

**Partial Agreement  
in the Social and Public Health Field  
Accord Partiel  
dans le domaine social et de la santé publique**



SEMINAR

COUNTERACT THE COUNTERFEITERS!

LIMITING THE RISKS OF COUNTERFEIT MEDICINES TO PUBLIC HEALTH  
IN EUROPE BY ADEQUATE MEASURES AND MECHANISMS

SHORT CONCLUSIONS

21-23 September 2005  
Council of Europe Strasbourg

## SHORT CONCLUSIONS

Inter alia, the seminar participants recommended to

### **Legal**

- develop an international legal instrument to combat pharmaceutical crime,

### **Structure of International Co-operation**

- urge political will for international co-operation and for support to concerned agencies and institutions/ organisations,
- define reporting requirements - including reporting obligations - and protocols with a view to accessible and valid information on counterfeit medicines,
- use the official network of control laboratories (OMCL) as a platform of analytical excellence, to collect and disseminate information on counterfeit medicines, for co-operation with law enforcement agencies, industry, regulatory authorities outside of Europe,

### **Public health**

- raise awareness through positive communication avoiding scaring people,
- discourage the public from purchasing medicines via illegal distribution channels,
- to train healthcare professionals to communicate the counterfeit medicines risk to patients,
- consider counterfeit and substandard medicines in the systems which are in place to survey medicines' safety on the market,
- enable the traceability of a medicine to patient level in case of a medicine recall,

### **Best practices for industry and distribution**

- implement a pharmaceutical security chain covering the manufacture, distribution and transport of active pharmaceutical ingredients, recipients, packaging material at the levels of wholesalers, parallel traders, carriers, pharmacists, doctors, nurses,
- perform stringent controls for granting and maintaining the licenses required for manufacture, distribution, trade,
- use and harmonise anti-counterfeiting technology where appropriate and effective (e.g. global coding system),
- promote over packing and over labelling as the only safe solution instead of opening and changing the original packaging,

### **Enforcement**

- establish in all concerned agencies a single point of contact (SPOC) for effective and rapid co-operation in case of a suspect counterfeit,
- promote the model established by the ad hoc group for a public health focused risk assessment,
- encourage health inspectorates to adopt standard operating procedures for active search and detection of counterfeit medicines,
- adapt the customs codes for medicines,

### **Training**

- create a multisectorial training committee for training for involved officials to assess specific needs, priorities, funding,
- promote education and awareness raising through activities of the Council of Europe Committee of experts on pharmaceutical questions.

The Council of Europe was recognised a centre of excellence in the quality control of medicines, a flexible multisector platform, an organisation with a comprehensive European membership, capable of bringing forward a consensus of a suitable level to protect European health care systems, ensuring the rule of law from the human rights and public health angle. These recommendations will be referred to relevant Council of Europe bodies at their forthcoming meetings to decide on a follow-up.