Press release

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Annual OMCL Network meeting focuses on role of OMCLs during the COVID-19 pandemic

The annual meeting of the European Network of Official Medicines Control Laboratories (OMCLs) took place from 12 to 15 May 2020, online and with a reduced programme due to the COVID-19 crisis. It was attended by more than 350 participants from 39 countries and was organised by the EDQM.

The meeting, initially scheduled to take place in Oslo, Norway, was reorganised in collaboration with the Norwegian Medicines Agency (NoMA) in response to the public health concerns posed by the pandemic. Following an opening address by Audun Hågå, Director General of NoMA, Director of the EDQM Susanne Keitel thanked the organisers and participants, saying that "the attendance of so many delegates from across the globe demonstrated the importance of this annual gathering and highlighted the key role of the Network at the time of the COVID-19 pandemic".

The COVID-19 crisis and its impact on the work of OMCLs and the co-ordination of the Network was the common theme of all six topic sessions during the annual meeting week. Both the OMCLs at national level and the EDQM as the Secretariat of the Network have successfully taken measures to guarantee business continuity during the critical phase of the pandemic.

These measures included assuring release of essential biological medicines (e.g. vaccines and clotting factors) through the Official Control Authority Batch Release (OCABR) procedure. Network OMCLs also contributed to mitigating the crisis by providing their technical expertise in the assessment and quality testing of "COVID-19 products". These included medicines (e.g. antiviral agents, muscle relaxants), medical devices (e.g. gloves and masks) and biocides (mainly hand sanitisers), often acquired by member states from third-country sources. OMCLs also supported the fight against illegal online sales of these products. Experience in this new field of activity was shared during the meeting.

All the measures taken in the context of the COVID-19 crisis demonstrate the ability of the Network to respond rapidly to new developments. This work will continue to be of the utmost importance as potential new treatments and vaccines to prevent the spread of the disease are developed, and OMCLs are readying themselves to help bring these products to patients in good time once their safety and efficacy has been demonstrated. Independent oversight of these medicines and vaccines, including independent lab testing, will play an important role in continuously ensuring public health in Europe and beyond.

Building on the experience gained from the cases of nitrosamine contamination in medicines, the Network agreed that OMCLs would need to continue developing screening methods and to focus their testing campaigns on "at-risk" product groups rather than on individual products. This could become an important activity for OMCLs, in addition to their classical market surveillance and quality defect testing obligations, and could lead to new concerted Network programmes.

The need to continue developing specialised centres was identified as a critical key strategic goal of the Network. This measure will allow the Network to face new challenges linked to the independent quality testing of innovative products (e.g. gene therapy products, monoclonal antibodies, auto-injector systems and others), but will require investment in new analytical techniques and additional manpower. Participants also agreed that sharing of

knowledge, expertise and data, and in general the professional exchange with peers were the top priority values of the Network.

Following the conclusion of memorandums of understanding, representatives of the Taiwan Food and Drug Administration and of the Krasnoyarsk branch of the Roszdravnadzor OMCL, Russian Federation, participated for the first time in the closed sessions of the European OCABR Network as Observers. In addition to the COVID-19 focus topic, the sessions dedicated to OCABR of human vaccines and human blood-derived medicinal products covered issues related to adapting and evolving technical and procedural aspects in order to best carry out this critical activity.

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Note for the Editor: Further information is available on the internet site **https://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. Our 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.

1. There are 40 members of the European Pharmacopoeia Commission: *Austria, Albania, 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.*

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