



STRASBOURG, 20/06/08

Note for the Editors: The Official Medicines Control Laboratories (OMCL) Network was formed in 1994, under the aegis of the Council of Europe, 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. For more information, please go to: www.edqm.eu.

13th ANNUAL MEETING OF EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES (OMCL), STRASBOURG, FRANCE, 2-6 JUNE 2008

The European Directorate for the Quality of Medicines & HealthCare (Council of Europe) held its 13th Annual Meeting of the Official Medicines Control Laboratory (OMCL) Network in Strasbourg from 2 to 6 June 2008. This conference was organised at the new headquarters of the EDQM that was inaugurated in 2007.

201 participants from 32 countries, representing 58 OMCLs attended a general meeting and different specialised sessions during which the quality control of medicines was discussed, in particular in the field of pharmaceuticals, biotech products and the official control authority batch release of human vaccines, human blood and plasma derivatives and immunological veterinary medicinal products. As in previous years, issues of particular importance were the exchange of experience and results, policy and guideline development for fostering mutual recognition, quality assurance, risk analysis and combating counterfeit drugs.

The Network has continued to fine-tune policy documents and adopted notably revised documents detailing the Terms of Reference of the General European OMCL Network (GEON), the definition of an OMCL and the criteria for membership within the Network by clearly defining the obligations and benefits of such a membership.

A technical guideline for the qualification of automatic titrators was adopted which shall also be proposed as a recommendation document to the European co-operation for Accreditation (EA). A risk-based model for the selection of products to be tested was adopted and will now be challenged in the OMCL Network in a 2 years' trial phase.

The contribution of the OMCLs to combating counterfeit medicines was outlined as well as a future outlook on the importance of this work. In the near future, the EDQM will initiate the development of a secured IT platform to allow the data exchange on counterfeits between OMCLs and enforcement authorities.

Other notable highlights from the 2007/2008 work programme of the GEON, which were addressed at the this year's conference, are the launching of a pool of expertise of OMCLs that are technically competent in gene therapy and who will contribute to defining future control methods and standards based on laboratory tests.

The work plan of the General OMCL Network for 2008/2009 will optimise the collaboration with GMP inspectors and ensure that a good relationship and rationale is developed between OMCL testing and GMP application.

In the sessions dedicated to the Official Control Authority Batch Release (OCABR) of human vaccines and medicinal products derived from human blood, the network paved the way for further reduction of the number of animals used for batch release purposes by the OMCLs. Furthermore it became obvious that work sharing is increasingly used between the different OMCLs involved in OCABR thus responding to the challenge of optimal use of resources.

Scientific sessions on a number of topics included exchange of information on pre-pandemic and pandemic influenza vaccines to help ensure effective strategies are in place when needed.

The prototype of the central database for batches processed by the OMCLs during OCABR was presented and this new database will now be progressively implemented during the second half of 2008. Fifteen new or revised guidelines were adopted (6 in the field of vaccines, 4 for blood derived products and 5 common documents applying to both fields). They will be placed on the EDQM web site in due time.

The OMCLs involved in the control of veterinary immunological medicinal products reviewed the system of batch control by OCABR (which includes testing by the OMCLs) and Official Batch Protocol Review. This was done together with a representative from the European Commission and with representatives from industry. The new system has been in place since March 2007. The involved parties agreed that – despite a few difficulties at the start - the system of OCABR and OBPR was developing in a very promising way. Further progress was also made in the development of



an alternative method for the potency assay of rabies vaccines, subject to completion of its validation before implementation.

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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