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OMCL Network successfully meets higher demand for independent experimental testing through enhanced work-sharing and collaboration

GEON Annual Meeting – 28-29 May 2016, Paris

Joint organisers: Agence nationale de sécurité du médicament et des produits de santé (ANSM), Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses), Agence nationale du médicament vétérinaire (ANMV) and the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe

The General European OMCL Network (GEON) successfully met increasing market demand in 2015 for independently testing the quality of medicines, blood-derived medicinal products and vaccines in Europe.

Reviewing the various work programmes of the Official Medicines Control Laboratories (OMCL) Network, this year's Annual Meeting heard that in 2015, the Official Control Authority Batch Release (OCABR) Network carried out 12% more protocol reviews and testing of final lots of blood-derived medicinal products under the OCABR system, compared to the previous year.

In 2015, the OCABR Network dealt with a combined total of almost 12,000 final lots proposed for OCABR for human blood-derived medicinal products and vaccines, independently confirming their quality through experimental testing and protocol review before they reached patients.

Representatives of 61 OMCLs from 38 countries (including Canada, Israel and Singapore) also heard that more than 1,000 product-testing projects were added to the OMCL Network's 2015 work programme for the market surveillance of medicinal products authorised in the European Economic Area (EEA) via the Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) system. The 996 test reports entered in the OMCL database in 2015 (slightly more than the 987 entered in 2014) represent a 23% increase compared to 2013, in the context of an average 10% increase per year since 2011.

Most of the MRP/DCP products tested in 2015 were generic drugs, reflecting their increasingly important role in healthcare systems, especially in those areas where safe, high-quality, cost-competitive medicines are a real necessity for patients. It is reported that 55% of all dispensed medicines in Europe are generics, and savings relative to branded products are estimated to be around 20 percent in the first year of generic entry in the market, rising to 25 percent after two years.

The sharing of workloads, resources and expertise among the OMCL Network members makes it possible to avoid duplication of work and gives them access to the latest technologies and selective methods of analyses. This and the mutual recognition of test results mean that member states can ensure an adequate market surveillance of authorised medicinal products, while reducing costs and ensuring the quality of medicines on the market in the interests of public health.

Based on these principles, the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe, which co-ordinates the GEON, launched a collaborative database system for MRP/DCP products in July 2007 to ensure communication between the participating OMCLs. As of December 2015, this database held some 7,300 testing records, with contributions from 34 OMCLs.



In practice, work-sharing for market surveillance across the OMCL Network produces a nine-fold benefit: during the period 2002 to 2015, a participating member state testing one product received test results for an average of nine products generated by other member states, enabling each OMCL to achieve a far higher coverage of products than it would be capable of doing on its own.

The 2016 GEON Annual Meeting provided an opportunity for OMCLs to further enhance this work; it was a forum for exchanging the latest technical information and discussing strategies for increasing the value of the GEON's contribution to public health: how to improve communication, optimise work-sharing and maintain coverage and depth of competence whilst remaining flexible and reactive in response to increasing demand in an evolving pharmaceutical world.

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NOTES FOR EDITOR:

Further information is available on the website 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 world-wide. The European Pharmacopoeia is legally-binding in Member States¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

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 and to foster mutual recognition of the results of quality control testing.

The **GEON was established in 1995**, following a joint decision in May 1994 by the European Commission and the Council of Europe to promote co-ordination and so avoid duplication between EEA member states in terms of the quality control of identical medicinal products on the market. The European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe co-ordinates the GEON, as part of its surveillance activities for marketed medicines.

Membership of the Official Medicines Control Laboratories (OMCL) Network is open to member states and Observers of the *Convention on the Elaboration of a European Pharmacopoeia* (an international treaty adopted by the Council of Europe in 1964). The signatories to the Ph. Eur. Convention – 37 member states and the European Union as of April 2016 – are committed to achieving harmonisation of the quality standards for safe medicines throughout the European continent and beyond (in addition to the member states there are 28

¹ There are thirty-eight 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, 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.



Observers, including WHO). The OMCL Network thus ensures that patients receive the same quality of pharmaceutical products throughout Europe and beyond.

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:

Full members (56 labs in 33 countries): Austria, Bosnia Herzegovina, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, The Former Yugoslav Republic of Macedonia, The Netherlands, Norway, Poland, Portugal, Romania, Republic of Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Ukraine, United Kingdom.

Associated members (10 labs in 9 countries): Australia, Belarus, Canada, Germany, Israel, Republic of Kazakhstan, Morocco, Russian Federation, Singapore.

Limited members (3 labs in 3 countries): Bulgaria, Croatia, Romania.

The newest member is the OMCL of Kazakhstan, which became an associated member of the Network in September 2015 after successfully undergoing a Mutual Joint Audit (MJA).

This **international collaboration reduces public health expenses** by sharing resources, and also influences future development through harmonised common standards. The sharing of workloads, resources and expertise among the OMCLs makes it possible to avoid duplication of work and gives them access to the latest technologies and selective methods of analyses. Special emphasis is placed on the establishment and maintenance of a common Quality Management (QM) system through the organisation of mutual joint audits and mutual joint visits. This system is necessary to facilitate mutual recognition of quality control test results amongst laboratories and to make the best use of resources. In addition, training courses are provided and guidelines on quality assurance are published and updated regularly.

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 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.

This Network elaborates guidelines that define the testing requirements for each product and establishes administrative procedures and guidance for OCABR-related activity in order to facilitate mutual recognition. These guidelines are published exclusively on the EDQM's website.

Through a review of manufacturers' protocols and targeted OMCL testing, the goal is to confirm that batches comply with the specifications defined in the relevant approved marketing authorisation dossier. It allows Official Control Authorities to test each batch of human vaccines and blood-derived medicinal products before they are placed on the market. Compliant batches receive an EU certificate which is accepted within the EU/EEA, Switzerland and Israel (the latter for human vaccines only), and is recognised as a sign of quality in other parts of the world.

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.

Article 82 of the Directive allows a member state, for human or animal health reasons, to request samples of each batch of a given IVMP to be submitted to a competent authority for control by an OMCL before it is placed on the market, and establishes conditions under which a restricted test scheme can be applied. This is referred to as the OCABR procedure.

It involves the testing of samples and a review of the manufacturer's batch protocol to confirm compliance with the approved marketing authorisation. The results of the testing must be mutually recognised by all other competent authorities requiring OCABR for that product. The list of products eligible for OCABR testing is regularly reviewed by the Network.

According to Article 81 of the Directive, IVMPs not eligible for OCABR can be controlled by checking the manufacturer's batch protocol; this is referred to as Official Batch Protocol Review (OBPR).

In both cases, compliant batches receive either an OCABR or OPBR EU certificate which is accepted within the EU/EEA and Switzerland and is also recognised as an indication of quality in other countries.

A series of product-specific guidelines and administrative procedures have been developed by specialised OMCLs within the Network in close collaboration with the European Commission, the European Commission's Veterinary Pharmaceutical Committee and industry.

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.