Focus

European action against counterfeit medicines

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Abstract
This article describes measures discussed by the Council of Europe’s Public Health Committee, Committee of Experts on Pharmaceutical Questions and Ad Hoc Group on Counterfeit Medicines to combat the spread of counterfeit medicines.

PART I
Preparatory Meeting (Council of Europe Member States)
Strasbourg, June 21, 2006

1. Introduction
Counterfeit medicines undermine public trust in medical therapies and health care systems, and present a significant threat to therapy: they kill patients either through lack of therapeutic effect or through an inherent toxicity.

2. Background
Case reports and studies indicate that the occurrence of counterfeit medicines is on the rise in Western industrialised countries and worldwide and is likely to increase in the near future. The Council of Europe Committee of Experts on Pharmaceutical Questions under the Partial Agreement Health Committee has commissioned a systematic study on legislation, administrative procedures and proposed models for best co-operation practices between Member States’ authorities and involved stakeholders to prevent counterfeiting and tackle suspected counterfeit medicines.

3. Council of Europe work programme
Alarmed by the occurrence of counterfeit medicines in the legal distribution chain, the Committee of Experts on Pharmaceutical Questions entrusted in 2003 the Ad Hoc Group on Counterfeit Medicines with a work programme to protect the patient and deter counterfeiters in Europe in co-operation with relevant international parties. The above mentioned study was carried out with a view to setting up a programme encompassing information exchange, risk management and risk communication, and rapid alert systems as well as training programmes.

Co-operation was established with the Council of Europe Parliamentary Assembly and the European Directorate on the Quality of Medicines. The Committee of Ministers encouraged the Committee of Experts on Pharmaceutical Questions to proceed with its activities in the framework of its programme.

4. Seminar “Counteract the counterfeiters”
The Committee of experts on pharmaceutical questions organised the seminar, “Counteract the Counterfeiters! Limiting the risks of Counterfeit Medicines to Public Health in Europe by Adequate Measures and Mechanisms”, which took place in Strasbourg on September 21-23, 2005, to discuss the follow-up to preliminary work results with an expert audience.

Two hundred participants from 40 Member States of the Council of Europe, European and international institutions and organisations, key industry and trade stakeholders and health professionals were present. The participants produced recommendations on specific legal and practical measures and their practical implementation, namely as regards the legal environment co-operation, control of public health challenges of
counterfeit medicines in Europe, training programmes, enforcement – networking and risk management, and best practices for industry and distributors3. The role of the Council of Europe was recognised as a centre of excellence in the quality control of medicines, a flexible multisectoral platform, and an organisation with a comprehensive European membership, capable of bringing forward consensus on means to protect European health care systems, ensuring the rule of law from a human rights and public health perspective.

5. Follow-up

In line with the multisectoral approach, the Committee of Experts on Pharmaceutical Questions has adopted the concrete and result-orientated plan of activities to combat counterfeit medicines proposed by the Ad Hoc Group. The plan deals with public health-related aspects of risk management, management and communication, international co-operation, training and education as well as law enforcement.

The Ad Hoc Group is co-operating closely with other Council of Europe bodies, in particular the Directorate General I, Legal Co-operation, and the European Directorate for the Quality of Medicines.

The current work priorities are:

• “Training programmes for officials involved in combating counterfeit medicines”: A model for a training programme based on needs will be made available to Council of Europe Member States in the fields of health, customs and police and a model for an education and awareness raising programme is provided.

• “Involvement of TOPRA” (The Organization for Professionals in Regulatory Affairs). TOPRA was invited to support this initiative by providing its expertise in training and continuous education. The broad range of training programmes already in existence (eg, TOPRA’s basic course, GMP seminars etc) could be adapted for fighting counterfeit medicines. In addition, the subject itself could be incorporated in many public programmes developed by TOPRA to create awareness about the situation and to help ensure that all involved in the research and development of medicines support the combat against counterfeit medicines. Due to its experience TOPRA has been invited to join the international conference “Europe against counterfeit medicines” for the Council of Europe Member States’ delegates, on June 21-22 in Strasbourg.

• “Anti-Counterfeiting Network of SPOCs and risk management of counterfeit medicinal products”. To ensure that information about counterfeits reaches the competent people through the different co-operation partners, it is important to define clearly recognisable contact points. Contacts at agencies are called Single Points of Contact (SPOCs) – contacts in private industry are called Responsible Persons (RPs).

