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Note for the Editors

Already in 1994 an Official Medicines Control Laboratories (OMCL) Network was formed under the aegis of the Council of Europe in Strasbourg, France, to co-ordinate the administrative and technical activities of the OMCL's, to facilitate the exchange of knowledge amongst authorities in Europe and to influence future development through harmonised common standards, based on the legal requirement for testing medicinal products.

11th ANNUAL MEETING OF EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES (OMCL), LIMASSOL, REP. CYPRUS, 9-12 MAY 2006

At the invitation of the European Directorate for the Quality of Medicines (EDQM) of the Council of Europe, almost 180 representatives from 32 countries* attended the Annual meeting of the European Network of the OMCLs.

The meeting was hosted in Limassol by the State General Laboratory and was opened by the Minister of Health of the Republic of Cyprus, Dr. Andreas Th. Gavrielides. It was organised to review the activities of the Network in 2005 and to discuss the work programme for the year to come.

This meeting was the opportunity to bring together the OMCLs of the General European Network in different areas of interest (physico-chemical, pharmaceutical, biological) to discuss and exchange viewpoints of common interest in the field of controlling and testing medicines by independent Official Medicines Control Laboratories (OMCL).

The following were discussed:

- The annual reports of activities of each laboratory, highlighting key issues and results. In this context, preliminary discussion on the risk analysis approach in defining the testing programme of the OMCLs was held.
- Results of tests on marketed medicines for human use and veterinary use (MSS studies); discussion of the current programme and adoption of the action plan for 2006. These collaborative studies organised by the EDQM serve as reliable indicators of the quality of products on the European pharmaceutical market.
- The progress report on the implementation of a harmonised programme on Quality Assurance in the different OMCLs including a review of the actions in assistance and maintenance of QA throughout the Network. The proficiency testing studies (PTS) programme for the coming year in both physico-chemical and biological fields, as well as the key outcomes of the 2005 programme. The network agreed to consider making publicly available their relevant guidelines and procedures as well as key outcomes.
- The status of the OMCL inventory database project. The future database for internal use within the OMCL network will host information about competences available throughout the network and is planned to become productive in 2007. The new computer application intends to improve communication and quick information exchange between the members of the network and aims to help to establish first contact in case there is a need to exchange expertise within the network, initiate work sharing and build-up further mutual recognition of data.
- Guidelines on general policies, such as the definition of an OMCL, terms of reference of the Advisory Group of the GEON, etc., and issues concerning the specific activities of OMCLs, such as the further development of qualification of equipment (for example, gas chromatography); this is to update the established set of specific guidelines.
- Concerning the role of OMCLs in combating counterfeiting, a procedure of key issues to take into consideration as well as an information exchange system with the Network. Some OMCLs presented their recent results and the strategies developed in this field of activity; in particular, the wish to intensify the co-operation with industry was endorsed.

In the field of Official Control Authorities Batch Release (OCABR) one new specific guideline for influenza vaccine and ten revised guidelines were all adopted. All these guidelines will be published by the end of 2006, implementation by 1 January 2007, and will also be electronically available on the EDQM website, as in the past. Several internal documents and procedures were also adopted. Additionally two new and two revised product specific guidelines for vaccines have been approved for external consultation within the months to come.

A break-out session concerning MRP-product testing group was held. The final report of the 2005 testing program was presented. In total 14 OMCL's actively participated in the program and approximately 280 projects could be finalised (180 in 2004). The testing group adopted a general document describing the principle of the co-operation in post-marketing surveillance of MRP-products. A status report of the MRP-product testing database project, which will be finalised in 2007, was provided.

The testing of traditional Chinese medicines was also discussed in a workshop of specialists to examine the possible contribution of the OMCLs in this field of activity.

* Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Canada, Croatia, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Serbia-Montenegro, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 46 member states.

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