of the Council of Europe, a number of member states and the European Commission as observers) held a series of six meetings in Strasbourg to prepare the above report and a preliminary draft Convention. The last meeting, at which a preliminary draft text of the Convention was adopted, took place on 2 to 4 February 2009.

13. 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 to 5 June and 1 to 4 September 2009 respectively.

14. The PC-ISP made a series of amendments to the draft Convention prepared by the PC-S-CP, notably with regard to the provisions on substantive criminal law, and at its last meeting adopted a draft text of the Convention, which was finalised by the European Committee on Crime Problems (CDPC) at its plenary meeting, 12 to 16 October 2009.

Preamble

15. The preamble describes the purpose of the Convention, namely to contribute to combating the counterfeiting of medical products and similar crimes involving threats to public health through penal sanctions, preventive measures and protection of victims. The Convention shall be applied without prejudice to the protection of intellectual property rights. However, the protection of such rights does not fall within the scope of the Convention (see Article 3 below).

16. The preamble underlines that in the application of the provisions of the Convention covering substantive criminal law, due consideration should be given to the purpose of the Convention and to the principle of proportionality.

17. The preamble to the Convention refers to important international players in the field of combating counterfeiting of medical products and similar crimes, namely the World Health Organization of the United Nations (WHO) and its International Medical Products Anti-Counterfeiting Taskforce (IMPACT), the G8, the European Union and the Council of Europe itself. The desirability for Council of Europe member states to extend their co-operation under the Convention to include non-member states is also underlined.

18. In this context, particular reference should be made to the following legal acts of the European Union governing medical products: Directives 2004/27/EC and 2004/24/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/28/EC of the European Parliament and of the Council, amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products, as well as Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC concerning medical devices.

Chapter I – Object and Purpose, principle of non-discrimination, scope, definitions

Article 1 – Object and purpose

19. Paragraph 1 deals with the object and 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, including through the criminalisation of 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).

20. 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 the counterfeiting of medical products, active substances, excipients, parts and materials. However, the provisions on substantive criminal law of the Convention shall obviously be applied without prejudice to any possible criminal prosecution of infringements of intellectual property rights to which a conduct criminalised under the Convention may also give rise.

21. Paragraph 2 provides for the establishment of a specific follow-up mechanism (Articles 23 – 25) in order to ensure an effective implementation of the Convention.

Article 2 – Principle of non-discrimination

22. 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 of the European Convention on Human Rights (ECHR).

23. 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".

24. The list of non-discrimination grounds in Article 2 is based on that in Article 14 ECHR and the list contained in Article 1 of Protocol No. 12 to the ECHR. However, the negotiators wished to include also the non-discrimination grounds of age, 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, and should not give rise to unwarranted a contrario interpretations as regards discrimination based on grounds not so included. 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.

25. 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 being discriminated against in the enjoyment of measures – as provided for in Chapter VI of the Convention – to protect their rights.

Article 3 – Scope

26. The scope of the Convention is expressly limited to medicines for human and veterinary use as well as medical devices, their active substances, excipients, 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, active substances, excipients, parts, materials and accessories under intellectual property law. Hence generic medical products are also included under the scope of the Convention.

27. After some discussion due to the particular regulatory approach 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 or placed on the market without being in compliance with the conformity requirements required by the domestic law of the Parties. Consequently, the parts, materials and accessories designated for use in the manufacturing of, or together with, medical devices have been included.

28. 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

29. The article contains several definitions which are used throughout the Convention: "Medical product", "medicinal product", "active substance", "excipient", "medical device", "accessory" "parts" and "materials", "document", "manufacturing", "counterfeit" and "victim".

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

31. 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 affect public health through the food chain, and indirectly in cases where diseases are transmitted from animals to humans as a consequence of inefficient veterinary medicines.

