Parliamentary Assembly
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COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

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

Parliamentary Assembly

1. The Parliamentary Assembly welcomes the draft Council of Europe convention on counterfeiting of medical products and similar crimes involving threats to public health[2] as the first binding international legal instrument to criminalise the counterfeiting of medical products and similar dangerous conduct and provide a framework for international co-operation on prevention and victim protection.

2. The Assembly has been actively involved in this matter from the outset and considers this draft convention to be the result of successful co-operation and synergies between the different bodies of the Council of Europe; a success based on positive interaction and constructive dialogue in which all parties involved were united by a common vision: to curtail the threat to patients from counterfeit medical products.

3. The counterfeiting of medical products as set out in the draft convention should not be confused with the issues of intellectual property rights or patent rights. Counterfeiting is a genuine public health and safety issue, which is part of a large and under-reported problem.

4. The Assembly takes the view that all strategies developed to combat counterfeit medical products should be in line with the principles of patient-centred health care, considering the impact of those strategies on the patient in terms of access to safe, high-quality and appropriate treatments and information.

5. The Assembly is increasingly concerned about the serious threat posed by counterfeiting to the life and health of vulnerable persons and patients in Europe and worldwide. It notes that the recent development of cross-border care and the introduction of online pharmaceutical sales and direct e-mail sales have amplified, which has brought increased attention to this problem at the European level.

6. Public trust in medical therapies and health-care systems needs to be protected as a way to ensure the right to life, as enshrined in Article 2 of the European Convention on Human Rights (ETS No. 5), and the right to health protection as also guaranteed by Article 11 of the European Social Charter (ETS No. 35). It is a recognised principle in the case law of the European Court of Human Rights that, both at European level and under national constitutions, any legislative or regulatory provision that fails to protect lives, or is liable to threaten life, can be condemned or censured as conflicting with the right to life. The public authorities are therefore required to put in place legislation ensuring that the right to life is protected against potential threats, in the spirit of the draft convention.

7. For this reason the Assembly points out that the draft convention, when defining the term "victim", should make explicit reference to any natural person suffering, or liable to suffer, adverse physical or psychological effects as a result of having used a counterfeit medical product. The mere fact that a person is likely to suffer any adverse effects on his or her health should qualify him or her as a "victim".

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1. *Text adopted by the Standing Committee,* acting on behalf of the Assembly, on 12 March 2010 (see Doc. 12160, report of the Social, Health and Family Affairs Committee, rapporteur: Mr Marquet).
2. Doc. 12130.

8. The Assembly also calls on member states to conduct awareness-raising programmes on the alarming and adverse physical or psychological effects of counterfeit medical products, how to avoid them and how to report any related suspicions to the competent authorities. The risks run by the most vulnerable population groups, such as children and the elderly, should be adequately taken into consideration. However, a delicate balance has to be carefully reached in conveying a clear message that protects patients without causing undue distress.

9. In addition, the Assembly strongly encourages member states to provide the necessary means for the training of government officials to promote risk-management and risk-prevention strategies and to encourage effective co-operation on a European and potentially global level in the various fields concerned, as provided for in Article 18 of the draft convention.

10. Given the seriousness of the problems posed by the counterfeiting of medical products and similar crimes, the Assembly calls on the Committee of Ministers to ensure a speedy adoption of the draft convention and calls on the member states to sign and ratify the adopted convention without unnecessary delay.

11. The Assembly stresses that the effective implementation of the draft convention will require committed and systematic interaction between states parties, through the monitoring mechanism provided for in Articles 23, 24 and 25, which would allow states parties to regularly consult each other regarding practical difficulties and to propose solutions.

12. The Assembly wishes to highlight that the draft convention will also be open to the participation of non-member states of the Council of Europe, in particular the observer states of the European Pharmacopoeia Commission; it would like provision to be made for a procedure making their accession to the convention as simple as possible and guaranteeing that the structures necessary for the convention's implementation exist in the countries concerned. In this regard, the Assembly invites the Committee of Ministers to consider the possibility of non-member states participating also in the funding of the monitoring mechanisms of the draft convention and to give careful consideration to the implications for developing countries.

13. Furthermore, the Assembly would welcome any useful development at the global level and calls on member states participating in the elaboration of a new international legal instrument to combat counterfeit medicines to work towards ensuring that the common goal of eradicating the counterfeiting of medical products is not lost due to a "proliferation of treaties" in the field. Any new convention on this subject should be complementary to the existing one, in a spirit of synergy, consistency and solidarity.

14. As already stressed in the past, the Assembly reiterates the invitation to the Committee of Ministers to solicit the Assembly's opinion at an earlier stage of the procedure leading to the adoption of draft conventions in order to allow for mutual respect and authentic co-operation between the two bodies.

15. Finally, the Assembly advocates two additions to the text of the draft convention and recommends that the Committee of Ministers amend it as follows:

15.1. in the fifth paragraph of the preamble, replace the words "Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms (1950, ETS No. 5)" with the words "Bearing in mind the Universal Declaration of Human Rights, proclaimed by the United Nations General Assembly on 10 December 1948, the Convention for the Protection of Human Rights and Fundamental Freedoms (1950, ETS No. 5), the European Social Charter (1961, ETS No. 35)";

15.2. in the heading of Article 1, after the word "purpose" add the words "and object";

15.3. in Article 2 after the word "language", add the word "age";

15.4. in Article 4.*k*, after the words "any natural person suffering", add the following ", or liable to suffer";

15.5. in Article 13.*d*, after the words "large-scale distribution", add the words "notably information systems, including the Internet".