

The European Network of Official Medicines Control Laboratories (OMCLs)



WORKING TOGETHER TO
PROTECT PUBLIC HEALTH
IN EUROPE EVERY DAY

www.edqm.eu

OMCLs

OFFICIAL
MEDICINES
CONTROL
LABORATORIES



CONTROLLING MEDICINES IN EUROPE

Strict control procedures throughout the entire life cycle of all medicines.

Before they reach patients and animals, **medicines are subject to marketing authorisations and strict control procedures.** Moreover, the quality, safety and efficacy of medicines continue to be evaluated after they have entered the market: **throughout their entire life cycle**, medicines can be selected by the authorities for independent quality control involving laboratory testing and other monitoring measures. Without these independent controls, patients and users of medicines in Europe could be exposed more often to defective (e.g. contaminated) or falsified and illegal products.

WHAT ARE THE EUROPEAN OMCLs?

Independent public laboratories with unique expertise to test medicines.

The **Official Medicines Control Laboratories (OMCLs)** are public institutions helping national competent authorities to control the quality of medicines.

By testing medicines independently of manufacturers (that is, without conflicts of interest and with guaranteed impartiality), the OMCLs have a fundamental role in ensuring the **quality, safety and efficacy of medicines.** When it comes to medicines in Europe, OMCLs play a major role in contributing to the overall welfare of patients and animals.

WHAT BENEFITS DO OMCLs BRING FOR EUROPEAN CITIZENS?

Safe medicines, fit for treating or preventing health problems in Europe.

Having a strong network of OMCLs serves the interests of all patients and users of medicines in Europe. A well-equipped OMCL, in terms of state-of-the-art technologies and human expertise, is essential for all countries: the OMCLs apply the strict monitoring and testing procedures that ascertain the quality of human and veterinary medicines. OMCLs establish surveillance programmes to test products on the market on the basis of specific risk criteria, randomly or in cases of public health emergencies. In addition, for certain sensitive products (e.g. vaccines or blood-derived products) they may test batches before they reach the market. This way, Europeans can be confident: OMCLs take all the measures within their power to ensure that medicines available on the market are of good quality and safe and fit for treating or preventing health problems.



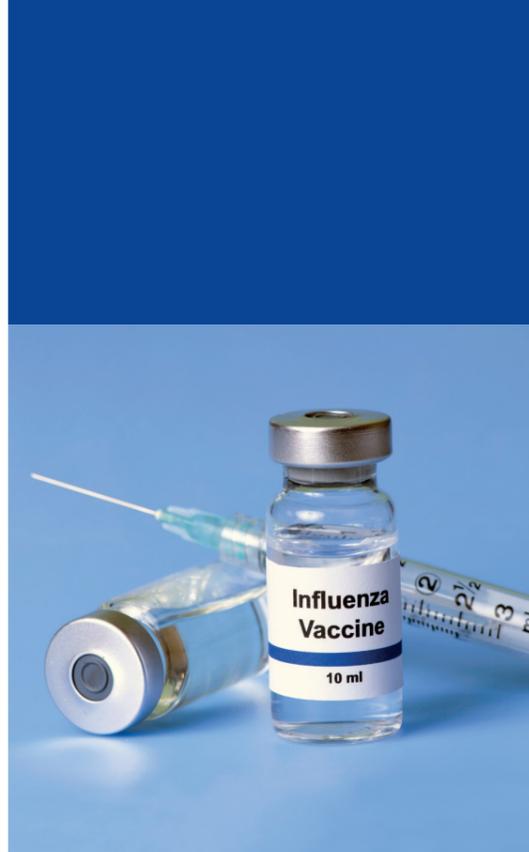
HOW DO OMCLs WORK IN PRACTICE, AT NATIONAL AND EUROPEAN LEVEL?

Contributing to medicine quality for the benefit of European patients and consumers.

OMCL activities

The OMCLs work in close co-operation with their national competent authorities (e.g. Ministries of Health/Agriculture or Medicines Agencies). Work is also carried out in support of other authorities, such as national enforcement agencies, police and customs.

These pages illustrate and describe some of the tasks carried out by OMCLs (depending on the scope of their activities).



- Controlling the quality of medicines for human and veterinary use at different phases of their life cycle (**pre-authorisation testing, pre- and post-marketing surveillance**); covered products range from chemically defined and biological products, such as **vaccines and blood-derived products**, to products manufactured using **biotechnology**.

