
# EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES[1]

The European Network of Official Medicines Control Laboratories (OMCL) established in 1995 is the consequence of a joint decision taken by the European Commission and the Council of Europe to promote co-ordination and so avoid duplication between European countries in terms of the quality control of identical medicinal products on the market. The OMCL Network, which is open to member states and observers of the European Pharmacopoeia Convention, thus ensures that patients receive the same and the expected quality of pharmaceutical products throughout Europe and beyond.

Created to prevent substandard medicinal products from reaching patients and compromising the efficacy of their treatment, the OMCL network nowadays brings together OMCLs from more than 40 countries. Operating independently of manufacturers and thus without any conflict of interest, this network allows pooling of resources and latest technologies with a view to saving public money and sharing expertise and best practices across European laboratories. Its work gives member states the support they need to monitor the quality of medicines and to ensure that no substandard product reaches European patients, potentially putting their health or the efficacy of their treatments at risk.

This pan-European cooperation network offers several advantages, including work-sharing and mutual recognition of test results. It operates on the basis of common standards, procedures and guidelines, and its work ensures that competent authorities at Member State level do not have to duplicate efforts, hence reducing the time, resources and costs related to testing medicinal products.

In 2017, more than 1,400 product-testing projects were added to the OMCL Network's work programme for the market surveillance of medicinal products authorised in the European Economic Area (EEA)[2] via the Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) system. As of December 2017, the MRP/DCP database was holding some 9,900 product testing records, with contributions from 34 different OMCLs.

Some 70 individual counterfeit/illegal products testing reports were issued by the network in 2017 via the OMCL's Know-X database, which contained 3,700 OMCL reports as of July 2018.

In practice, OMCLs participating in the co-ordinated surveillance programmes benefit in return from access to a far greater number of test results than they would be able to generate individually, avoiding duplication of work and thus reducing costs.

Special emphasis is placed on establishing and maintaining 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 OMCL NETWORK AT A GLANCE

- A network of independent public laboratories appointed by the national authorities and coordinated by the EDQM;

[1] As of 1/08/2018

[2] The European Economic Area is an economic union consisting of 31 European states: the 28 member states of the EU and 3 of the 4 member states of the European Free Trade Association (EFTA): Iceland, Liechtenstein and Norway.


- Main objective: 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;
- Currently 36 European and 5 countries outside of Europe participate in the various activities/programmes of the Network;
- Around 70 laboratories pool human and technical resources to implement testing programmes.

## THE OMCL NETWORK'S ACTIVITIES

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 MRP and DCP system. The choice of products to be tested is made using a risk-based approach. For example, in the latter case, the most tested products during 2017 in the group of MRP/DCP products were generic medicines, including these active pharmaceutical ingredients (APIs): hydrochlorothiazide, amlodipine, valsartan, telmisartan and perindopril (treatment of high blood pressure), quetiapine and aripiprazole (antipsychotic), pregabalin (antiepileptic), pantoprazole (gastric acid blocker) and voriconazole (antifungal);
- general Market Surveillance Studies (MSS) on products marketed throughout Europe and beyond, for example generic drugs and herbal preparations;
- specific testing (using the Official Control Authority Batch Release procedure) 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 for internal use via its Know-X database, which contained 3,700 OMCL reports as of July 2018;
- testing of active pharmaceutical ingredients (APIs) used in the manufacture of medicines;
- quality monitoring of stockpiled medicines; and
- testing of unlicensed pharmacy preparations.