Fact sheet

European Network of Official Medicines Control Laboratories

The OMCL Network at a glance

- A network of independent public laboratories appointed by national authorities and co-ordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM).
- The network's main objectives are 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 countries and seven non-European partners participate in the various network activities and programmes.
- Around 70 laboratories pool human and technical resources to implement testing programmes.

Background and mission

In 1994, the European Commission and the Council of Europe made a joint decision to promote co-ordination in the quality control activities of European OMCLs, and the European Network of Official Medicines Control Laboratories (the OMCL Network) was set up by the EDQM one year later. It is open to member states and observers of the Convention on the Elaboration of a European Pharmacopoeia (the European Pharmacopoeia Convention).[1] It ensures that patients in Europe and beyond receive pharmaceutical products meeting the same quality requirements.

Created to prevent substandard medicinal products from reaching patients and potentially putting their health or the efficacy of their treatment at risk, the OMCL Network nowadays brings together OMCLs from more than 40 countries. Operating independently of manufacturers and thus without any conflict of interest, the network allows pooling of resources and latest technologies with a view to rationalising the expenditure of public funds and sharing expertise and best practices among European laboratories and beyond. Its work gives member states the support they need to monitor the quality of medicines marketed in Europe.

Benefits

This pan-European co-operation 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 national competent authorities can avoid duplication of effort. This allows medicinal products to be tested in a more efficient and cost-effective manner. 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.

Special emphasis is placed on establishing and maintaining a common quality management 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 among laboratories and to make the best use of resources. In addition, training courses (including hands-on training for smaller groups and training visits on specific topics organised for individual members) are provided, and discussion groups, workshops and other scientific events organised. Guidelines on quality assurance are also published and updated regularly.

1. List of European Pharmacopoeia members and observers.

The OMCL Network's activities

In 2021, 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 January 2022, the MRP/DCP Product Testing database contained almost 14 700 testing records, with contributions from 34 different OMCLs. Some 130 individual falsified or illegal product testing reports were issued by the network in 2021 via the Know-X database, which contained 4 100 OMCL reports as of January 2022.

The main areas covered by the OMCL surveillance programmes are:

- market surveillance of pharmaceutical products that have received a Community Marketing Authorisation (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. With respect to the MRP/DCP product testing programme, the most frequently tested products in 2021 were generic medicines, including the following active pharmaceutical ingredients (APIs): hydrochlorothiazide (hypertension), amlodipine (hypertension and angina pectoris), ramipril (hypertension), levothyroxine sodium (hypothyroidism), rosuvastatin (hypercholesteraemia), ezetimibe (hypercholesteraemia), losartan (hypertension) and praziquantel (anthelminthic treatment). Regarding the Centrally Authorised Products (CAP) Sampling and Testing Programme, this annual testing activity has been carried out jointly by the European Medicines Agency (EMA) and the EDQM since 1999, with a focus on medicines authorised via the centralised procedure;
- general market surveillance studies (MSSs) 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), including COVID-19 vaccines, prior to their release to the market. In 2021, OMCLs released more than 1 600 lots of the four COVID-19 vaccines conditionally approved in the EU, representing billions of doses all combined;
- testing of falsified or illegal medicines. The network issues individual testing reports for internal use via its Know-X database and carries out specific market surveillance testing programmes (Market Surveillance Studies on Suspected Illegal Products, MSSIP). By the end of 2021, five studies in total had been finalised and the results published on the EDQM website;
- testing of APIs used in the manufacture of medicines including specific API fingerprint studies (MSSFP). An API fingerprint is a specific analytical profile that includes information on the physico-chemical properties of the substance. API fingerprint studies are performed to identify substandard or falsified APIs, which represent a threat to patient health;
- quality monitoring of certain medical devices;
- testing of unlicensed pharmacy preparations.

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2. The European Economic Area is an economic union consisting of 30 European states: the 27 member states of the European Union and three of the four member states of the European Free Trade Association (EFTA): Iceland, Liechtenstein and Norway.