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Enhanced quality control of medicines within European Official Medicines Control Laboratories

2017 meeting of Official Medicines Control Laboratories (OMCLs) emphasised work sharing and information exchange for the benefit of public health. Participants were also introduced to the European Commission's Vaccine to Vaccine project (VAC2VAC), for promoting the reduction of animal use in testing the safety of vaccines.

Representatives of 61 OMCLs from 38 countries (including non-European countries, such as Canada, Israel, Kazakhstan and Singapore) met between 15 and 19 May 2017 in Budapest for the annual meeting of the European OMCLs' Network. These official control laboratories share the task of controlling the quality of medicinal products available on the market, for the benefit of human and animal health throughout Europe.

This one-week meeting, hosted in rotation by Member States and organised this year with the support of the Hungarian National Institute of Pharmacy and Nutrition (NIP), functions as an exchange platform for updating the competence and coordinating the work of all OMCLs. In addition, important decisions are taken, such as those concerning the way vaccines and other medicines are monitored through laboratory controls across the different European Member States. Experts from all Member States come together to exchange the knowledge and experiences in testing medicines, a fundamental aspect to ensuring the quality of medicines through a pan-European perspective.

The sharing of resources and expertise also makes it possible to avoid duplication of work and ensures that all laboratories across Europe are familiar with the latest technologies and methods of analysis, so they can establish themselves as excellent centres of expertise within the Network. The result is a proper pan-European surveillance system which allows national authorities to work together and exchange alerts through reliable channels of experts. This is what ensures that all European patients and consumers can benefit from good quality medicines, regardless of their nationality.

Result recognition and rapid information exchanges

During the meeting in Budapest, results and future programmes for proficiency testing studies were discussed. These essential tools not only demonstrate expertise in different laboratory techniques, they also lay the basis for the mutual recognition of test results by the various participating Member States. In particular, discussions focused on ways to maintain the common Quality Management Systems that all OMCLs have implemented on the basis of standard ISO/IEC 17025. Laboratories also discussed their strategy for sharing information concerning quality issues of tested medicines: a series of information-exchange tools were assessed in terms of their effectiveness and suitability for allowing reliable exchanges of important scientific and product information.

These efforts are essential to encourage transparency and trust among the control laboratories of Europe. They lay the basis for efficient and rapid reactions in the event of concerns about the quality of medicines on the market in any given European country. In a new development, OMCLs agreed to initiate a pilot phase for sharing market surveillance information on nationally authorised veterinary vaccines.

In the field of counterfeit/illegal medicines, analytical programmes were discussed together with possible updates to Know-X, the database collating reports on counterfeit/falsified medical products

detected in Council of Europe Member States. This database, which plays a key role in encouraging co-operation and in providing all European officials with up-to-date intelligence on counterfeit/falsified medicines across Europe, will undergo some significant updates to streamline its efficiency and encourage more stakeholders to use it.

Towards replacement of animal testing

In line with the network's commitment to reduce animal use in testing the quality of medicines, the new Vaccine to Vaccine project (VAC2VAC)[1] was highlighted in various sessions. The project aims to develop and validate non-animal tests for batch release testing and is part of the Innovative Medicines Initiative (IMI)[2], a public-private partnership co-funded by the EU Commission to improve the development of medicines in Europe. The goal was to make all involved OMCLs aware of the initiative and of the possibility of contributing to this important work once the collaborative study phase begins. The 3Rs principle, which advocates the reduction, replacement and refinement of the use of animal tests, is recognised as a priority by the OMCL network and the EDQM.

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NOTES FOR THE EDITORS:

The Council of Europe's **EDQM** is a leading organisation in the protection of public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. EDQM standards, such as the European Pharmacopeia are legally binding in Member States and are recognised as a scientific benchmark world-wide. The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

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.
Further information is available on the website www.edqm.eu

The main objective of the **General European Network of Official Medicines Control Laboratories (GEON)** is to ensure the consistent quality of medicinal products for human and veterinary use across Europe and to foster mutual recognition of the results of quality control testing. The GEON was established in 1995, following a joint decision by the European Commission and the Council of Europe to promote coordination in the quality control of identical medicinal products on the European market. The European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe coordinates the activities of the GEON, as part of its surveillance activities for marketed medicines.

The **OMCL Network** currently comprises 69 public laboratories in 41 countries (36 in Europe, 5 outside of Europe) that are independent from manufacturers and provide human and technical resources to implement testing programmes.

The main areas covered by the OMCL surveillance programmes are:

- market surveillance of pharmaceutical products that have received a Community Marketing Authorisation (which is valid throughout the EU/EEA) or have been authorised through the

[1] More information on the project can be found here: http://www.vac2vac.eu/
[2] More information on the initiative can be found here: https://www.imi.europa.eu/

Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP). The choice of products to be tested is made using a risk-based approach;

- general Market Surveillance Studies (MSS) on products marketed throughout Europe, for example generic drugs and herbal preparations;
- specific control of a number of biological products (blood derivatives and vaccines for human or veterinary use) prior to their release to the market;
- testing of counterfeit/illegal medicines; the Network issues individual counterfeit/illegal product testing reports via its Know-X database, which contained 2,500 OMCL reports as of April 2016;
- testing of active pharmaceutical ingredients (APIs) used in the manufacture of medicines;
- testing of unlicensed pharmacy preparations.

Official Control Authority Batch Release (OCABR) of Biologicals for Human Use
The activities of the human OCABR Network ensure the harmonised application of Article 114 of EU Directive 2001/83/EC as amended, by fostering the mandatory mutual recognition of batch release for human vaccines and medicinal products derived from human blood and plasma.

OCABR/OBPR of Immunological Veterinary Medicinal Products (IVMPs)
The activity of the Veterinary Batch Release Network (VBRN) focuses on the independent control of immunological veterinary medicinal products (IVMPs) according to Articles 81 and 82 of EU Directive 2001/82/EC, as amended.

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.*

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