

## Introduction

### **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**

Counterfeit medicines undermine public trust in medical therapies and health care systems, and present a significant threat to patient safety: they kill patients either through lack of therapeutic effect 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).**

Counterfeit medicines are on the rise in western industrialised countries and are a form of pharmaceutical crimes.

As a follow-up to the stipulations in the Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security<sup>1</sup>, the Committee of experts on Pharmaceutical Questions (P-SP-PH) under the Public Health Committee (CD-P-SP) of the Partial Agreement Division in the Social and Public Health Field, set up an Ad hoc Group on Counterfeit Medicines in 2003. The Ad hoc group was entrusted with establishing a specific action plan including a survey, information exchange, risk management procedures and rapid alert systems as well as training programmes. 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 (e.g. WHO, European Commission, European Patent Office).

This has led to a comprehensive work schedule with a focus on public health protection and possibilities for improved legal co-operation as regards counterfeit medicines and other forms of pharmaceutical crime.

In 2004, the Ad hoc Group carried out the first systematic study<sup>2</sup> on legislation, administrative structures and procedures applicable to counterfeit medicines; stakeholders' views in member states and stakeholder associations.

Among other relevant conclusions in the regulatory field, the study confirmed previous assumptions of a regional market share of counterfeit medicines in Europe of up to at least 10 %. Often, organised crime is involved.

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 means and measures"<sup>3</sup> which took place in Strasbourg from 21 to 23 September 2005.

200 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 seminar conclusions dealt with legal

and practical measures and their practical implementation, international co-operation, control of public health challenges of counterfeit medicines in Europe, training programmes, enforcement – networking and risk management, best practices for industry and distributors.

The role of the Council of Europe was 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, ensuring the rule of law from a human rights and public health perspective.

The Ad hoc Group has translated the conclusions into a comprehensive and multisectorial strategy on the risk management of counterfeit pharmaceuticals and related forms of pharmaceutical crimes in Europe with a clear priority on the protection of public health: the current work programme aims at developing co-operation structures and procedures for detecting at the earliest possible moment signals of suspect pharmaceuticals, analytical verification, assessment of the risk for public health by the competent (drug regulatory) authority, establishing and taking actions to protect public health in co-operation with all stakeholders, training and for preparing the ground for the implementation of adequate legal provisions.

With a view to a synergistic strategy against counterfeit medicines and pharmaceutical crime across the organisation and its member states, the European Directorate for the Quality of Medicines and Health Care/Network of Official Medicines Control Laboratories (EDQM/OMCL) and the Council of Europe Directorate I, Legal Affairs, is represented in the Ad hoc Group on Counterfeit medicines and/or support the above Ad hoc Group plan of activities.

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 expert support of the Council of Europe through its Ad hoc Group on Counterfeit Medicines and the European Directorate for the Quality of Medicines and Health Care. It profited from the previous Council of Europe seminar. 1000 participants from 36 countries, among them political decision makers, representatives of the Russian Federation Government and President’s Administration, the Council of Federation, the State Duma, the Ministries of Health and Social Development, Justice, Internal Affairs, the Federal Customs Service, the Commonwealth of Independent States, delegates from the Russian pharmaceutical chain, international and European institutions and organisations, experts from a variety of healthcare institutions, pharmaceutical manufacturers and distributors of medicines contributed to the international perspective of the Conference and its results.

The Conference declaration (“Moscow Declaration”) adopted by the participants established a strong appeal to all stakeholders of pharmaceutical security in the public and private sectors to take their responsibilities towards public health protection in the field of pharmaceutical crime, including the counterfeiting of medicines, by developing a convention on pharmaceutical crime including counterfeit medicines and providing for the political environment to ensure its implementation.

**Counterfeiting of medicines is a criminal act with a dramatic impact on the health of the most vulnerable persons, patients.**

**No loopholes for medicine counterfeiters, therefore the Council of Europe is examining possible action for a regional co-operation!**

1. ResAP(2001)2, paragraph 8: "...counterfeit pharmaceuticals pose real threats. In order to combat these dangers, the authorities, manufacturers, wholesalers, pharmacists and intergovernmental organisations must co-operate..."

2. Presentation\_Seminar\_CountMed public

3. Council of Europe Survey on counterfeit medicines; Consultants Dr J. Harper, Mr B. Gellie. Available through Council of Europe Publishing: <http://book.coe.int>