SPOCs have the following functions:

- To represent a certain co-operation partner (area) in the field of counteracting counterfeiters (eg, drug regulatory authority, customs, police, justice)
- To co-ordinate all measures in their own area of responsibility
- To act as contact point in a nation wide network, consisting of the SPOCs of the different areas.

Drug Regulatory Authorities (DRAs) possess a profound knowledge of medicinal products and should therefore have a key role in assessing the risk of a signal indicating a counterfeit medicine. It is therefore recommended that the SPOC of the DRA co-ordinates the risk assessment of a counterfeit signal as well as the derived activities to protect public health. He should also act as contact point (National SPOC) in an international network, consisting of the SPOCs of the different national DRAs.

Companies (eg Marketing Authorisation Holders of genuine products, distributors/wholesale traders) should identify a RP who can act as contact point for agencies in dealing with a specific counterfeit case. Companies and other private associations should identify one or more contact points for general strategic co-operation activities with the agency network.

The main outcome will be improved information exchange, resulting in a faster reaction to identified counterfeit medicines and a standardised approach towards tackling the problem. This will improve tracking and tracing of counterfeit medicines in the future.

- “Tighten up customs to alertness in relation to counterfeit medicines“. National provisions related to medicines have proven ineffective in cross border pharmaceutical surveillance. Literally, they fail at national borders. Pharmaceutical crime is not bound to one activity and is frequently marked by geographical partition. Proposals for adaptations of legislation and co-operation protocols will be made with a view to providing the necessary tools to drug regulatory and customs authorities.

- “Active surveillance and identification of counterfeit products in the legal distribution chain”: GMP-GDP instruments are designed for quality surveillance. Supplementary guidance on quantitative elements aimed at securing supply chain integrity will be proposed, considering that counterfeit tracking and tracing should cover finished products, active pharmaceutical ingredients and packaging material. The adapted instruments are targeted at authorities and stakeholders in the private sector who should apply secure business practice.

- “Public health challenges of counterfeit medicines in Europe and education of the public”; the aim is to decrease the risk presented by counterfeit medicines to public health.

The above approach takes account of the European situation, while not losing sight of the global dimension of medicine counterfeiting.

6. Conference in Moscow

The main conference of the Committee of Experts on Pharmaceutical Questions took place in Moscow (October 23-24, 2006) under the aegis of the presidency of the Russian Federation of the Council of Europe Committee of Ministers.

TOPRA had been invited to participate in the field: “Training and education” for officials involved in combating counterfeit medicines.
The targets of this session were:

1. Establishment of training methods
2. Preparation of information pack
3. Survey on training needs
4. Delivery of pilot training
5. Learning the “train the trainer” philosophy.

PART II reports on the results of the Symposium in Moscow and “Part III” covers the final “Moscow Declaration”.

PART II

Symposium in Moscow (October 23-24, 2006)

The participants in the international conference, “Europe against Counterfeit Medicines” considered 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
   - Co-operation 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 co-operation 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 of a compulsory system of notification of counterfeit medicines for all convention participants, including via the inter-sector Single Points of Contact (SPOCs) network.
7. Develop an action plan for states in relation to fake medical products discovered (confiscation, return to country of their origin, destruction).
8. Co-operation between public and commercial organisations and professional associations on matters to do with prevention of trade in counterfeit medicines.
9. Consider the potential for the establishment of a system of notification of counterfeit medicines for all convention participants, including via the inter-sector Single Points of Contact (SPOCs) network.
10. Make a study of the potential for involving 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.
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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 for monitoring the circulation of counterfeit medicines to include pharmaceutical associations, patient rights protection groups, associations of doctors and nurses and other organisations.
15. Arrive at a consensus on the measures that should be taken to prevent the circulation of counterfeit 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 the potential for the establishment of a compulsory system of notification of counterfeit medicines for all convention participants, including via the inter-sector Single Points of Contact (SPOCs) network.

The running of targeted seminars and training sessions on matters that are of mutual interest to OMCL and MQCC specialists
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:
   - Co-operation 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.

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of the quality requirements for medicines in Commonwealth of Independent States member countries.

19. Promote co-operation 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.

PART III

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

Moscow Declaration
Moscow, Russian Federation, October 23-24, 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 of 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 October 23-24, 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 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 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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References

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