

## **Counterfeit medicines in Europe – a multisectorial action programme of the Council of Europe to protect the patient and deter counterfeiters**

### **Background**

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).

This was an illegal counterfeit medicines factory discovered by UK police and MHRA in North London. The factory was able to produce 500,000 counterfeit medicines daily. The suspects were prosecuted and awarded between 3 and 5 1/2 years imprisonment.

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.

Counterfeit medicines are on the rise in western industrialised countries.

A study<sup>1</sup> carried out by the Council of Europe indicates a 10% market share of counterfeit medicines in Europe. Often, organised crime is involved. The Council of Europe Committee of experts on pharmaceutical questions (P-SP-PH) under the Partial Agreement Public Health Committee (CD-P-SP), has already called for multisectorial and concerted action in its Resolution AP(2001)2 on the role of the pharmacist on health care security, paragraph 8: "... counterfeit pharmaceuticals pose real threats. In order to combat these dangers, the authorities, manufacturers, wholesalers, pharmacists and intergovernmental organisations must co-operate...".

In reaction to reports on occurrences of counterfeit medicines in the legal distribution chain, the P-SP-PH established in 2003 a multisectorial ad hoc Group on counterfeit medicines. It entrusted the ad hoc Group with a specific action plan including the above-mentioned survey, information exchange, risk management procedures and rapid alert systems as well as training programmes. The ad hoc group and its 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). The European Medicines Agency adopted the rapid alert notification procedure and form adapted for counterfeit medicines after consultation with European medicines enforcement officers. The original proposal for adaptation was made by the ad hoc Group under the rapporteurship of the Swiss delegate in October 2004.

The Council of Europe Parliamentary Assembly, the European Directorate on the Quality of Medicines, DG I Legal Affairs are co-operation partners in the frame of the project.

### **Seminar**

The P-SP-PH organised the seminar "Counteract the Counterfeiters ! Limiting the Risks of Counterfeit Medicines to Public Health in Europe by Adequate Measures and Mechanisms, 21 – 23 September 2005, to discuss the follow-up to results of preliminary work with an expert audience.

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 participants produced recommendations on specific legal and practical measures and their practical implementation, namely as regards legal environment, 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.

1 HARMONISED PROVISIONS, LEGISLATION / ADMINISTRATIVE STRUCTURES AND PROCEDURES APPLICABLE TO COUNTERFEIT MEDICINES; STAKEHOLDERS VIEWS AND EXPERIENCES. Study report; March 2005. In press, available by the end of 2005