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

Report

Social, Health and Family Affairs Committee

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Summary

The draft convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health is the first binding international legal instrument to criminalise the counterfeiting of medical products and similar dangerous conducts and provide a framework for international co-operation on prevention and victim protection. The amendments recommended by the Social, Health and Family Affairs Committee are intended to strengthen the protection of patients of all ages who make use of counterfeit medical products. The committee also stresses that co-ordination between national and international bodies is critical to ensure effective enforcement of the legislation on counterfeit medicines. It is therefore of utmost importance that European and international organisations involved in this matter first and foremost join forces and make use of synergies.



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A. Draft opinion

1. The Parliamentary Assembly welcomes the draft Council of Europe convention on counterfeiting of medical products and similar crimes involving threats to public health as the first binding international legal instrument to criminalise the counterfeiting of medical products and similar dangerous conducts 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. The Assembly notes that the recent development of cross-border care and the introduction of online pharmaceutical sales and direct e-mail sales have amplified and raised attention to this problem at the European level.
6. Public trust in medical therapies and health-care systems need to be protected as a way to ensure the right to life, as enshrined in Article 2 of the European Convention on Human Rights, and the right to health protection as also guaranteed by Article 11 of the European Social Charter. 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”.
8. The Assembly also calls on member states to engage in awareness-raising initiatives 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 scale 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 in relation to 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. 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 possible 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 its 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 Article 2 after the word “language”, add the word “age”.

15.2. In Article 4.k., after the words “any natural person suffering”, add the following “, or liable to suffer”.

B. Explanatory memorandum by Mr Marquet, rapporteur

1. Background and political environment

1. At their 1075th meeting on 20 January 2010, the Ministers' Deputies asked for the Parliamentary Assembly's opinion on the draft convention of the Council of Europe on counterfeiting of medical products and similar crimes involving threats to public health, drawn up at the request of the Committee of Ministers by the Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP).
2. On 25 January 2010, the Assembly referred the request of the Committee of Ministers for an opinion to the Social, Health and Family Affairs Committee, which appointed me rapporteur.
3. The Assembly has been actively involved in this matter since the outset. In its [Recommendation 1673 \(2004\)](#) on counterfeiting: problems and solutions, the Assembly called for reinforced policies to combat counterfeiting, including better data collection, improved controls at customs, intensified communication with industry and the public and the harmonisation of legislation at European level.
4. In [Recommendation 1794 \(2007\)](#) on the quality of medicines in Europe, for which I was rapporteur, the Assembly stressed the urgent need for states to take measures to protect the safety of patients in response to the increasing spread of counterfeit medicines. The Assembly recommended that the Committee of Ministers ask Council of Europe member states, non-member states and the contracting parties to the Convention on the Elaboration of a European Pharmacopoeia to make provision for an international legal instrument, in the form of a convention, designed to introduce new legislation including a new offence relating to pharmaceutical crime, to establish specific penalties for counterfeiting and impairing the quality of medicines and lay down rules governing jurisdiction allowing the interests of victims of pharmaceutical crime to be taken into account.
5. The Declaration of the International Conference "Europe against counterfeit medicines" organised in Moscow on 23 and 24 October 2006, under the Russian Federation Chairmanship of the Committee of Ministers, and the conclusions of the high-level Conference of Ministries of Justice and the Interior on "Improving European Co-operation in the Criminal Justice Field", held in Moscow on 9 and 10 November 2006, paved the way for the development of a draft convention and provided for the favourable political environment to foster its implementation.
6. As a representative of the Assembly, I had the honour of contributing to the work of the Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP), composed of 11 specialists, representatives of a number of member states and of the European Commission as observers, which was responsible for preparing a preliminary draft convention. I am pleased to report to my fellow Assembly members that the final text of the draft convention includes many of the issues and concerns that were raised during the preparatory meetings.
7. I also wish to congratulate the Ad hoc Committee on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (PC-ISP) and the European Committee on Crime Problems (CDPC). All member states and observers of the Council of Europe that took part in this effort showed commitment and determination in sharing the same objectives and in finding a compromise. Furthermore, I take this opportunity to praise the work of the European Directorate for the Quality of Medicines and HealthCare (EDQM) and the European Pharmacopoeia Commission for their tireless efforts in dealing with the safe use of medicines in society.
8. Looking forward to the successful implementation of this convention, I would like to stress a number of issues with regard to major public health objectives, communication-related aspects and international governance and co-operation mechanisms.

