25 May 2018, Strasbourg, France

OMCLs discuss Brexit and updates to medicines' testing methods at annual meeting

The Annual Meeting of the Official Medicines Control Laboratories (OMCLs) took place on 14-18 May in Sarajevo (Bosnia and Herzegovina). It was attended by 230 participants from 38 countries, representing 65 official laboratories and including a representative of the OMCL Network, the Taiwan Food and Drug Administration, which just joined the Network as an associated member. Representatives from Canada, Israel, the Russian Federation and Singapore also attended the event, which was jointly organised by the EDQM and the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (ALMBiH).

Opening the event Susanne Keitel, Director of the EDQM, thanked the organisers and participants, mentioning how "the attendance of so many delegates from across the globe demonstrates the importance of this annual gathering and highlights that the protection of public health transcends geographical and political borders."

The impact of Brexit on patients' access to good quality medicines

A special session on Brexit, involving manufacturers from the human vaccine and blood derived medicines sectors, looked at the implications for batch testing and batch release in the Official Control Authority Batch Release (OCABR) Network and helped to prepare for the situation after 31 March 2019, when the United Kingdom will leave the European Union. Stakeholders gave their views on the potential impact of the UK's withdrawal on the organisation of independent testing and discussed the needs of both the manufacturers and the OMCLs to ensure that regardless of the outcome of Brexit, patients continue to receive good quality medicines in a timely and efficient way. Mutual recognition of batch release after Brexit will depend on the outcome of the negotiations between the UK and the remaining EU Member States. Regardless of the decision on mutual recognition of OCABR and participation in the OCABR network, the UK will remain an important member of the General Network of OMCLs (GEON). The aspect of Brexit was also touched on in the session of the Veterinary Batch Release Network (VBRN) who are responsible for independent release of immunological veterinary medicinal products. In the VBRN session there was also a focus on the contribution of post market surveillance testing of IVMPs to the overall control strategy for this type of product.

Israel extends participation in OCABR activities

Among the various sessions held during the event, the OCABR Network focused on vaccines and human blood derived products. Following the signature of a Memorandum of Understanding with the OCABR Network in 2017 on activity related to blood derived medicinal products, Israel participated for the first time in the blood session; the country already participates in the vaccine sessions which include mutual recognition in the context of the Agreement on Conformity Assessment and Acceptance of industrial products (ACAA) with the European Union (EU).

Testing medicines and generics

A session on pharmaceuticals focused on practical experiences in testing medicines by applying physico-chemical and pharmaceutical analytical methods, with a focus on success stories emerging from the collaboration within the Network. Finally, regarding products authorised by the Mutual Recognition or Decentralised Procedure (MRP/DCP), the implementation of the Heads of Medicines Agency (HMA) risk-based model, which will support the products selection for market surveillance programmes, was one major point of discussion.

Alternative testing methods for biologicals
During a session on biologicals, the OMCLs reported on selected aspects from their testing activities of biologicals. The achievements of the European Pharmacopoeia and the OMCLs in the application of the 3R principles (Replacement, Reduction and Refinement) and in the development of alternative testing methods were also presented, along with an overview of the results of the Biological Standardisation Programme (BSP) and the Bio-Proficiency Testing Scheme studies (Bio-PTS) Programme.

Testing for counterfeit/illegal medicines
Work was brought forward in the field of Counterfeit/Illegal Medicines too, where discussions focused on authenticity testing strategies, new training sessions for small-sized OMCLs, closer collaboration within the OMCLs Network and improvements to the Know-X database – the secured IT platform which includes records of falsified medicines cases shared between OMCLs, police, customs and health authorities.

New ISO requirements
The new version of ISO 17025:2017 on "General requirements for the competence of testing and calibration laboratories" was also discussed and specific attention was paid to how OMCLs will prepare for its implementation and how this revised standard will affect the Mutual Joint Audit (MJA) Programme.

Illustrating the role of the OMCLs in protecting public health
Finally, the work accomplished to communicate the role and achievements of the OMCLs in Europe was also presented: a new communications tool-kit will support OMCLs across Europe in raising awareness on their work, engage with stakeholders and showcase their success stories.

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 **https://www.edqm.eu/**
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 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 thirty-nine members of the European Pharmacopoeia Commission: *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, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, 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 47 member states.