32. For the purposes of the Convention, 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.

33. 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, Directive 2001/83/EC, as amended, on the Community code relating to medicinal products for human use, and Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

34. A “medical device” is defined in letter e. The definition covers a whole range of devices, from relatively simple objects such as spatulas, devices for oral or parenteral administration to technically complicated devices such as incubators or heart-lung machines, as well as in vitro diagnostic medical devices. The definition used in the Convention is inspired by the legal acts of the European Union on medical devices, in particular Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member states relating to active implantable medical devices and Council Directive 98/79/EC on *in vitro* diagnostic medical devices, and the legal acts amending them.

35. A “medicinal product” is composed of “active substances and excipients”, which terms are defined in letters c and d. Likewise; a “medical device” is made of “parts” and “materials”, which are defined in letter g. Medical devices, may be used with “accessories”, which term is defined in letter f.

36. Since the counterfeiting of medical products is often done through falsifying or interfering with the documentation accompanying a medical product, the *ad hoc* committee found it useful to also introduce a new, all-encompassing definition of “document” (cf. letter h). This definition is intended to cover all kinds of documents such as certificates of analysis, certificates of authorisation, licenses, invoices, shipping and freight documents as well as the packaging and labelling of the final medical product. While finished medical products encompass the packaging and labelling, the *ad hoc* committee also wanted to cover the supply of the falsified packaging and labelling separate to the product.

37. Letter i., 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 co-operation under the World Health Organisation (WHO).

38. Though the terms “counterfeit” and “counterfeiting” are also used in a more narrow sense in the field of protection of intellectual property rights, the *ad hoc* committee decided to use these terms for the purposes of this Convention in the sense in which they are widely understood and used, i. e. corresponding to “false” and “manufacturing a false product and passing it off as genuine”.

39. The term “counterfeit” is therefore defined in letter j as a “false representation as regards identity and/or source”.

40. 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. The *ad hoc* committee decided to consider an adulterated medical product (i.e. a medical product – usually a powder or a liquid – made poorer in quality by intentionally adding or substituting another undeclared substance) simply as a counterfeit and hence not introduce “adulterated medical product” as a specific defined term, different from “counterfeit medical product”. Finally, the term “source” should be understood in a wide sense, thus including also the supply and

distribution history of the medical product, active substance, excipient, part, material or accessory in question.

41. The *ad hoc* committee suggested to focus the provisions on victims in the Convention on natural persons suffering adverse physical or psychological effects as a result of having used a counterfeit medical product, or a medical product which has been subject to a criminalised conduct as set out in Article 8. Hence, for the purposes of this Convention, physical or legal persons incurring purely financial losses resulting from the conducts criminalised under the Convention are not covered under the definition of "victim" in letter k. Since in some cases the consequences of having used counterfeit or otherwise unsafe medical products may only manifest themselves in the long term, it should be underlined that a person cannot be excluded from enjoying the rights of victims accorded under this Convention merely because he or she has not yet suffered any adverse effects, but is nevertheless likely to do so at a later stage.

Chapter II – Substantive criminal law

42. Chapter II contains the substantive criminal law provisions of the Convention. The offences described therein are considered to be so inherently dangerous to public health that Articles 5 to 8 will be applicable also in cases where only a potential threat to public health has been detected, and no actual physical or psychological damages to victims have materialised. In practice, this means that the competent authorities of a Party will not have to prove that a certain conduct on the part of the perpetrator has led to actual damages to public or individual health, as long as the conduct in question falls under one or more of the categories of offences set out in Articles 5 to 8.

43. The offences described in Articles 5 to 8 are only punishable when committed intentionally. The interpretation of the word "intentional" is left to domestic law.

Article 5 – Manufacturing of counterfeits

44. This article obliges Parties to establish as offences the intentional manufacturing of counterfeit medical products, their active substances, excipients, parts, materials and accessories. As regards medicinal products, and as appropriate medical devices, active substances and excipients, this shall also apply to the adulteration thereof. As mentioned under Article 4, "adulteration" has not been specifically defined in this Convention, but the concept of adulteration is to be understood as making a product poorer in quality by injuriously adding or substituting another undeclared substance. As some medical devices either are themselves liquids or powders that can be adulterated, or are integral to the administration of medicinal products that can be adulterated, paragraph 2 also applies to medical devices.