2. Patient safety comes first

9. As a doctor, I have always held the firm belief that patients should feel secure that the medicines they purchase are of the highest quality. Any incident of a counterfeit medicine being supplied unwittingly to a member of the public is dangerous and unacceptable. They have serious adverse health effects, especially on children, on the elderly or in pregnancy.

10. Counterfeits also negatively affect treatment outcomes of patients who are inadvertently administered counterfeit products. Medicines containing no active substance, the wrong active substance or the wrong dosage of active substance can turn life-saving medicines into life-threatening ones. Counterfeit medical products threaten patient safety by, at best causing no improvement or, worse, causing an added burden of disease and even death.

11. Counterfeits which are simply placebos could present a danger if they prevent a patient from receiving a crucial course of medication. Even if a patient is only injured, the effects can be devastating and there is often no regulatory or other recourse for the patient to obtain redress against the counterfeiter.

12. In addition to the direct risk of harm to patients, counterfeit drugs produce harm and cost for caregivers, health system resources and the health delivery system at large. They endanger public health by increasing the risk of antimicrobial resistance and they erode patient trust in health professionals and health systems.

13. I believe that the unambiguous scope of the draft convention is a major step forward in the protection of public health. The comprehensive definition of medical products in fact includes medicinal products, medical devices and accessories, active substances, excipients, parts and materials for the production of medical products.

14. As it was also stressed during the preparatory work of the draft convention and reflected in the draft explanatory report prepared by the CDPC, I take the view that Article 4.k of the draft convention, which defines 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.

15. I am therefore of the opinion that the draft convention must explicitly acknowledge that merely the fact that a person is likely to suffer any adverse effects on his or her health should qualify him or her as a “victim”.

3. Extent of the phenomenon and online pharmacies

16. Evidence suggests that the availability of counterfeit medicines and medical devices is a growing threat worldwide. Recent cases have uncovered sophisticated international networks engaged in the distribution and supply of counterfeit medicines. Many European countries, though, are not typically manufacturers of counterfeit medicine – they are often transit points, distribution hubs and/or end user markets.

17. Although the World Health Organization (WHO) began collecting data on counterfeit drugs in the early 1980s, until about 10 years ago they were regarded as a problem only in developing countries. The situation has changed quickly: by 2001, counterfeit versions of major prescription medicines were appearing all over Europe. In many of the countries of the former Soviet Union the proportion of counterfeit medicines is above 20% of market value.¹

18. The latest intelligence available on the incursion of counterfeit medicines in the European Union reveals a worrying trend: the volume of counterfeit medicines seized has increased exponentially in recent years, with more than 500 000 products discovered in 2005, twice the level found in 2004. In 2006, this figure was reported to have increased by more than five times, to 2.7 million. This explosion continued throughout 2007.²

19. Counterfeiters target the most lucrative markets, copying high-value, high-turnover and high-demand medicinal products. The recent development of cross-border care and the introduction of online pharmaceutical sales and direct e-mail sales have amplified this problem and at the same time raised attention to it at the European level. As fears over swine flu peaked in the summer of 2009, search engine queries for “Tamiflu” soared by 1 400%, according to a report from a Canadian software security firm.³ The correlation is not hugely surprising, nor is the news that counterfeit Tamiflu is thriving on this sudden Internet-based interest. With just an Internet connection and a credit card, medicines that are stringently regulated in Europe and global markets can be bought effortlessly over the Internet.⁴

1. WHO – IMPACT (International Medical Products Anti-Counterfeiting Taskforce), Counterfeit drugs kill, updated May 2008.

2. European Commission, Taxation and Customs Unions, report on community customs activities on counterfeit and piracy results at the European border, 2007.

3. Dmitry Samosseiko, Sophos Labs Canada, The partnerka – what is it, and why should you care?, Sophos Inc., Virus Bulletin Conference, September 2009.

