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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.

12TH ANNUAL MEETING OF EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES (OMCL), PRAGUE, CZECH REPUBLIC, 7-11 MAY 2007

The European Directorate for the Quality of Medicines & HealthCare (Council of Europe) has held from 7 to 11 May 2007 its 12th Annual Meeting of the Official Medicines Control Laboratory (OMCL) Network in Prague. This conference was organised with the help and support of the State Institute for Drug Control of human medicines and the Institute for the State Control of Veterinary Biologicals and Medicaments in the Czech Republic.

216 participants from 33 countries, representing 51 control laboratories attended 8 different specialised sessions during which the quality control of medicines was discussed, in particular in the field of pharmaceuticals, and the official control authority batch release of biologicals (vaccines, human plasma derivatives and immunological veterinary medicinal products). As usual, issues of particular importance were the harmonization of testing programmes, exchange of experience and results, policy and guideline development for fostering mutual recognition, quality assurance, risk analysis and combating counterfeit drugs.

This annual conference is the opportunity for official control laboratories across Europe to share ideas and to develop common working procedures and policies in order to ensure the availability of high quality and safe medicines for patients in Europe. A representative from the European Commission was also present to ensure a seamless flow of information between the Network and his institution; representatives from associated members to the Network, Canada and Australia, were also participating in the meeting.

During the general session of the meeting, the delegations renewed the composition of the Advisory Group of the General OMCL Network. This body of 8 representatives from different European Control Laboratories supports EDQM in organising and structuring the Network and develops the necessary draft guidelines, policy papers etc. governing the Network. The Network has updated its policy concerning the rules and procedures of the Network and has also adopted additional guidelines on equipment and in particular UV-Visible and IR spectrophotometry. The evaluation of the progress in the implementation of Quality Assurance (QA) procedures continued and viewpoints were exchanged on the different models used to define control programmes based on risk assessment.

Other notable highlights from this year's conference are the adoption of the guideline for Batch Release of Human Papilloma Virus Vaccine, as well as the targeted discussion on rabies vaccines for veterinary use potency assay with a focus on refinement and improvement of the in vivo assay and an eventual aim of advancement towards 3R alternatives. Efforts are to begin on a work plan for further harmonising approaches in this field (Standard Operating Procedure, validation, QA).

The participants also unanimously decided to grant Morocco the status of Associate Member of the OMCL Network following their successful audit earlier this year.

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 47 member states.

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