PUBLIC CONSULTATION

In Preparation of Legal Proposal to Combat Counterfeit Medicines for Human use

Key Ideas for Better protection of Patients against the risk of Counterfeit medicines

11/3/2008 **Commission launches a Public consultation**

Comments and ideas of the State Institute for Drug Control on the "Legal Proposal" and the "Key ideas"

1. SUKL welcomes the initiative of the European Commission to prepare the Legal Proposal to Combat Counterfeit Medicines for Human use.
2. We also support the proposals to combine various measures, to improve the existing regulatory framework, to minimise the infiltration of counterfeit medicines into the legal distribution chain and the risks for the patients.
3. We identify ourselves with the idea of combination of various measures in the three proposed areas. We also support the idea of tightening inspections and supervision to be able to control the GMP, GDP and to trace the active ingredients of medicinal products also in third countries.
4. In this respect, however, we are especially concerned that inspections of the import and distribution operating in third countries would represent an excessive administrative burden for the individual National Regulatory Authorities.
5. We believe that this system of inspection in third countries would only be feasible if a system of mutual recognition of inspecitons/findings and an adequate work-sharing system among the EU National Competent Authorities were introduced, similar to the work-sharing system operating in the case of GMP or PSUR assessment.
6. We recommend to analyse also the role and possible contribution of the customs control, tax offices at the external border of the Community to minimise the risk of counterfeit medicines entering the European Community.