45. Paragraph 3 allows for the Parties to declare reservations with regard to the application of paragraphs 1 in so far as excipients, parts and materials are concerned, and paragraph 2 as regards excipients.

46. The *ad hoc* committee considered this possibility to declare reservations necessary in the light of the different concepts of member states of the Council of Europe with regard to the need for regulating the manufacture of excipients, parts and materials.

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

47. Article 6, paragraph 1, obliges Parties to establish as offences the intentional supplying and trafficking in counterfeit medical products, active substances, excipients, parts, materials and accessories.

48. The terms “supplying” and “offering to supply” are not specifically defined, but understood to cover, in their widest sense, the acts of brokering, procuring, selling, donating or offering for free as well as promoting (including through advertising these products).

49. The act of “offering to supply” is a separate criminal conduct clearly distinct from an “attempt to supply”, cf. Article 9. A person may thus “offer to supply” by brokering a deal on counterfeit medical products, or by advertising counterfeit medical products e.g. through a website or by sending so called spam-mails to potential customers. Often these persons are not themselves in possession of the counterfeit medical products in question, but are nevertheless an important link in the illegal distribution chain.

50. This conduct is obviously not the same as an attempt to supply, in which case the supplier is normally in possession of the counterfeit medical products, but for some reason is not able to accomplish the criminalised conduct by actually supplying the customer with counterfeit medical products.

51. 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 (CETS No. 197) (2005) and is not intended to have a different content or scope for the purposes of this Convention. For the purpose of clarity, “keeping in stock, import and export” have been added to illustrate the concept of trafficking.

52. Paragraph 2 allows for the Parties to declare reservations with regard to the application of paragraphs 1 and 2 in so far as excipients, parts and materials are concerned. The *ad hoc* committee considered this possibility to declare reservations necessary in the light of the different concepts of member states of the Council of Europe with regard to the need for regulating the manufacture of excipients, parts and materials of medical devices.

Article 7 – Falsification of documents

53. This article obliges Parties to establish as offences the intentional falsification of documents. Falsification can either take place through the making of a false document from scratch, or through unlawfully amending or changing a document with regard to its content and/or its appearance. In both cases the aim is to deceive the person reading or looking at the document into believing that the medical product, active substance, excipient, part, material or accessory, which the document accompanies, is legitimate and not a counterfeit or the subject of a criminal conduct as described in Article 8, paragraph 1. The term “document” as defined under Article 4 is very broad and covers not only certificates and similar documents used in trade and commerce, but also the packaging and labelling of medical products as well as texts provided on internet sites which are specifically designed to accompany the product in question.

54. Paragraph 2 allows for the Parties to declare reservations with regard to the application of paragraph 1 in so far as documents related to excipients, parts and materials are concerned. The *ad hoc* committee considered this possibility to declare reservations necessary in the light of the different concepts of member states of the Council of Europe with regard to the need for regulating the manufacture of excipients, parts and materials of medical devices.

55. Finally, as regards Articles 5 to 7, it should be noted that the mere possession of counterfeit medical products, active substances, excipients, parts, materials and accessories as well as 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 as an attempt under Article 9.

56. The *ad hoc* committee, after some discussion, decided not to provide for the specific criminalisation of the possession of equipment that could be used to commit the criminal acts set out in Articles 5, 6 and 7 as an independent conduct, 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 falsification of documents. However, such equipment may of course play an important role as evidence, if that link could be established. Finally, possession of equipment could also be considered as an attempt (see under Article 9), if a criminal intention could be demonstrated.