4. According to WHO estimations 50% of medicines purchased over the Internet from sites that conceal their physical address are counterfeit. See World Health Organization (2006) WHO fact sheet, No. 275.

20. In some ways, I believe that the Internet has improved the pharmaceutical market, with increased patient access and economic efficiency, but it is also a major source of counterfeit distribution. The source of the medicines and its chain of custody remain largely mysterious to the consumer. An online pharmacy that hides its physical address is more likely to sell counterfeits instead of the legitimate branded drugs it offers. According to the WHO, medicines purchased over the Internet from illegal sites are counterfeit in over 50% of cases.⁵

21. The anonymity of the Internet is also attractive to customers for buying medicines associated with social stigmas. Counterfeit medicine in fact originally focused upon “lifestyle” medicines, including erectile dysfunction and weight loss medicines but it is now also focusing on “lifesaving medicines”, including cancer and “heart” medicines.

22. Many websites advertise and supply the medicines illegally, with inadequate consultation, no prescriptions and often no involvement of qualified health-care professionals. Traditional e-mail advertising spam has evolved into a complex web-based industry which creates new challenges for law enforcement, user education and security laboratories.

23. I believe that a precautionary approach is needed in order to take all the necessary measures to protect the safety of patients and consumers in response to the increasing spread of the phenomenon. With this regard, I was pleased to note that the use of large-scale distribution, including through information technology systems, for supplying counterfeit medical products was considered to be an aggravating circumstance in the terms of the draft convention.

24. However, I also observe that information technology systems should not be “demonised” and I support the views of the European Patients’ Forum, insofar as health strategies must consider what factors lead patients to buy medicines from unregulated sources. These may include low cost, accessibility, convenience, stigma attached to certain conditions, such as mental and sexual health conditions, as well as lack of awareness of the danger.⁶ The relative anonymity encourages people to access advice and products for which they would be reluctant to ask their health-care provider or pharmacist.

25. Poverty is also an aggravating factor that drives patients towards cheaper medical products. Policy makers need therefore to address these factors and to ensure that costs of improved safety measures are not solely born by patients and thus contribute to increasing health inequalities.⁷

26. I take the view that, in those countries where online sales of pharmaceutical products are legal, it would be desirable to move towards a quality label for all health websites, to enable citizens to discern between trustworthy websites and unlawful sites.

4. Communication, training and monitoring strategies

27. The key to the successful implementation of the draft convention lies in making the public aware of the alarming and adverse physical or psychological effects of counterfeit medical products, for that is the only way to create the sort of pressure that can compel leaders in democratic societies to act and to ensure the full implementation of its provisions.

28. However, it has to be said that counterfeit medicine is an emotive subject and it is vital to any anti-counterfeiting strategy that a balanced message is communicated to the public in order not to cause panic. It is easy to alarm patients to the extent that they stop taking medicines that in the vast majority of cases are perfectly safe, with the resulting detrimental effect upon their health.⁸

29. It is critical that the public, health-care professionals, supply chain, industry and other stakeholders are aware of the risks, extent, and availability of counterfeit medicine and devices.

5. WHO, Counterfeit medical products – Report of the 61st World Health Assembly, 7 April 2008 and of the 124th Session of the WHO Executive Board, 18 December 2008.

6. European Patients’ Forum position on the legislative proposal on counterfeit medicinal products adopted by the European Commission on 10 December 2008 (position paper of 9 May 2009).

7. European Public Health Alliance (EPHA), Position on Counterfeit Medicines (released on 9 December 2009).

8. Medicines and Healthcare products Regulatory Agency (MHRA), Anti-counterfeiting strategy 2007-2010, United Kingdom.

30. The public need sufficient and appropriate information about counterfeit medicines, how to avoid them and how to report any related suspicions to the competent authorities. Therefore, educational programmes to increase consumer awareness of counterfeit products and the risk of buying medicines from unauthorised channels should be put in place. This might include the launch of a 24-hour anti-counterfeiting hotline, as it was already foreseen in the United Kingdom anti-counterfeiting strategy for 2007-2010.

31. Sometimes the counterfeits are poor and easily detectable, but more often they are extremely good copies designed to deceive the patient; visual examination is unlikely to identify the fake and only laboratory analysis will make that determination. Clearly, health professionals, supply chains, industry, police and customs agencies and other stakeholders need a differentiated strategy, advice and training.

