The Chairmanship of the Russian Federation in the Committee of Ministers of the Council of Europe

International Conference - Europe against Counterfeit Medicines

Moscow Declaration

Moscow, Russian Federation,
23-24 October 2006

1. We, the participants of the International Conference, organised within the Programme of the Chairmanship of the Russian Federation in the Committee of Ministers of the Council Europe - the representatives of governmental institutions and agencies of the member states of the Council of Europe and of participating states of the Commonwealth of Independent States, of the Secretariat and the Parliamentary Assembly of the Council of Europe, as well as international and European organisations and institutions, key stakeholders from the essential pharmaceutical sectors, medical professionals, and representatives of professional and civil associations having met in Moscow, Russian Federation, on 23 – 24 October 2006, in order to:

- discuss pressing tasks in the fight against counterfeit medicines in European countries and on an international scale and the legal and organisational means and possibilities of opposing this phenomenon;
- reconfirm that the protection of human beings and their lives and health with all legal means including civil and criminal law shall be at the centre of attention of all member states of the Council of Europe and its future legal instrument in this area – a convention of the Council of Europe;
- bring forward a consensus among the civil society, the state and governmental, as well as private sectors of manufacturers and distributors of medicines with regard to practical measures to be taken with a view to optimising the protection of society and of the economy against the detrimental consequences of counterfeit medicines:
- consider the compensation of patients for damages resulting from counterfeit medication;
- encourage and advance the process of formulating under the aegis of the Council of Europe the appropriate international legal instrument (the Convention) on the co-operation in the field of the fight against counterfeit medicines, the production and distribution of which should be qualified as pharmaceutical crime;
- ensure co-ordination of the activities of the participants of this Conference in consistence with the conclusions of the Conference;

2. Considering that counterfeit medicines:
- represent a serious threat to everybody's health in Council of Europe member states and worldwide, while their production and distribution may constitute a prerequisite of violation of a human right to the maximum feasible degree of physical and mental health and the relevant human rights enshrined in the Universal Declaration of Human Rights and in the European Convention on the Protection of Human Rights and Fundamental Freedoms;
- are not subject to controls of quality, safety and efficacy as set out in the legislation in force in European states;
- are reported in an ever increasing number both in Europe and worldwide, in particular, in view of the trade via the Internet;
- have no internationally recognised harmonised legal definition and are not covered by unified international enforcement practice to fight against them;
- are in the illegal circulation and bypass the state tax system, infringe intellectual property legislation, and consequently harm the interest of consumers and state budgets and the budget of law abiding citizens and companies;
- undermine the confidence which patients and healthcare professionals should have in safe medicines and other healthcare products;
- are produced by counterfeiters who are criminals, often well-financed, well-equipped with the most recent technology and often belong to international organised and economic crime networks, which respect and observe neither laws nor state borders;

3. Call on the competent authorities, manufacturers, wholesalers, pharmacists and intergovernmental and non-governmental organisations for close co-operation in order to combat the threats posed by counterfeit medicines;

4. Reaffirm that the member states of the Council of Europe have a responsibility both to their populations and to other member states and to the world to strive for the promotion and respect of their obligations to defeat the counterfeiting of medicines and other pharmaceutical crime;

5. Express our concern with regard to the fact that there is no integrated European instrument, counteracting all aspects of international pharmaceutical crime, including the counterfeiting of medicines and other healthcare products, and encouraging public health protection and safety;

6. Taking into account the above, we are convinced that an international legal instrument - a Convention on combating pharmaceutical crime - should be developed without delay under the aegis of the Council of Europe and adopted, using international practical experience and knowledge in the field of law, economic regulation, public healthcare and the quality control of medicines;

7. Consider it advisable to cover the following issues within the international legal instrument (a convention) to be developed:
- legal definitions of key terms in the field of combating the counterfeiting of medicines and their distribution;
- prevention of counterfeiting of pharmaceuticals *inter alia* using the measures included in paragraph 9 of the Declaration;
- a protocol of state actions with regards to identified counterfeit pharmaceuticals and their distribution (confiscation, return to the country of origin and their destruction);
- recognition that acts of counterfeiting medicines and distribution thereof as well as involvement in such acts are criminal acts and establishment by the participants of the Convention of respective punishments for these crimes, taking due account of their seriousness;
- co-operation between healthcare authorities and law enforcement agencies of the member states of the Council of Europe;
- development of mandatory systems of reporting on counterfeit medicines for all the parties to this Convention, *inter alia* via an intersectoral network of Single Points of Contact (SPOCs);
- the links between such a Convention and other international legal instruments dealing with money laundering and financing of terrorism as well as cyber-crime;

8. Have due respect of the role and accomplishments of the Council of Europe in the field of consumer health protection, formulation of international standards in the field of public healthcare and quality control of medicines; appreciate highly the efforts of the European Directorate of the Quality of Medicines, the Partial Agreement in the Social and Public Health Field and the Council of Europe Directorate

General I - Legal Affairs, which is contributing to formulating legal standards and international co-operation in the field of combating crime;

9. Invite all governments of the member states of the Council of Europe to provide the necessary means for the training of governmental officials in the field of combating pharmaceutical crime ensuring close collaboration with healthcare professionals and providers as well as wide dissemination of information to the general public about the threat to life, health and unpredictable consequences of using counterfeit medicines.