Article 8 – Similar crimes involving threats to public health

57. The article covers certain offences that are considered by the *ad hoc* committee 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 1, are not counterfeited. In fact, these products are intentionally manufactured, kept in stock for supply, imported, exported, supplied, offered to supply, or placed on the market without authorisation (medicinal products) or without being in compliance with the conformity requirements (medical devices) as laid down in the domestic law of the Parties.

58. An example of the offences set out in paragraph 1, is the well attested existence of a sprawling black market for medicinal products for hormonal treatment produced without authorisation as means of doping for sports persons and others, who want to enhance their physical performance artificially. The abuse of such medicinal products 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 manufacture of a medical product, which is then diverted through the black market for a wholly illegal purpose and gain by criminals with a view to unauthorised supplying or offering to supply thereof. It is a fact that legitimate anabolic steroids used for medical purposes are also sold into the black market for performance enhancement of sports persons and others.

59. In addition to the offences enumerated in paragraph 1 (see above), paragraph 2 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 required by the domestic law of the Party”.

60. With this provision the *ad hoc* committee wanted to target the intentional abuse of original documents for criminal purposes related to the conducts set out in paragraph 1 of the article, e. g. to cover up the fact that a medicinal product has been manufactured without authorisation by pairing the unauthorised product with original documents intended for another – authorised – medicinal product. The commercial use of documents outside of the legal medical product supply chain without criminal intent, such as the legitimate selling and/or buying of waste paper (e.g. unused packaging) for recycling purposes is obviously not covered by the provision.

61. As in the case of Article 6 above, the terms “supplying” and “offering to supply” are not specifically defined, but understood to cover, in their widest sense, the acts of procuring, selling or offering for free as well as brokering and promoting (including through advertising these products).

62. Possession of medicinal products and/or documents with an intent to commit any of the criminal acts set out in Article 8 could be considered as an attempt under Article 9.

Article 9 – Aiding or abetting and attempt

63. 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.

64. Paragraph 1 requires Parties to establish as 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.

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

66. The interpretation of the word “attempt” is left to domestic law. The principle of proportionality, as referred to in the Preamble of the Convention, should be taken into account by Parties when distinguishing between the concept of attempt and mere preparatory acts which do not warrant criminalisation.

67. Paragraph 3 allows for the Parties to declare reservations with regard to the application of paragraph 2 (attempt) to offences established in accordance with Articles 7 (falsification of documents) and 8 (similar crimes involving threats to public health), due to differences in the criminal law systems of member states of the Council of Europe.

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

Article 10 – Jurisdiction

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

70. Paragraph 1, sub-paragraph 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.

71. Paragraph 1, sub-paragraphs 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 impediments to the latter state's exercising its jurisdiction and it is therefore useful for the Registry State to also have jurisdiction.

72. The first part of paragraph 1, sub-paragraph d, ("by one of its nationals") 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.

73. The second part of paragraph 1, sub-paragraph d, ("by a person habitually residing in its territory") applies to persons having their habitual residence in the territory of the Party. It provides that 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. However, the criterion of attachment to the state of the person concerned being less strong than the criterion of nationality, paragraph 4 allows Parties not to apply this type of jurisdiction or only to do it in specific cases or conditions.

74. Paragraph 2 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 2, 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. However, paragraph 4 allows Parties not to apply this type of jurisdiction or only to do so in specific cases or conditions.

75. Paragraph 3 concerns the principle of *aut dedere aut judicare* (extradite or prosecute). Jurisdiction established on the basis of paragraph 3 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 3 does not prevent

Parties from establishing jurisdiction only if the offence is punishable in the territory where it was committed, or if the offence is committed outside the territorial jurisdiction of any state.

76. Paragraph 4 allows for the Parties to declare reservations with regard to the application of paragraph 1, sub-paragraph d, and paragraph 2, of this article.

77. 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 5, 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.

78. The bases of jurisdiction set out in paragraph 1 are not exclusive. Paragraph 6 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 11 – Corporate liability

79. Article 11 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 11 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.

80. 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.

81. 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.