- Providing analytical evidence to support **investigations into suspected cases of falsified medicines** in line with the **MEDICRIME Convention**¹, abuse or other related issues.
- Controlling **packaging and labelling** of medicines.
- Developing testing methods, including work related to the **European Pharmacopoeia**² and the establishment of reference standards for the control of medicines.



- Performing analysis of all types of medicines, including **herbal, homeopathic and radiopharmaceutical products**, as well as their **active pharmaceutical ingredients (APIs) and excipients**.



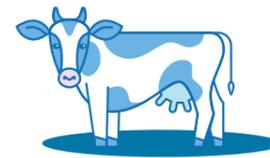
- Providing laboratory expertise for marketing authorisation dossiers (both for the first authorisation of a medicine for the European market and during its entire life cycle), as well as for **pharmacovigilance assessments, investigations of quality defects and inspections of medicines manufacturers** to ensure compliance with Good Manufacturing Practice (GMP).
- And for some OMCLs: laboratory testing on **medical devices, diagnostic products, premixes for medicated feeding stuffs for veterinary use, food supplements, cosmetics and ink for tattoos**.

¹ The Council of Europe's MEDICRIME Convention is the first international criminal law instrument that addresses the counterfeiting/ falsification of medical products. It establishes as offences: manufacturing, supplying or offering to supply, and trafficking falsified medical products; falsification of documents; any unauthorised manufacturing or supplying of such products that does not comply with requirements. The Convention lays down measures to prevent crimes and protect victims and witnesses, including a co-operation framework for health, police and customs authorities at national and international level.

² The European Pharmacopoeia (Ph. Eur.) is the collection of quality standards for the control of medicines in the signatory members (including the European Union) to the Convention on the Elaboration of a European Pharmacopoeia. These quality standards are legally binding and require mandatory compliance in order to obtain marketing authorisation for a medicinal product in Europe.

WHO BENEFITS FROM THE WORK OF THE OMCLs?

Supporting European authorities in protecting the health of European patients and consumers across the entire product chain.



ANIMALS



PATIENTS



PRE-AUTHORISATION OF NEW MEDICINES ON THE MARKET

FOR NEW MEDICINES:

The scientific analysis provided by the laboratories supports the work of National Competent Authorities (the medicines agencies) and their quality assessors in verifying the authorisation dossier of a new medicinal product.



SOLID SCIENTIFIC EXPERTISE FOR MINISTRIES, POLICE, CUSTOMS AND COMPETENT AUTHORITIES AT NATIONAL LEVEL.

FOR SENSITIVE PRODUCTS OF INTEREST TO PUBLIC HEALTH:

On certain products, the Official Control Authority Batch Release (OCABR) Network (a specific group of the OMCLs) provides the scientific analysis to support National Competent Authorities (the medicines agencies) and the Pharmaceutical industry in ensuring that each individual batch of sensitive products is fit for use.



INSPECTORS

MONITORING MEDICINES ALREADY ON THE MARKET

MEDICINES ALREADY ON THE MARKET (in the legal distribution chain): post-marketing surveillance testing.

The OMCLs' scientific analysis supports the work of the inspectorates or pharmacovigilance groups of National Competent Authorities (medicines agencies).



CUSTOMS



POLICE

FALSIFIED MEDICINES (in the legal or illegal distribution chain):

The OMCLs support enforcement groups within National Competent Authorities (medicines agencies), as well as police, customs, courts, but also inspectorates tasked with controlling food and cosmetics.

WHAT IS THE ADDED VALUE OF THE GEON, THE GENERAL EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES?

GEON: a co-ordinated network of OMCLs to ensure effective performance and rapid response at pan-European level.

OMCL activities at European level: the General European OMCL Network

In reflection of the global dimension of medicines markets, the OMCLs co-operate actively at European level, too. They do so through the General European OMCL Network (GEON). In addition, a number of non-European OMCLs have joined the Network as associated members.

This network is co-ordinated by the **European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe** in Strasbourg, the international organisation upholding **human rights, democracy and rule of law in Europe**. The network supports laboratories across Europe in making the best use of their **expertise, technical capacity and financial resources**, so as to ensure appropriate control of medicines in Europe. The activities of the GEON are funded in part by the European Union.