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Appendix

Conclusions from the Workshops

of the International Conference "Europe against Counterfeit Medicines"

Moscow, 23-24 October 2006

The participants in the international conference "Europe against Counterfeit Medicines" consider it necessary to:
1. Draft, under the aegis of the Council of Europe (CE), and adopt an international legal document (convention) on how to combat counterfeit medicines, the production and distribution of which should be considered as offences in the pharmaceutical sphere.

2. Include in this future convention:
• legal definitions of the main concepts in respect of combating counterfeit medicines and their distribution;
• prevention of counterfeiting of medicines, including application of the measures proposed in point 9 of the Moscow Declaration;
• an action plan for states in relation to fake medical products discovered (confiscation, return to country of their origin, destruction);
• recognition of actions to counterfeit medicines and to distribute them, as well as connivance in such actions, as criminal offences, and establishment by the countries who are signatories to the convention of appropriate punishment for these offences based on their degree of seriousness;
• cooperation between health care agencies and law enforcement agencies in Council of Europe member countries;
• creation of a compulsory system of notification of counterfeit medicines for all convention participants, including via the inter-sector Single Points of Contact (SPOCs) network;
• linking of the convention to international legal enactments concerning the fight against money-laundering and the financing of terrorism, and also the fight against cyber-crime.

3. Develop a mechanism for information interaction between public and commercial organisations and professional associations on matters to do with prevention of trade in counterfeit medicines.

4. Create a compulsory system of notification of counterfeit medicines for all convention participants, including via the inter-sector Single Points of Contact (SPOCs) network, functioning on the basis of formalised procedures for the management of risks and rapid response systems.

5. Develop close cooperation between the state, the public and private medicines manufacture and distribution sectors, patient rights protection organisations, professional associations and other interested organisations in combating threats linked to the manufacture and distribution of counterfeit medicines.

6. Consider the potential for the establishment in Russia, as an element of cooperation between the state, civil society and the public and private sectors, of an institute of pharmaceutical safety, one of its aims being to identify and prevent the distribution of counterfeit medicines.

7. Organise cooperation between medicinal quality control agencies in European countries and the Council of Europe to promote an exchange of information and harmonisation of legal and normative regulation in this sphere.

8. Hold consultations on the involvement of the European Directorate for the Quality of Medicines of the Council of Europe (EDQM) in supplementary training for specialists from the Russian pharmaceutical industry.

9. Request the Federal Inspectorate for Health and Social Development (Roszdravnadzor) and Medicinal Quality Control Centres (MQCCs) of the Russian Federation, the EDQM and the network of Official Medicines Control Laboratories (OMCL) of the Council of Europe to organise:
• cooperation on matters to do with methodological approaches to medicinal quality control;
• the running of targeted seminars and training sessions on matters that are of mutual interest to OMCL and MQCC specialists;
• preparation of methodological recommendations, manuals and textbooks on medicinal quality control.

10. Make a study of the potential for involvement of specialists at Russian MQCCs in proficiency testing studies (PTS) and quality assurance (QA) audits run by the network of Official Medicines Control Laboratories (OMCL) of the Council of Europe.

11. Give consideration to the potential for organising joint quality control of medicines for certain indicators with the joint involvement of subordinate organisations of Roszdravnadzor, the MQCCs and the OMCL.

12. Upgrade the system for monitoring the circulation of counterfeit medicines to include pharmaceutical associations, patient rights protection groups, associations of doctors and nurses and other organisations.

13. Carry out a regular analysis of material published on the Internet, with the aim of identifying and preventing illegal trade in medicines, including counterfeit products, and illegal advertising of medicines.

14. Upgrade the system of protective marking of medicines.

15. Arrange cooperation with the mass media on matters to do with the proper airing of the problem of counterfeiting of medicines.

16. Determine the criteria for and scope of information on the counterfeiting of medicines that should be accessible to all.

17. Look at the potential for an official translation into Russian of the most important contents of the European Pharmacopoeia.

18. Study of the potential for the European Directorate of Quality of Medicines of the CE to be involved in work on harmonisation of the quality requirements for medicines in Commonwealth of Independent States member countries.

19. Promote cooperation between members of the Commonwealth of Independent States in the sphere of upgrading and harmonisation of legal and normative requirements for trading and marking of medicines.