82. 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 12 paragraph 2 are met, namely that the sanction or measure be "effective, proportionate and dissuasive" and include monetary sanctions.

83. 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 12 – Sanctions and measures

84. This article is closely linked to Articles 5 to 8, which define the various offences that should be made punishable under domestic law. In accordance with the obligations imposed by those articles, Article 12 requires Parties to match their action to the seriousness of the offences and lay down sanctions which are "effective, proportionate and dissuasive". In the case of an individual committing an offence established under Articles 5 and 6, 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 (CETS 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. Offences under Article 8 (manufacture and supply without authorisation or without the product being in compliance with regulatory requirements) cover a wide range of behaviour from more formal violations of national administrative requirements to organised acts seriously affecting the health of individuals. While the seriousness is comparable to the behaviour criminalised by Articles 5, 6 and 7, minor violations of regulatory legal requirements (which may be of quite different nature and structure in Parties) may not always necessitate criminal sanctions in the technical sense. Fines of a non-criminal (i.e. regulatory or administrative) nature may therefore be considered sufficient in view of the overall context and structure of domestic law and penal sanctions.

85. Legal entities whose liability is to be established under Article 11 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.

86. 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 apply none of these measures or envisage other measures.

87. 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 (CETS 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 (CETS 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.

88. Paragraph 3 a, provides for the seizure and confiscation of 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 the Convention or to facilitate their commission. Moreover, proceeds of the offences, or property whose value corresponds to such proceeds may be seized or confiscated.

89. The Convention does not contain definitions of the terms “confiscation”, “instrumentalities”, “proceeds” and “property”. However, Article 1 of the Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime 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.

90. Paragraph 3 b, allows for the destruction of medical products, active substances, excipients, parts, materials and accessories that are the subject of an offence established under the Convention.

91. Paragraph 3 c, addresses in a general wording the various administrative measures that Parties may undertake in order to prevent future offences, including re-offending. The permanent or temporary ban on a perpetrator to carry on a commercial or professional activity in connection with which the offence was committed, or the withdrawal of professional licenses from perpetrators are examples of what such measures could include.

Article 13 – Aggravating circumstances

92. 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. 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.

93. 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 address those aggravating circumstances and permits Parties to retain their fundamental legal concepts.

94. 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.

95. 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 is in the first line obviously health professionals, but the application of the aggravating circumstance is not restricted to health professionals.

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

97. 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 *ad hoc* committee found that the use of information systems, including the Internet, for supplying counterfeit medicinal products 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 outreach provided by 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 get at the criminals behind various Internet sites, offering cheap (i.e. mostly counterfeit) medicines or other medical products.

98. 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 Organised 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".

99. 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.

Article 14 – Previous convictions

100. 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.

101. 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.

102. The principle of international recidivism is established in a number of international legal instruments. Under Article 36 paragraph 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.

103. 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, 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.

104. Therefore Article 14 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.

105. 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 (CETS 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. 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.

Chapter III – Investigations, prosecution and procedural law

Article 15 – Initiation and continuation of proceedings

106. Article 15 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 16 – Criminal investigations

107. 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.

108. 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 "principles of national law" should be understood as also encompassing basic human rights, including those provided under Article 6 of the ECHR.

109. "Effective investigation" is further described as including financial investigations, covert operations, controlled delivery and other special investigative techniques. These could encompass 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, but if a Party chooses to conduct investigations

using these special techniques, the principle of proportionality, as referred to in the Preamble of the Convention, will also apply.

110. The *ad hoc* committee underlined 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 and the Second Additional Protocol to the European Convention on Mutual Legal Assistance in Criminal Matters (CETS No. 182).

