



THE EDQM AT A GLANCE

Protecting human and animal
health in Europe with good quality
medicines and healthcare

European Directorate for the
Quality of Medicines & HealthCare



Contents

ABOUT THE EDQM	4
WHAT DOES THE EDQM DO?	6
HOW DOES THE EDQM FUNCTION?	10
WHO BENEFITS FROM THE WORK OF THE EDQM?	14
EDQM: ADDED VALUE AND GLOBAL IMPACT	18

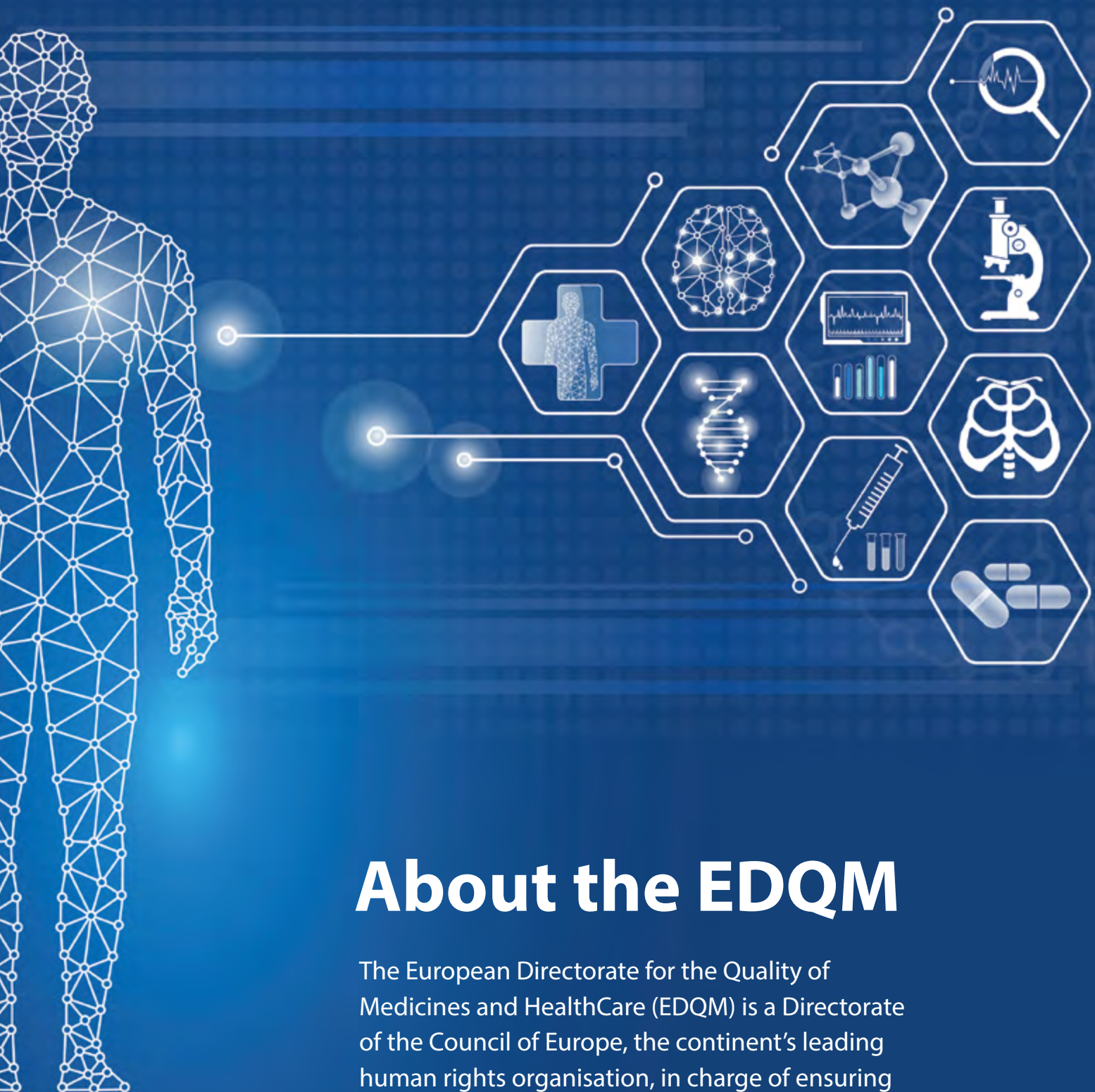
French edition

L'EDQM en bref

Translation of this publication may be carried out by external parties. However, it must be authorised by the EDQM, Council of Europe, before being reproduced or published in any form or by any means, electronic (CD-Rom, internet, etc.) or mechanical, including photocopying, recording or any information storage or retrieval system. All other correspondence concerning this document should be addressed to the EDQM (<https://go.edqm.eu/hd>).