32. Multisectorial training can be a major contribution to the fight against counterfeit medicines as it promotes risk management and risk-prevention strategies and encourages effective co-operation on a European and potentially global scale in the various fields concerned.

33. The EDQM recently developed a specific programme for training on counterfeit medicines and is actively engaged in developing and managing an ongoing training platform through a network of single points of contacts (SPOCs). This training platform supports training for officials within the drug regulatory authorities (DRAs), police and customs authorities and aims at improving practices and co-operation across sectors and borders, promoting good practices and model approaches. It also prepared the ground for an effective implementation of relevant national and international legislation.

34. Prevention remains an essential aspect and co-operation with other European and international organisations such as WHO and the European Union remains critical. As provided for in Article 18 of the draft convention, I strongly encourage governments to provide the necessary means for the training of government officials in the field of combating counterfeiting of medical products and to request assistance via the EDQM's ongoing training platform.

35. The complex nature, causes and consequences of counterfeiting of medical products and similar crimes also require a monitoring mechanism which is truly multisectorial and multidisciplinary in approaches used and expertise available to the Committee of the Parties. In this context, I call upon the Committee of Ministers to encourage the Committee of the Parties to take into account in its functions, as provided for in Chapter VIII on the monitoring mechanism, of the views expressed by competent steering bodies such as the European Committee on Crime Problems (CDPC) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), as well as other representatives.

36. Furthermore, the Committee of the Parties should be encouraged to benefit from the support and technical expertise of all health authorities' expert committees supervised by the EDQM, in particular the European Pharmacopoeia Commission, the European Network of Official Medicines Control Laboratories (OMCL) and the Committee of Experts on Minimising the Public Health Risks Posed by Counterfeiting of Medical Products and Related Crimes (CD-P-PH/CMED) as regards situation reports, flagging up new or changing trends as regards the criminal phenomenon, training, and presenting solutions of a technical nature in life-threatening health issues. I would like to stress that the above support would be carried out in the context of established and regularly convened expert bodies which would be cost-effective and contribute to synergies and transversal co-operation within the Council of Europe.

5. International governance, partnership and co-operation

37. The fight against counterfeit medicines is a co-operative undertaking and there is an urgent need for international solidarity. No single regulator, company or indeed country can tackle the disease of counterfeit medicine alone, a holistic approach is required. As a global issue, it needs to be addressed by multiple stakeholders including legislators, regulators and enforcement agencies, health professionals, business partners and trade organisations.

38. I took note of the initiative launched by the Chirac Foundation on 12 October 2009 in Cotonou calling for states around the world to meet in Geneva in 2010 for a global conference aimed at establishing the basis of an international convention to combat counterfeit medicines.

39. I consider such a global instrument to be a useful development and at the same time I underline the fact that the draft Council of Europe convention on counterfeiting of medical products and similar crimes involving threats to public health is addressing exactly this problem.

40. Furthermore, this legal instrument will be open for participation by non-member states of the Council of Europe in 2010, whereas a global convention may be years away from entering into force.

41. The Committee of Ministers must therefore remain vigilant and willing to co-operate with other international partners, in particular WHO and the European Union. It should place its expertise at the service of a possible new global convention to ensure the highest possible degree of synergies between the different legal instruments at the European level and worldwide.

6. Conclusions

42. I am pleased to support this draft convention, which sets out the views of decision makers and human rights, public health and criminal law experts. Since the beginning, the objective has been to make sure that the Council of Europe member states equip themselves with robust systems to prevent counterfeit medicines penetrating into the European supply chain and if penetration occurs, to have appropriate legal instruments in place and safeguards to detect counterfeits early and to protect the public accordingly.

43. However, I am also aware that by itself, a legal instrument will not stop the international manufacturing and trade of counterfeit medical products. Political will is needed to enforce laws and to set up an efficient and co-ordinated system of checks and tracing mechanisms allowing identification and safe recall. Police and custom authorities should be given more tools to arrest and prosecute counterfeiters. Specific measures against illegal online sales of medicines must also be taken.