Chapter IV – Co-operation of authorities and information exchange

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

111. Networking at national level based on a multidisciplinary and multisectoral approach is a key element in the fight against counterfeiting of medical products and similar crimes. Hence, Article 17 provides for the co-operation and information exchange between the competent authorities in order to prevent and combat effectively the counterfeiting of medical products and similar crimes involving threats to public health. In this context, it should be noted that the involvement of health authorities in the prevention and combat of counterfeiting of medical products and similar crimes is a key tool for the efficient protection of public health. In addition, paragraph 2 provides for the facilitation of assistance to be provided by the relevant commercial and industrial sectors to the competent authorities as regards risk management, as these sectors have vast product expertise.

112. 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. In particular, the Council of Europe model on a network of Single Points of Contact (SPOC) developed by the Committee of Experts on Minimising Public Health Risks posed by Counterfeit Medical Products and Related Crimes (CD-P-PH/CMED) of the Council of Europe served as inspiration for the drafters of the Convention. This Council of Europe SPOC model is already in operation within the EU medicines enforcement sector and has been tabled as a working contact model for the International Medical Product Anti-Counterfeiting Task Force (IMPACT) under the World Health Organization (WHO), by the Permanent Forum on International Pharmaceutical Crime and the International Criminal Police Organization - INTERPOL. However, Article 17 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.

Chapter V – Measures for prevention

Article 18 – Preventive measures

113. Paragraphs 1 and 2 of this article provide for two key preventive measures in combating counterfeiting of medical products and similar crimes, namely the introduction, at national level, of quality and safety requirements of medical products on the one hand, and measures ensuring the safe distribution of such products on the other. The *ad hoc*

committee considered that it should be left to the domestic law of each Party to define the appropriate quality and safety requirements as well as the measures ensuring safe distribution. As one example of the latter type of measures, which a Party may consider to adopt, the introduction of adequate track and trace systems on medical products could be mentioned. Such track and trace systems can have different features, but are essentially ensuring the traceability of a given medical product to its source.

114. 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.

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

Chapter VI – Measures for protection

116. The protection of, and assistance to, victims of crime has long been a priority in the work of the Council of Europe.

117. The horizontal legal instrument in this field is the European Convention on the Compensation of Victims of Violent Crime (CETS No. 116) from 1983, which has since been supplemented by a series of recommendations, notably Recommendation No. R (85) 11 on the position of the victim in the framework of criminal law and procedure, Recommendation No. R (87) 21 on the assistance to victims and the prevention of victimisation and Recommendation Rec(2006)8 on assistance to crime victims.

118. Furthermore, the situation of victims has also been addressed in a number of specialised conventions, including the Council of Europe Convention on the Prevention of Terrorism (CETS No. 196), the Council of Europe Convention on Action against Trafficking in Human Beings (CETS No. 197), both from 2005, and the Council of Europe Convention on the Protection of Children against Sexual Exploitation and Sexual Abuse (CETS No. 201) from 2007.

119. Taking into account the potential grave consequences for victims of counterfeiting of medical products and similar crimes, the *ad hoc* committee found that it was justified to provide specifically for the protection of such victims, and also to ensure that victims of the crimes established under this Convention are being kept informed about relevant developments in their cases by the competent national authorities and that – subject to the domestic law of the Parties – they are being given the possibility to be heard and to supply evidence.

120. It is recalled that, the term “victim” as defined in Article 4, letter k, of the Convention is limited to natural persons suffering adverse physical or psychological effects as a result of one or more of the conducts criminalised by the Convention. Legal persons are not intended

to be covered by the provisions on victims in Chapter VI, nor are persons suffering only financial losses in connection with a conduct criminalised under the Convention.

Article 19 – Protection of victims

121. Article 19 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.

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

122. 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.

123. 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. As indicated by the wording “the general progress of the investigation or proceedings”, Parties are not always obliged to provide victims with detailed information about aspects of the investigation or the proceedings, as in some situations the proper handling of the case may be adversely affected by the disclosure of information.

124. The article goes on to list a number of procedural rules designed to implement the general principles set out in Article 20: the possibility, for victims, of being heard, of supplying evidence (subject to this being permitted under the domestic law of a Party), 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.

125. 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.

126. 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.