Photos: © Council of Europe, Shutterstock.com
Layout: Big Family, Strasbourg

© Council of Europe, October 2019
Printed at the Council of Europe



About the EDQM

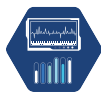
The European Directorate for the Quality of Medicines and HealthCare (EDQM) is a Directorate of the Council of Europe, the continent's leading human rights organisation, in charge of ensuring the **basic human right of access to good quality medicines and healthcare in Europe.**

The EDQM protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. The standards set by the EDQM are recognised scientific benchmarks and are applied in Europe and beyond.

The EDQM's work covers a wide range of areas, each requiring specific expertise and scientific know-how. It is responsible for:



establishing the **official quality standards of the *European Pharmacopoeia*** (Ph. Eur.), which prescribe how human and veterinary medicines and substances used in their manufacture should be tested and quality controlled;



granting **Certificates of Suitability (CEPs)** to manufacturers after they have demonstrated that the substance they produce can be adequately controlled by the quality standards defined in the Ph. Eur;



co-ordinating a network of **Official Medicines Control Laboratories (OMCLs)** to ensure effective, independent quality controls of medicines in Europe;



providing policies and model approaches for the **safe use of medicines**, including guidelines on pharmaceutical care;



drafting ethical, safety and quality **standards for blood transfusions and organ, tissue and cell transplantations**;



working with national, European and international organisations to protect public health from the dangers of **falsified medical products**;



establishing **standards for cosmetics and food contact materials** and co-ordinating a network of **Official Cosmetic Control Laboratories (OCCLs)** to ensure and monitor the quality of cosmetics on sale in Europe.



What does the EDQM do?

The task of the EDQM is to ensure **protection of human and animal health** in Europe by promoting access to good quality medicines and healthcare.



Quality of medicines

The *European Pharmacopoeia* (Ph. Eur.) provides **legally binding standards (or monographs)** for the quality control of medicines. These quality standards are **based on science** and ensure that any impurities that may arise during the manufacturing process are identified and suitably controlled, **so that medicines are not harmful to health**. The legal basis for these standards lies in the Council of Europe's Convention on the Elaboration of a European Pharmacopoeia.

The EDQM also provides the **reference standards** established alongside the monographs, which are essential for carrying out the **tests and assays** described in the corresponding monographs. The **continuous availability** of reference standards is crucial for the application of the official methods described in the *European Pharmacopoeia*.

In order to market products in Europe, pharmaceutical companies must demonstrate that all the ingredients used in their medicinal product can be suitably controlled by the **quality requirements** set out in the *European Pharmacopoeia*. The EDQM's Certificates of Suitability attest that this is the case. The Certification Procedure is complemented by a **risk-based programme of inspections** carried out by the EDQM all over the world to verify compliance with Good Manufacturing Practices (GMPs). Inspections also ensure that all the information and data provided by manufacturers in their dossiers is accurate.



Market surveillance of medicines

The quality control of medicines is not only ensured through mandatory requirements applicable for the batch release of medicines. In fact, **quality is monitored throughout the entire life-cycle of a medicinal product**, thus preventing low-quality, contaminated, falsified or illegal medicines from entering distribution chains and reaching the patient. For this reason, the EDQM co-ordinates **independent market surveillance programmes** which are carried out by official testing laboratories in the various member states, known as **Official Medicines Control Laboratories (OMCLs)**. These programmes cover all types of medicinal products circulating in Europe, from simple tablets to more complex preparations such as vaccines.



Combatting falsified medical products

Falsified medical products are a threat to public health. If these products enter the legal supply chain, consumers and patients risk becoming exposed to harmful substances or to products which do not contain the right amount or any active ingredients at all. In addition to the work done by the OMCL Network, the EDQM is engaged in the fight against falsified medical products through a series of initiatives, like those based on the **MEDICRIME Convention of the Council of Europe**. This convention lays the basis for curbing the problem worldwide, by identifying what constitutes a falsification of medical products, supporting the dissemination of best practices and bringing together organisations across the globe to exchange information and promote co-operation. In particular, the **EDQM facilitates national and international co-operation among customs, police, health and judicial authorities**. Regular training and a network of national contact points provide the framework for ensuring rapid and efficient responses to this threat to public health.



