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AD HOC COMMITTEE ON COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH
(PC-ISP)

KEY ISSUES RELATED TO THE DRAFT CONVENTION OF THE COUNCIL OF EUROPE ON COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH

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

Background:

1. At its meeting on 19 and 20 February 2009, the Bureau of the European Committee on Crime Problems (CDPC) instructed the Secretariat to provide the Ad Hoc Committee on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (PC-ISP) with a paper highlighting the key issues related to the draft Convention on counterfeiting of medical products and similar crimes involving threats to public health prepared by the Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP), with a view to facilitating negotiations.

2. The Secretariat has thus produced the present document focusing on four issues deemed to be of major importance, namely: the use of the term **"counterfeiting"**, the scope of **"similar crimes"**, the inclusion of **medical devices** under the scope of the draft Convention, and finally the issue of **jurisdiction** with regard to offences established under the draft Convention.

Use of the term "counterfeiting"

3. The term "counterfeiting" is usually applied to describe the unlawful forgery, copying, or imitation of an item. The term can also apply to the unauthorised possession of a counterfeit item, with the intention to deceive or defraud by claiming or passing the item as genuine.

4. Given the connotations of "counterfeiting" with "copying" or "imitating", it is clear that the term could be understood as closely associated with the protection of intellectual property rights.

5. This particular understanding of "counterfeiting" with regard to medical products was already discussed in the framework of the World Health Organisation (WHO) of the United Nations, where a number of States have reservations about the use of the term.

6. The question, which was raised by some delegates in the PC-S-CP, is whether using the word "counterfeiting" in the draft Convention may turn out to be counterproductive with regard to a direct participation of a number of non-European States in the essential co-operation on prevention and repression of counterfeiting of medical products and similar crimes involving threats to public health, which will be provided under the future Convention.

7. Hence, the possibility of substituting "counterfeiting" with "falsifying" has been raised in the PC-S-CP, as the latter, slightly broader, term essentially covers the same criminal conducts as "counterfeiting", but does not seem to carry the same connotations with regard to protection of intellectual property rights. In this context it should be noted that in a recent legislative text of the European Union[1] the phrase "medicinal products which are falsified in relation to their identity, history or source" is used when referring to a category of counterfeit medical products also covered by the draft Convention.

8. When considering the options as regards the use of the term "counterfeiting", the PC-ISP should take into account that the draft Convention expressly does not intend to cover the protection of intellectual property rights, but should be applied without prejudice to the protection of such rights, including through criminal prosecution.

[1] See "Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source" (COM(2008) 668 final) of 10.12.2008

Scope of "similar crimes"

9. According to the specific terms of reference of both the PC-S-CP and the PC-ISP, "tampering with and adulteration of medical products" are given as examples of "similar crimes".

10. During the preparation of the draft Convention, the PC-S-CP had extensive discussions on the specific meaning and scope of both the terms "counterfeiting" and "similar crimes". In the end, the PC-S-CP decided to consider the criminal acts of "tampering with and adulteration of medical products" as sub-categories of "counterfeiting", since any "tampering with" and/or "adulteration of" a medical product would by definition make the product "counterfeit", i.e. having a false representation of its identity and/or source (cf. Article 4, b, of the draft Convention). Therefore, in the view of the PC-S-CP, "tampering with" and/or "adulteration of" a medical product are crimes that are de-facto identical to "counterfeiting" of a medical product and should hence not be considered as "similar crimes".

11. The PC-S-CP also deemed it useful to introduce the term "related crimes" in connection with the criminalisation of counterfeiting of medical products. This term is intended to cover acts that are accessory to counterfeiting, i.e. supplying, promoting or trafficking of counterfeit medical products (cf. Article 5, 1, of the draft Convention).

12. However, the PC-S-CP found that the term "similar crimes" could well be understood to cover another type of pharmaceutical crime which is distinct from counterfeiting, but similar in terms of the threat posed to public health, namely the unauthorised manufacturing or supplying of non-counterfeit medical products, ingredients and components.

13. According to the PC-S-CP, the acts of manufacturing and supplying of medical products, ingredients and components without authorisation and/or in breach of the standards for quality, safety and efficacy as required by the internal law of a Party to the future Convention, involve by definition threats to public health and should hence be subject to regulation under the draft Convention.

The inclusion of medical devices

14. During the preparation of the draft Convention, the PC-S-CP discussed whether to include or exclude medical devices from the scope of the Convention.

15. The PC-S-CP was fully aware of the fact that the manufacturing and supplying of medical devices is generally not regulated in the same way as for medicinal products. However, the Group of experts decided that – due to their omnipresence – leaving out medical devices from the scope of the draft Convention would effectively undermine the very purpose of the Convention, i.e. to protect public health. For the same reason, the PC-S-CP was of the opinion that the future Convention should not provide for the possibility to make reservations in respect of the application of various provisions related to medical devices.

16. The draft Convention therefore criminalises the counterfeiting of medical devices in the same way as for medicinal products. It also foresees that Parties to the future Convention should introduce criminal or administrative sanctions for the manufacturing and supplying of medical devices without authorisation and/or in breach of the standards for quality, safety and efficacy as required by their internal law.

17. It should be noted that neither does the draft Convention oblige Parties to introduce such standards, nor can criminal or administrative sanctions be imposed by a Party with reference to

the draft Convention, where there are no requirements for authorisation for manufacturers/suppliers of medical devices or standards for quality, safety and efficacy for medical devices in place under the internal law of that Party.

Jurisdiction

18. The issue of jurisdiction is regulated in Article 8 of the draft Convention.

19. Taking into account the global character of, in particular, counterfeiting of medical products, the PC-S-CP opted for a rather extensive concept of jurisdiction, while at the same time introducing the possibility for Parties to the future Convention to limit the application of certain parts of Article 8.

20. Paragraph 1, a – c, of Article 8 introduces jurisdiction based on the territoriality principle.

21. Paragraph 1, d and e, of Article 8 is based on the nationality principle.

22. Paragraph 2, of Article 8 does away with the requirement of "double criminality" as regards the manufacturing and supplying of counterfeit medical products and the falsification of documents accompanying a counterfeit medical product, where the offence caused the death of, or damage to the physical and mental health of, the victim, the offence was committed in the framework of a criminal organisation, or the perpetrator has previously been convicted of offences of the same nature.

23. Paragraph 2 also applies to the unauthorised manufacturing and supplying of non-counterfeit medical products on the same conditions as for the counterfeit medical products.

24. Paragraph 3, of Article 8 is based on a variant of the nationality principle, namely that the victim is a national of , or habitually residing in, the territory of the Parties.

25. Paragraph 4, of Article 8 obliges a Party to the future Convention to establish jurisdiction in cases where the alleged offender is present in its territory and cannot be extradited to another Party because of his/her nationality.

26. Paragraph 5, of Article 8 provides for the possibility for a Party to make reservations as regards the establishment of jurisdiction under paragraph 1, d and e, and paragraphs 2 – 4 of the draft Convention.