

29 June 2022, Strasbourg, France

OMCL Annual Meeting 2022: European Strategies for Work Sharing and Collaboration in Testing of Medicines

The 27th Annual Meeting of the European Network of Official Medicines Control Laboratories (OMCLs) was held from 13 to 17 June 2022 at the Council of Europe, in Strasbourg (France). Over 230 participants – from 36 countries and representing 60 OMCLs – attended this meeting organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM). Nine sessions were held during the meeting week; the General Session alone drew over 180 participants. This event, after the 4th OMCL Falsified Medicines Symposium held in May in Rome, was the second major in-person meeting of the OMCL Network since restrictive COVID-19 pandemic measures were lifted.

Highlights of the General Session of the Annual Meeting included a presentation by representatives from the Malta Medicines Authority, participating in the meeting for the first time, on Malta's current project to set up an OMCL on their territory. Participants in the General Session also discussed action taken around the four strategic network goals, which included examples of activities of specialised centres (such as those related to the nitrosamine incidents) and intensified collaboration between OMCLs and inspection services at national level.

Specialised activities addressed at the General Session included the use of mass spectrometry in OMCLs for the testing of biotherapeutics and small molecule medicines, for example in cases of suspected falsification, to support quality defect reports and good manufacturing practice (GMP) findings or in connection with the detection and quantification of mutagenic impurities in medicines. Several member states also reported their experience of moving and refurbishing laboratory facilities. The implementation in OMCLs of rules on measurement uncertainty was addressed in the quality assurance part of the programme, as well as the pros and cons of remote audits.

A number of scientific presentations in the field of physico-chemical and biological analytics were given during the Annual Meeting, in the General Session and in other sessions, including the General Biologicals and the Pharmaceutical Sessions. In addition to classical medicines, they covered testing activities in the field of medical devices, illegal medicines, gene therapy products and pharmacy preparations.

The activities of OMCLs involved in Official Control Authority Batch Release (OCABR) were addressed during four sessions dedicated to the topics of immunological veterinary medicinal products (IVMPs), human vaccines, medicines derived from human blood and plasma (MDHBPs, such as clotting factors and immunoglobulins), and in a common session for general issues in human OCABR. All these sessions reviewed the highlights of activities over the last year and included scientific presentations, related in large part to reducing the use of animals in quality control testing. The review made apparent that in addition to the more than 1 600 lots of COVID-19 vaccines released in 2021, the network was able to avoid any disruption to the regular release of other human vaccines, MDHBPs and IVMPs. It also highlighted the importance of co-ordination among network members and pooling resources to address current and future needs.

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

The EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation, and the monitoring the application of quality standards for

safe medicines and their safe use. Its standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states.¹ Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

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*1. There are 40 members of the **European Pharmacopoeia Commission**: Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine, United Kingdom and the European Union.*

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.