Parliamentary Assembly
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COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Recommendation 1794 (2007)[1]

The quality of medicines in Europe

Parliamentary Assembly

1. The counterfeiting of medicines has developed into an industry that kills hundreds of thousands of people a year.

2. What was once confined to small-scale production is now an activity that can be associated with organised crime.

3. The counterfeiting of medicines is a scourge affecting 10% of the world medicines market, and its growth has been facilitated by globalisation and the expansion of transborder trade, as well as the ease of use of modern technologies.

4. According to a survey by the Organisation for Economic Co-operation and Development (OECD), the resulting losses amount to some €500 billion a year, with the sums concerned eluding national taxation systems. Counterfeit medicines therefore generate huge profits for counterfeiters, who are never arrested or prosecuted.

5. Counterfeiting affects not only medicines, be they generic or not, but also medical devices, cosmetics and veterinary products. It therefore represents a serious threat to the health of individuals and may lead to the failure of treatment, the worsening of diseases and may even sometimes be the cause of death. The Parliamentary Assembly underlines that the emergence of counterfeit medicines undermines the confidence both of individuals and of health professionals.

6. The Assembly notes that parallel trade has been growing rapidly over the last decade. Providing that proper checks, including traceability, are made by distributors, consumer safety will be maintained.

7. The Assembly further notes that counterfeit medicines are beginning to appear in Europe as a result, in particular, of a lack or the inadequacy of regulations on quality control and distribution. Counterfeit medicines circulate illegally, bypass taxation systems and undermine the interests of consumers and of state and private industry budgets.

8. Moreover, the rules on the export of medicines vary from one country to the next, making any international controls or sanctions practically impossible.

9. As noted by the participants at the conference “Europe against Counterfeit Medicines” held in Moscow on 22 and 23 October 2006, counterfeiting has been tackled mainly from the industrial property rights approach rather than from that of the protection of the rights of the individual. The participants also regretted the fact that there is no legal instrument on matters relating to crime in the pharmaceutical field.

10. The Assembly notes that this legal vacuum means that appropriate national authorities are either inexistent or weak, and therefore underlines the need to make provision for an international legal instrument establishing specific offences relating to counterfeiting medicines so that counterfeiters can be arrested and criminally prosecuted.

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1. Assembly debate on 20 April 2007 (18th Sitting) (see Doc. 11193, report of the Social, Health and Family Affairs Committee, rapporteur: Mr Marquet). Text adopted by the Assembly on 20 April2007 (18th Sitting).

11. The Assembly is also concerned by the growth in sales of medicines over the Internet which could lead to uncontrolled transborder trade in medical products that could be dangerous to public health and impunity for counterfeiters.

12. The Assembly therefore underlines the need to regulate Internet sales and establish real international co-ordination, in co-operation with the police, customs authorities, the judiciary and health professionals.

13. In light of the above, there is an urgent need for states to take measures to protect the safety of patients in response to the increasing spread of counterfeit medicines.

14. The Assembly therefore recommends that the Committee of Ministers of the Council of Europe ask Council of Europe member states, non-member states and the Contracting Parties to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50) 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 to lay down rules governing jurisdiction allowing the interests of victims of pharmaceutical crime to be taken into account.

15. The Assembly also calls on Council of Europe member states, non-member states and the Contracting Parties to the Convention on the Elaboration of a European Pharmacopoeia to:

1. use the departments within the Organisation to collect and disseminate information;
2. organise public information campaigns on the risks entailed in using counterfeit medicines, to encourage people to use legal distribution channels;
3. promote inter-agency co-operation between the police, customs authorities, the judiciary, health professionals and other relevant medical bodies;
4. draft legislation on medicines, including provisions prohibiting the manufacture, import and sale of counterfeit medicines, in order to regulate the manufacture and import of medicines and prevent counterfeit medicines from entering pharmaceutical distribution networks;
5. introduce surveillance systems, in liaison with laboratories and distribution networks;
6. establish a comprehensive system for the traceability of medicines, with the aim of producing a fully-fledged register of pharmaceutical products;
7. set up a special system for monitoring and checking the quality of medicines dispatched for humanitarian purposes;
8. set up, in conjunction with the European Directorate for the Quality of Medicines and HealthCare, a training scheme for staff and professionals concerned so that they can take appropriate action to deal with crime in the pharmaceutical field;
9. establish a system for checking the identity of online pharmacies.

16. The Assembly asks the Committee of Ministers to recommend to those states which have not already done so to:

1. sign and ratify the Convention on the Elaboration of a European Pharmacopoeia;
2. sign and ratify the Convention on Cybercrime (ETS No. 185).