44. Finally, to ensure effective enforcement of the legislation on counterfeit medicines, co-ordination between national and international bodies is critical. It is therefore of utmost importance that European and international organisations involved in this matter first and foremost join forces and make use of synergies.

Reporting committee: Social, Health and Family Affairs Committee

Reference to committee: [Doc. 12130](#), Reference 3637 of 25 January 2010

Draft opinion unanimously adopted by the committee on 28 January 2010

Members of the committee: Mrs Liliane **Maury Pasquier** (Chair), Mrs Pernille Frahm (1st Vice-Chair), Mr Bernard **Marquet** (2nd Vice-Chair), Mr Pieter **Omtzigt** (3rd Vice-Chair), Mr Francis Agius (alternate: Mrs Marie-Louise **Coleiro Preca**), Mr Konstantinos Aivaliotis (alternate: Mrs Sophie **Giannaka**), Mr Milos **Aligrudić**, Mrs Karin **Andersen**, Mrs Magdalena Anikashvili, Mrs Sirpa **Asko-Seljavaara**, Mr Lokman **Ayva**, Mr Mario **Barbi**, Mrs Meritxell Batet Lamaña, Mr Andris Berzinš (alternate: Mrs Ingrida **Circene**), Mrs Rosa Delia **Blanco Terán**, Mr Roland Blum (alternate: Mr Laurent **Béteille**), Mrs Olena Bondarenko, Mrs Boženna Bukiewicz, Mrs Karmela **Caparin**, Mr Igor Chernyshenko, Mr Desislav Chukolov, Mr Agustín Conde **Bajén**, Mrs Viola von Cramon-Taubadel, Mr Imre **Czinege**, Mr Karl Donabauer, Mrs Daniela Filipiová, Mrs Ilija Filipović, Mr Paul **Flynn**, Mrs Doris Frommelt, Mr Marco **Gatti**, Mr Ljubo Germič, Mr Valeriu **Ghiletchi**, Mr Neven Gosović (alternate: Mr Obrad **Gojković**), Mr Luc Gouty, Mrs Claude **Greff**, Mrs Dzhema **Grozdanova**, Mr Michael **Hancock**, Mrs Olha **Herasym'yuk**, Mr Andrej **Hunko**, Mr Ali Huseynov, Mr Fazail Ibrahimli, Mr Denis **Jacquat**, Mr Birkir Jón Jónsson, Mrs Marietta Karamanli, Mr Włodzimierz Karpiński, Mr Michail **Katrinis**, Mr András Kelemen, Mr Peter Kelly (alternate: Mr Ronan **Mullen**), Baroness Knight of Collingtree (alternate: Mr Tim **Boswell**), Mr Haluk **Koç**, Mr Jan Kovarcík, Mr Oleg **Lebedev**, Mr Paul **Lempens**, Mrs Christine **McCafferty**, Mr Armen Melikyan, Mr Patrick Moriau, Mr Félix **Müri**, Mrs Christine **Muttonen**, Mrs Carina **Ohlsson**, Mrs Lajla Pernaska, Mr Zoran **Petreski**, Mrs Marietta de Pourbaix-Lundin, Mr Cezar Florin Preda, Mr Vjerica Radeta, Mrs Maria Pilar **RibaFont**, Mr Nicolae Robu, Mrs Maria **de Belém Roseira**, Mrs Marlène Rupperecht, Mr Indrek Saar, Mr Maurizio Saia (alternate: Mr Giacomo **Stucchi**), Mr Fidas **Sarikas**, Mrs Anna Sobecka, Mrs Michaela **Šojdrová**, Mr Marc **Spautz**, Mrs Arūnė Stirblytė (alternate: Mrs Birutė **Vèsaitė**), Mr Oreste Tofani, Mr Mihai Tudose, Mr Mustafa **Ünal**, Mr Luca **Volontè**, Mr Johann Wadephul, Mr Victor Yanukovych (alternate: Mr Ivan **Popescu**), Mr Vladimir Zkidkikh, zz. (alternate: Mrs Svetlana Goryacheva)

NB: The names of the members who took part in the meeting are printed in **bold**

Secretariat of the committee: Mr Mezei, Ms Lambrecht, Ms Arzilli