Pharmaceuticals and pharmaceutical care

The work of the EDQM also covers **pharmaceutical care and practices** – an essential aspect for ensuring public health protection – and good patient care in Europe. The way a medicine is prescribed, delivered or taken by a patient are all key factors that have a direct impact on the efficacy of a treatment. The EDQM is tasked with providing guidance to professionals concerned with pharmaceutical care by promoting knowledge, skills and values in care and practices involving medicines. This activity covers a wide range of subjects that are relevant to pharmaceutical practice, providing patients with **access to good quality medicines, promoting patient-centred care, using medicines efficiently, and ensuring the quality and safety of pharmacy preparations**.



The European Paediatric Formulary

Medicines for adults may not always be suitable for children and many have not been specifically tested or developed for children prior to their approval. By way of its **European Paediatric Formulary (PaedForm) project**, the EDQM aims to close the current gap by supporting paediatricians across Europe in the preparation of good quality medicines for young patients. The PaedForm is intended to provide healthcare professionals, such as pharmacists and clinicians, with the specific quality standards for the correct preparation of unlicensed medicines suitable for children.



Substances of human origin: blood components, organs, tissues and cells

Blood, organs, tissues and cells are used in a number of life-saving medical treatments. This is the case, for example, of blood transfusions to replace blood lost during surgery, or an organ transplant in the case of organ failure. **The EDQM sets ethical, safety and quality standards for substances of human origin used in medical therapies.** Through its programmes and legal instruments, the EDQM works to ensure the quality and safety of transfusions and transplantations in Europe.



Protecting consumer health

The work programme of the EDQM also includes the development of standards for improving the protection of consumers in Europe. Through its European network of **Official Cosmetics Control Laboratories (OCCLs)**, the EDQM co-ordinates **market surveillance studies aimed at testing cosmetic products** on the European market for compliance with quality standards. The EDQM also fosters cross-border co-operation and the sharing of technical expertise within the OCCL network, in line with the latest European and international standards.

Safety aspects related to **materials in contact with food** (such as metals, paper, board or cork) also fall within the remit of the EDQM. Activities include the development of standards, technical guidance and state-of-the-art methodologies ensuring the safety and quality of these materials.



edqm
European Directorate
for the Quality
& Health Care

COUNCIL OF EUROPE
DIRECTION GÉNÉRALE
de la qualité
du médicament
& des soins de santé
CONSEIL DE L'EUROPE

How does the EDQM function?

In all its areas of competence, the work of the EDQM is guided by **committees of experts** composed of representatives from national authorities with specific expertise in the domain of each committee.



Quality of medicines

The *European Pharmacopoeia* is drafted collectively by more than 700 experts in the various fields of medicines from Europe and the rest of the world, organised into domain-specific working groups. The competence of these experts is internationally recognised. They typically work for national authorities responsible for the licensing and surveillance of medicines, official medicines control laboratories, inspectorates, universities and pharmaceutical and chemical industries. These experts meet regularly to ensure that the quality standards in the *European Pharmacopoeia* always remain up-to-date with the latest scientific and technological advances and meet the demands of all stakeholders concerned with the quality of medicines.

The **European Pharmacopoeia Commission** is the decision-making body of the *European Pharmacopoeia*. It is composed of experts nominated by the member states that have signed the Convention on the Elaboration of a European Pharmacopoeia. The Commission is responsible for adopting the legal standards in the *European Pharmacopoeia* and taking decisions, such as changes to the work programme and the appointment of experts to working groups.

The official **reference standards** of the *European Pharmacopoeia*, the substances used to test the quality of medicines and medicinal ingredients, are established by the **EDQM's laboratory**, which regularly works in collaboration with centres of scientific expertise in European member states, including the Official Medicines Control Laboratories.

The procedure for **Certification of Suitability to the monographs of the *European Pharmacopoeia***, or Certification Procedure in short, relies on the work of a network of about 100 assessors who come from national competent authorities across Europe. To apply for a certificate (CEP), manufacturers submit a detailed dossier describing how their substance is manufactured and controlled in order to **demonstrate that its quality can be adequately controlled with respect to the *European Pharmacopoeia* standards**. A dedicated steering committee takes general policy decisions and approves the appointment of the assessors. The procedure's **inspection programme** is conducted by the EDQM with the support of inspectors from national supervisory authorities. The EDQM also performs **joint inspections with authorities worldwide**, including the US Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration (TGA) and co-operates closely with the World Health Organization (WHO) and the European Medicines Agency (EMA). The EDQM is also regularly in contact with national inspectorates and international partners, thus allowing the continuous exchange of information and data on manufacturing sites all around the world.