With its mission of protecting public health in Europe, the EDQM/Council of Europe strives to bring added value to the work of the GEON by:

- Promoting work-sharing amongst the more than 70 OMCLs from over 40 countries, favouring cost-efficient testing activities and market surveillance studies.
- Ensuring the mutual recognition of test results carried out by all European OMCLs to avoid duplication of work.
- Harmonising testing activities through the use of common standards based on legal requirements.
- Promoting exchange of knowledge and expertise to ensure state-of-the-art analytical procedures for all OMCLs.
- Providing discussion platforms where OMCLs can share scientific information, approaches and strategies.

Pan-European co-ordinated surveillance programmes

The GEON implements different programmes for testing medicines at the OMCLs: the Centrally Authorised Procedure (CAP) Product Sampling and Testing Programme (run jointly with the European Medicines Agency), the Post-Marketing Surveillance Scheme for Mutual Recognition Procedure- (MRP) and Decentralised Procedure- (DCP) products, the Market Surveillance Study (MSS) Programme and the Official Control Authority Batch Release (OCABR) testing activities for certain biological products and immunological veterinary medicinal products (IVMPs).

Benefits

OMCLs participating in the co-ordinated surveillance programmes benefit in return from access to a far greater number of surveillance test results than they would be able to generate individually³, avoiding duplication of work and thus reducing costs.

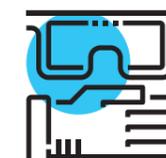
³ For a history and achievements of the different programmes, please refer to the OMCL Network pages on www.edqm.eu

SHARING OF EXPERTISE AND BEST PRACTICES

MORE THAN 70 OMCLS OVER 40 COUNTRIES



Methods



Technical tools



Quality standards



Expertise



Training



So here is why we need OMCLs



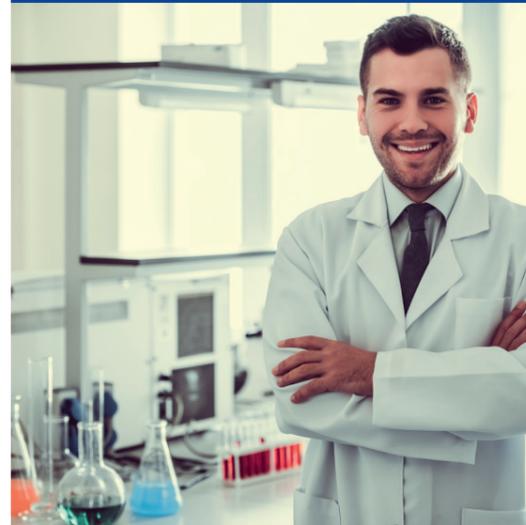
How does the GEON ensure up-to-date competence and efficiency of the OMCLs?

The GEON supports the OMCLs in their tasks of bringing scientifically based added value and providing timely advice to governments, authorities and citizens. The GEON helps OMCLs by:

- Implementing a **Quality Management System (QMS)** completely harmonised across Europe and run in accordance with the ISO/IEC 17025 standard.
- Ensuring strict compliance with the **quality standards for medicines set by the European Pharmacopoeia**.
- Providing **Guidelines** on the QMS, to support the smooth application of ISO/IEC 17025 requirements for OMCLs.
- Organising **Mutual Joint Audits/Visits, Training Visit Programmes (MJA/MJV/TV), Hands-on Training Sessions and Proficiency Testing Schemes (PTS)** to monitor the implementation, maintenance and further development of the QMS.
- **Running training projects to enhance the transfer of know-how** within the Network, i.e.: technical and quality management training, as well as tuition programmes on IT tools.
- Providing **safe and rapid IT platforms** allowing the exchange of confidential information which facilitates the **mutual recognition of test results**.



With their unique **scientific expertise** in the field of medicines and their **independent statute**, the OMCLs play an important role in supporting the protection of public health in Europe.



To meet the challenges posed by quality defects or by substandard and falsified medicines, it is essential to continue investing in the technical and scientific capacity of OMCLs throughout Europe; this should also be a priority for national public health protection policies.





With their surveillance activities, these public laboratories contribute to ensuring the quality of human and veterinary medicines in Europe.

For more information about the European OMCL Network and its activities, please contact:

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