16 June 2015, Strasbourg, France

OFFICIAL MEDICINES CONTROL LABORATORIES: 20 YEARS OF SHARED EXPERIENCE, 1-5 June, Brussels, Belgium

It was under this banner that the 20th Annual Meeting of the European OMCL Network took place in Brussels from 1 to 5 June 2015. This anniversary meeting was co-organised with the help and support of Belgium's Scientific Institute of Public Health (WIV-ISP), Federal Veterinary and Agrochemical Research Centre (CODA-CERVA) and Federal Agency for Medicines and Health Products (FAGG-AFMPS) and brought together more than 240 participants from 61 OMCLs as well as European medicines agencies and the European Commission. The Singapore Pharmaceutical Laboratory of the Health Sciences Authority (HSA) participated for the first time, after the HSA became an associated member of the Network in May 2014.

At the opening of the Annual Meeting, Dr Josiane Van der Elst, Director General DG Inspection of FAGG-AFMPS, stressed the importance of work-sharing and underlined the active role that the Belgian OMCLs have played since the General European OMCL Network (GEON) was founded in 1994.

In her welcome address, Dr Susanne Keitel, Director of the EDQM, thanked the OMCLs for their contribution and continued dedication to the work of the Network. She stated that “this 20th Annual Meeting is one of celebration” and that the Network had achieved “important milestones and landmark events over the last twenty years that have shaped it”.

The conference consisted of 9 sessions and featured renowned experts from a diverse range of specialist fields such as human and veterinary official control authority batch release and market surveillance of chemical and biological medicines including active ingredients, pharmaceuticals and biotechnology products. The Counterfeit/Illegal Medicines Working Group also met for the third time under the umbrella of the annual meeting, to discuss the different Network programmes which have been developed over the past years in the fight against falsified medicines.

The Network agreed to intensify its work on the testing of falsified biologicals which appear to be increasingly present in Europe. For this purpose, specific training programmes for OMCLs will be offered and an OMCL guidance document on the interpretation of screening results for peptides and proteins is under preparation. The Network will also seek closer collaboration with customs laboratories and customs authorities to target illegal medicines and new narcotic drugs.

Quality Management Systems (QMS) topics were addressed in several sessions during the meeting, notably the topic of ‘assurance of the veracity of test results’ in line with Chapter 5.9 of the ISO norm 17025. The discussions focused on Proficiency Testing Studies (PTS) and on alternative approaches when such studies do not exist in certain technical fields.

In the Official Control Authority Batch Release (OCABR) programmes, co-operation within the human OCABR and Veterinary Batch Release (VBRN) networks in addressing the practical and regulatory challenges related to parallel trade of immunological veterinary medicinal products (IVMPs), human vaccines and medicines derived from human blood, has begun. The OCABR Network has also intensified technical exchanges and work-sharing to tackle specific challenges related to methods, and to reduce the use of animals in regulatory testing.

During the General Session, the Network elected four (out of eight) new members of the GEON Advisory Group. The newly assembled group then elected a new Chairperson, Dr Dora Partassides, Laboratory for the Quality Control of Pharmaceuticals, Cosmetics and Food Supplements, Nicosia, Cyprus.
The next Annual Meeting of the European OMCL Network will be held in Paris, France, in co-operation with the French National Agency for Medicines and Health Products Safety (ANSM), from 23 to 27 May 2016.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 - E-mail: caroline.letarnec@edqm.eu

Note for the Editor: Further information is available on the internet site www.edqm.eu

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 OMCLs, 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.

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

There are now thirty-eight members of the European Pharmacopoeia Commission: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union. There are twenty-seven observers: Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Brazil, Canada, China, Georgia, Israel, Madagascar, Malaysia, Moldova, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, the Russian Federation, Senegal, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).

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.