Market surveillance of medicines

The **Official Medicines Control Laboratories (OMCLs)** are national laboratories responsible for **controlling and testing the quality of human and veterinary medicines**, before and after they enter distribution chains. Their testing activities are independent of the manufacturers' and provide essential analytical and technical support to the work of regulatory authorities tasked with controlling the quality of medicines. The OMCLs conduct joint market surveillance programmes and activities through a network co-ordinated by the EDQM. This facilitates the exchange of knowledge and expertise, optimising the use of technical skills and resources available within all OMCLs.

The other important task of the OMCLs includes analysing samples suspected of being either **falsified or illegal medicines**.



Combatting falsified medical products

The expert committee in charge of activities related to falsified medical products is composed of representatives from relevant health and law-enforcement sectors, as well as European and international organisations. The work of this committee aims at **supporting professionals involved in the fight against falsified medical products**; it does so through the implementation of multi-sectorial approaches and tools that facilitate information exchanges on the management, prevention and follow-up of the risks posed by the falsification of medical products and similar crimes.



Pharmaceuticals and pharmaceutical care

The activities in this area are led by a committee tasked with **supporting European authorities in making medication processes safer, more effective and accessible** to those who need them. Through a series of dedicated programmes and policies, the committee works to promote good pharmaceutical care and healthcare practices for the correct preparation, use and administration of medicines. The committee also promotes the **consistent classification of medicines** in community and hospital pharmacies, primary-care services and hospices, so as to strike the ideal balance between promoting the correct use of medicines and ensuring access to medicines for patients in Europe when needed.



Substances of human origin: blood components, organs, tissues, cells

The work of the EDQM in the areas of blood transfusion and transplantation are co-ordinated by two committees composed of leading experts on ethical, scientific, legal and organisational issues. They are tasked with **ensuring that blood transfusions or organ, tissue or cell transplantations in Europe remain safe and ethical for both the recipient and the donor.**



Protecting consumer health

The EDQM's Committee for Cosmetics and Consumer Health is responsible for strengthening the quality control of cosmetic products and promoting their safe use. The EDQM also co-ordinates common work programmes across a pan-European network of **Official Cosmetics Control Laboratories**, which are in charge of controlling cosmetics on the European markets.

The Committee for Food Contact Materials and Articles develops standards and policies aimed at **ensuring the safety and quality of materials used in contact with food**, from aluminium foil to kitchen utensils.

Who benefits from the work of the EDQM?

The work of the EDQM protects **citizens' basic human right of access to good quality medicines and healthcare** in Europe.

With their high-level scientific and technical expertise, the EDQM's committees of experts support **authorities at national level** in policy making and in market surveillance, and also bring added value to **market players** by creating the conditions for an efficient and level playing field in Europe.





European patients and consumers

Access to good quality medicines and healthcare is one of the **fundamental human rights at the basis of European democracies** today. Thanks to the EDQM's work, citizens can be confident in the quality, safety and efficacy of their medicines.

Before medicines enter distribution chains, the binding standards of the *European Pharmacopoeia* ensure their quality, complemented by the independent controls and thorough tests carried out by the Official Medicines Control Laboratories.

This way everyone in Europe can be confident that the risk of being exposed to sub-standard, contaminated or falsified medicines is kept to a minimum. In healthcare too, the standards and recommendations set by the EDQM ensure that medical treatments and care delivered in hospitals, be they medicines, vaccinations, transfusions or transplantations, are of good quality.



Healthcare and pharmaceutical professionals

The EDQM acts as a **platform for exchanging expertise and best practices on new and emerging challenges** in the field of medicine and healthcare. It then makes this knowledge available to healthcare and pharmaceutical professionals across Europe, enabling them to deliver good healthcare and contribute to ensuring adequate protection for patients in Europe.

This allows pharmaceutical industry and healthcare professionals to actively engage with the EDQM and to participate in its standard-setting processes. When developing resolutions, technical guides, specialised databases and other tools to share information and knowledge, **the EDQM always strives to listen to all stakeholders' concerns** and to make the high level of expertise of its expert groups and committees available to healthcare professionals across Europe.



