Press release

22 September 2021, Strasbourg, France

OMCL Annual Meeting 2021: European Quality Control Programmes and Strategies for Medicines

The 26th Annual Meeting of the European Network of Official Medicines Control Laboratories (OMCLs) took place from 6 to 10 September 2021 and was held virtually due to the ongoing pandemic situation. The meeting, organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM), was attended by more than 500 participants from 42 countries over the course of the week.

Participants in the general session of the Annual Meeting discussed the growing need for specialised testing activities due to the rising complexity of chemical and biological analytical techniques, which requires the investment in new and often costly equipment. As a consequence, a number of network activities are conducted in specialised centres and over time specific networks and working groups have been established. Throughout the week, examples of specialised testing activities were presented and discussed, including the use of cell-based potency assays, for which an increase in capacities will become necessary. The network also reviewed potential needs for independent control testing of gene therapy products, a growing product group in the European market, and agreed to foster this initiative subject to necessary investments in equipment and human resources.

Other specialised activities addressed at the general session – as well as in several contributions during other sessions of the Annual Meeting week – were OMCLs' efforts in the determination of potential mutagenic contaminants such as nitrosamines and other compounds in medicines. The Official Control Authority Batch Release (OCABR) of COVID-19 vaccines was also highlighted in the general session. This procedure allowed these essential new medicines to reach the European market without delay, while assuring their high quality by means of independent batch-to-batch testing in an official control laboratory.

Despite the strain of the pandemic situation and the extra workload, the OMCL Network laboratories, thanks to effective contingency planning, maintained the level of regular official batch release of other biological products and market surveillance activities, thus contributing to the protection of public and animal health in Europe and beyond.

Other topics discussed at the general session were examples of regional co-operation within the General European Official Network (GEON), which contributes on a local level to work and resource sharing, one of the key principles of the network. Participants in the Annual Meeting also learned about the activities of the newly formed Heads of Medicine Agencies (HMA) Post-Marketing Risk Assessment Tool Working Group, carried out in support of prioritising market surveillance testing activities in Europe. This multidisciplinary group aims at extending risk assessment of products to factors arising after introduction of products on the market.

In reaction to the pandemic situation, the peer audit programme (Mutual Joint Audits) of the network has been transformed until further notice into full remote audits. This helped all OMCL members to become ISO 17025:2017 compliant by early 2021. This guarantees that OMCL Network members operate under a highly exacting and harmonised quality system.

A number of scientific presentations in the field of physico-chemical and biological analytics were held in different meeting sessions. They covered technical developments for market surveillance of medicines, as well as official batch release of vaccines and human blood derived medicinal products.

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Representatives from the Australian Therapeutic Goods Administration (TGA) participated as observers for the first time in the human vaccine OCABR session thanks to a Memorandum of Understanding signed in November 2020, thus extending the networking activity.

There was strong participation in the Veterinary Batch Release Network (VBRN) session, a meeting which did not take place at the 2020 Annual Meeting. Discussions focussed on the review of important scientific and procedural issues and the value of post-market surveillance testing for immunological veterinary medicinal products in addition to batch release activities.

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, Turkey, Ukraine, United Kingdom and the European Union.