127. In addition to Article 20 paragraph 3, dealing with the status of victims as parties to criminal proceedings, the States Parties must take account of Article 6 of the ECHR. Even though Article 6, paragraph 3.c. of the 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 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.

128. Paragraph 4 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 (CETS No. 201) of 25 October 2007.

129. Paragraph 5 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 Parties 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 21 – International co-operation in criminal matters

130. The article sets out the general principles that should govern international co-operation in criminal matters.

131. 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. In this context, particular reference should be made to the European Convention on Extradition (CETS No. 24), the European Convention on Mutual Assistance in Criminal Matters (CETS No. 30), the European Convention on the Transfer of Sentenced Persons (CETS No. 112), the Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime (CETS No. 141) and the Council of Europe Convention Laundering, Search, Seizure and Confiscation of the proceeds from Crime and on the Financing of Terrorism (CETS No.198).

132. In the same way as for paragraph 1, paragraph 2 obliges Parties to co-operate, to the widest extent possible and on the basis of relevant international, regional and bilateral legal instruments, on extradition and mutual legal assistance in criminal matters concerning the offences established by the Convention.

133. 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 sign the Convention (cf. Article 28). The requested Party will act on such a request in accordance with the relevant provisions of its domestic law which may provide for conditions or grounds for refusal. Any action taken shall be in full compliance with its obligations under international law, including obligations under international human rights instruments.

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

134. As indicated by the title, Article 22 covers only administrative measures and is not concerned with international co-operation in criminal matters (see Article 21. above). This provision obliges Parties to co operate on protecting and providing assistance to victims, cf. paragraph 1 of the article.

135. According to paragraph 2, the Parties shall designate a national contact point for receiving requests for information and/or co-operation outside the scope of international co-operation in criminal matters. The national contact point shall be established without prejudice to the internal reporting systems of the Parties. The *ad hoc* committee considered that it should be left to a Party to decide on how it would organise its national point of contact and the mechanism of information transmission with the relevant internal sectors in the fight against counterfeiting of medical products and similar crimes.

136. Paragraph 3 of the article obliges Parties to endeavour to include, where appropriate, 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 – Follow-up mechanism

137. 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.

Article 23 – Committee of the Parties

138. Article 23 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.

139. 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.

140. 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 follow-up 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 Parties to ensure its credibility.

141. 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.

142. 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 implementation of the Convention by the Parties, including the European Union, is effectively monitored.

143. The Committee of Ministers shall decide on the way in which those Parties which are not member states of the Council of Europe are to contribute to the financing of these activities. The Committee of Ministers shall seek the opinion of those Parties which are not member states of the Council of Europe before deciding on the budgetary appropriations to be allocated to the Committee of the Parties.

Article 24 – Other representatives

144. Article 24 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 multisectoral and multidisciplinary approach. It refers, firstly, to the Parliamentary Assembly and the European Committee on Crime Problems (CDPC), and, secondly, more unspecified, to other relevant intergovernmental or scientific committees of the Council of

Europe which, by virtue of their responsibilities would definitely make a worthwhile contribution by taking part in the monitoring of the work on the Convention. These committees are the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), and the Commission of the European Pharmacopoeia and its Advisory Group of the General Network of Official Medicines Control Laboratories (GeON). In this context, it should be noted that the CD-P-PH is specifically mandated to co-operate with the CDPC to minimise public health risks posed by counterfeit medicines and other forms of pharmaceutical crimes.

145. The importance afforded to involving representatives of relevant international bodies and of relevant official bodies of the Parties, as well as 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 wording "relevant international bodies" in paragraph 3, is to be understood as inter-governmental bodies active in the field covered by the Convention. The wording "relevant official bodies" in paragraph 4, refers to officially recognised national or international bodies of experts working in an advisory capacity for Parties to the Convention in the field covered by the Convention, in particular as regards medicinal products and medical devices.

