

Protecting patients in Europe from counterfeit medicines and other forms of pharmaceutical crime and deterring counterfeiters – a multisectorial programme of activities of the Council of Europe

The Council of Europe is an intergovernmental organisation which aims:

- to protect human rights, pluralist democracy and the rule of law;
- to promote awareness and encourage the development of Europe's cultural identity and diversity;
- to seek solutions to problems facing European society;
- to help consolidate democratic stability in Europe backing political, legislative and constitutional reform.

Set up on 5 May 1946, the Council of Europe has now 47 member states. The Council of Europe covers major issues facing European society other than defence: its work programme includes among others the following fields of activity: human rights, legal co-operation, social cohesion, health, local democracy and trans-frontier co-operation, the environment and regional planning, youth, education, culture, heritage and sport.

Amongst the results of the Council of Europe's work programmes are legal instruments (conventions, agreements, recommendations) in the light of which member states may subsequently harmonise and amend their own legislation to comply with them).

Counterfeit medicines pose a public health risk...

Counterfeit medicines undermine public trust in medical therapies and health care systems, and present a significant threat to patient safety: they may harm seriously patients through lack of therapeutic effect and/or through an inherent toxicity.

A counterfeit medicine is deliberately and fraudulently mislabelled with respect to source and/or identity, and includes medicines with correct ingredients, wrong ingredients, incorrect quantities of active ingredients, and/or products with fake packaging (WHO, 1992).

Counterfeiting of medicines is a form of pharmaceutical crime which does not stop at borders of regions or states.

Preparing the ground for the Council of Europe activities...

As follow-up to the stipulations of Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security¹, the Committee of experts on Pharmaceutical Questions of the Partial Agreement in the Social and Public Health Field set up the Ad hoc Group on Counterfeit Medicines in 2003. The Ad hoc group was entrusted with a comprehensive work programme focusing on public health protection and possibilities for improved co-operation of member states and other stakeholders as regards counterfeit medicines and other forms of pharmaceutical crime.

The Ad hoc Group's composition and project approach are multisectorial, bringing together officials from Council of Europe member states, European institutions, associations of pharmaceutical industry and trade and international organisations.

Continuing the way forward - milestones and results

In 2004, the Ad hoc Group carried out the first systematic study¹ on legislation, administrative structures and procedures applicable to counterfeit medicines; stakeholders' views in member states and stakeholder associations.

In 2005, the Committee of experts and its Ad hoc Group 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, 21-23 September 2005.

The International Conference "Europe against Counterfeit Medicines", Moscow, 23-24 October 2006, was organised by the Russian Federation under the aegis of its Chairmanship of the Committee of Ministers with support of the Council of Europe Ad hoc Group on Counterfeit Medicines and the European Directorate for the Quality of Medicines & HealthCare (EDQM).

Current work programme and outlook ...

The Ad hoc Group has translated the conclusions of the above conferences into a strategy for developing practical measures and tools for public and private stakeholders. The measures prioritise public health protection from counterfeit medicines and other forms of pharmaceutical crimes, respond to regional needs may have applicability beyond Europe:

- The current work programme aims at developing training programmes for member states officials and other stakeholders to combat the public health risk posed by counterfeit medicines and pharmaceutical crimes through transfer of know-how and proven practices. Furthermore, it aims at refining co-operation structures and procedures and the facilitation of international co-operation through supporting a network of single points of contact within the Council of Europe member states.
- The Ad hoc Group carried out a survey on the training needs and competencies among member states' drug regulatory agencies, official medicines control laboratories, and police and customs agencies. The World Customs Organisation (WCO) and Interpol have provided valuable co-operation as regards the training needs survey.

Training course "Working across disciplines and borders - Best practices to combat counterfeiting of medicines and to protect public health", 6-7 December 2007

A multisectorial pilot training will be organised by the Ad hoc Group on 6 and 7 December 2007 taking account of the above survey on training needs and competencies and using the "train the trainers" approach.

The training is aimed at:

- increasing participants' awareness of the context in which counterfeit medicines develop and the serious risk they pose to public health,
- suggesting best practices for managing efficiently cases by and across the involved health and law enforcement sectors,
- giving a broader insight into the responsibilities and approaches of regulatory and enforcement agencies,
- showing areas for and means of improved co-operation,
- offering a forum for interactive exchange of expertise and experiences at the training and possibly after the training,
- supplying the necessary basis for the organisation of follow-up training in the participants respective countries.

The target audience comprises officials from the Drug Regulatory Authorities, Police and Customs who are either actively or potentially involved in combating crime involving counterfeit medicines or in managing officials in charge of this area.

The trainers have relevant expertise and profound working experience dealing with fighting counterfeit medicines and other pharmaceutical crimes. They come from the public sectors of health or law enforcement and from the pharmaceutical industry.

Depending on the evaluation of the training by the participants, the organisation of follow-up training courses is envisaged.

A web of synergistic measures – sustainable co-operation across sectors

Transfer of know-how and proven practices through training addressing the promotion of international co-operation will increase the effectiveness of member states' and concerned stakeholders' fight against criminals and their networks involved in the perpetration of medicines' counterfeiting and other forms of pharmaceutical crime: training will contribute to decreasing the risk of damage to patients' lives by counterfeit medicines and other forms of pharmaceutical crimes in Europe and beyond, to making these forms of crime less attractive to criminals, to avoiding loss of scarce health care resources and of legitimate revenues of the pharmaceutical supply chain.

The European Directorate for the Quality of Medicines & HealthCare (EDQM) / Network of Official Medicines Control Laboratories (OMCL) and the Council of Europe Directorate for Human Rights and Legal Affairs, and the Ad hoc Group on Counterfeit medicines are co-operating in developing measures and

instruments aiming at protecting public health from counterfeit medicines and other pharmaceutical crimes.

The role of the Council of Europe is a recognised as a centre of excellence in the quality control of medicines, a flexible multisectorial platform, an organisation with a comprehensive European membership, capable of bringing forward a consensus on means to protect European health care systems, strengthening international co-operation against the counterfeiting of medicines and other related crimes from a human rights and public health perspective.

Health is a social human right - counterfeiting of medicines is a criminal act with a dramatic impact on the health of the most vulnerable persons - patients.