146. The possibility of admitting representatives of inter-governmental, governmental and non-governmental organisations and other bodies actively involved in preventing and combating counterfeiting of medical products and similar crimes as observers was considered to be an important issue, if the monitoring of the application of the Convention was to be truly effective.

147. Paragraph 6 prescribes that when appointing representatives as observers under paragraphs 2 to 5 (Council of Europe bodies, international bodies, official bodies of the Parties and representatives of non-governmental organisations), a balanced representation of the different sectors and disciplines involved (the law enforcement authorities, the judiciary, the pharmaceuticals and medical devices authorities, as well as civil society interest groups) shall be ensured.

Article 25 – Functions of the Committee of the Parties

148. 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 Parties to improve their policies in this field using a multisectoral and multidisciplinary approach.

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

– 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;

– 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;

– 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. In this context, the Committee of the Parties may avail itself of the expertise of relevant Council of Europe committees and other bodies. In addition to the committees mentioned above under the commentary to Article 24, paragraph 1, the Committee of Experts on Minimizing Public Health Risks posed by Counterfeit Medical Products and Related Crimes (CD-P-PH/CMED), which is, inter alia, tasked with the development and promotion of multisectoral risk prevention and management strategies for public health protection from counterfeit medical products and related crimes, and the General European Network of Official Medicines Control Laboratories (OMCL) could be mentioned as examples of such expert committees and bodies of the Council of Europe.

150. Paragraph 4 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 25.

Chapter IX – Relationship with other international instruments

Article 26 – Relationship with other international instruments

151. Article 26 deals with the relationship between the Convention and other international instruments.

152. In accordance with the 1969 Vienna Convention on the Law of Treaties, Article 26 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 26, 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.

153. Article 26, 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.

154. 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 27 – Amendments

155. 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 non-member states having participated in the elaboration of the Convention, to states enjoying observer status with the Council of Europe, to the European Union and to any state invited to sign the Convention.

156. The CDPC and other relevant Council of Europe intergovernmental or scientific committees will prepare opinions on the proposed amendment, which will be submitted to the Committee of the Parties. 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

157. With some exceptions, Articles 28 to 33 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 28 – Signature and entry into force

158. The Convention is open for signature by Council of Europe member states, the European Union, and states not members of the Council of Europe which took part in drawing it up (Israel and Japan) and states enjoying observer status with the Council of Europe. In addition, with a view to encouraging the participation of the largest possible non-member States to the Convention, this article provides them with the possibility, subject to an invitation by the Committee of Ministers, to sign and ratify the Convention even before its entry into force. By doing so, this Convention departs from previous Council of Europe treaty practice according to which non-member States which have not participated in the elaboration of a Council of Europe Convention usually accede to it after its entry into force.

159. Article 28 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 Parties is needed to successfully set about addressing the major challenge of combating counterfeiting of medical products and similar crimes. Of the five Parties which will make the Convention enter into force, at least three must be Council of Europe members.

Article 29 – Territorial application

160. This provision is only concerned with territories having a special status, such as overseas territories, the Faroe Islands or Greenland in the case of Denmark, or Gibraltar, the Isle of Man, Jersey or Guernsey in the case of the United Kingdom.

161. It is well understood, however, that it would be contrary to the object and purpose of this Convention for any contracting Party to exclude parts of its main territory from the Convention's scope and that it was unnecessary to make this point explicit in the Convention.

Article 30 – Reservations

162. Article 30 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 31 – Friendly settlement

163. Article 31 provides that the Committee of the Parties, in close co-operation with the European Committee on Crime Problems (CDPC) and other relevant Council of Europe intergovernmental or scientific committees, shall follow the application of the Convention and facilitate the solution of all disputes related thereto between the Parties. Coordination with the CDPC will normally be ensured through the participation of a representative of the CDPC in the Committee of the Parties.

Article 32 – Denunciation

164. Article 32 allows any Party to denounce the Convention.

Article 33 – Notification

165. Article 33 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 Union).