Policy makers and authorities

The efficient protection of patient and consumer health comes at a cost, but **by providing legal frameworks founded in fundamental human rights, by sharing scientific excellence, technical expertise and know-how, and by co-ordinating surveillance activities**, the EDQM allows member states participating in its work to **make the best use of scarce resources** and deliver the best possible healthcare services to their citizens. In contrast, activities run exclusively at national level tend to be more expensive as they do not benefit from shared resources and experience or may be hampered by difficulties in finding the right expertise.

Legal treaties or other instruments, such as the MEDICRIME Convention or recommendations on access to healthcare, provide **effective legislative frameworks**. This is all for the benefit of national governments wanting to ensure that their **citizens are well protected and have access to good quality medicines and healthcare**.

Co-operation programmes co-ordinated by the EDQM are invaluable, as they mutualise efforts and provide participants with access to **state-of-the-art quality assurance systems, technical and regulatory guidance, and cutting-edge analytical methodologies and databases**.

This way the EDQM supports national authorities in the **correct application of international and European legislation**, as in the case of the EDQM's Blood Guide. The analytical methodologies it makes available also offer relevant added value and support to authorities, like those involved in the fight against falsified medicines or in cosmetics testing.

Today, the pharmaceutical legislation of the European Union also makes direct reference to the *European Pharmacopoeia*, as well as to the EDQM's Certification of Suitability and Official Control Authority Batch Release (OCABR) procedures and guidelines for vaccines and blood products and the Good Practice Guidelines for blood establishments.



Medicine makers

The pharmaceutical industry plays a key role in **improving access to innovative medicines and therapies**. To this end, the European Pharmacopoeia Commission strives to ensure that its **standards always remain up-to-date**, keeping pace with constantly evolving scientific knowledge and the changing needs of patients. For this reason, it welcomes **participation and feedback from the pharmaceutical industry** when drafting new texts or revising existing ones. This guarantees that the *European Pharmacopoeia* remains relevant to medicine makers in delivering quality pharmaceutical products.

The work of the OMCL network also contributes to the maintenance of an **efficient and level playing field in Europe**, where all producers of medicines, be they in Europe or beyond, can rest assured that everyone on the market meets the specifications and abides by legal requirements. By checking medicines' compliance with quality standards, OMCLs are a **driver for market discipline in Europe** and ensure that only those producers who comply in full with legislative requirements can access the European medicines market.



Animal health and welfare

The EDQM is also actively committed to protecting and improving the health and welfare of animals used for experimental purposes. In line with the Council of Europe's Convention on the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes, the EDQM and the European Pharmacopoeia Commission work towards reviewing all animal tests in several areas of their activities and applying the 3Rs principle – Replacement, Reduction and Refinement – to the use of animals for testing purposes.

In addition, the EDQM runs a dedicated Biological Standardisation Programme (BSP) focusing on the elaboration of **alternative test methods** for the quality control of biologicals that are aimed at **reducing reliance upon animals in laboratory testing**.

EDQM: added value and global impact

Thanks to the work of the EDQM, everyone in Europe and beyond can benefit from harmonised standards in the field of medicines and healthcare.



The EDQM plays a significant role in protecting public health in Europe and beyond. It has been at the forefront of **setting standards for the quality control of medicines and their safe use since 1964**. Its work supports health systems at national level and enhances patients' protection by enabling reliable testing of medicines, setting legally binding standards and post-market surveillance programmes that ensure only good quality medicines are kept on the market.

The EDQM's guidance on pharmaceutical care, transplantation and transfusion ensures that the **best scientific knowledge** available in these fields is disseminated throughout Europe and made available to all professionals in healthcare centres and hospitals.

Finally, the co-ordination of testing programmes and analytical activities across networks of European laboratories, whether tasked with the control of medicines or cosmetics, provide dedicated **support to national competent authorities** in ensuring they are always up-to-date with the latest information on health risks and testing techniques.

The manufacture of medicines is increasingly globalised. Likewise, the need for international harmonisation in pharmaceutical standards has become increasingly important to improving access to medicines, while maintaining adequate safeguards for quality. **The EDQM strives to promote harmonisation of pharmacopoeial and healthcare standards around the world**: consistent specifications help reduce the need for additional analytical tests, hence reducing the cost of bringing medicines to market, while improving patients' access to innovative medicines.

Today, the EDQM actively supports global harmonisation initiatives that facilitate exchanges, strengthen co-operation and most importantly, open the door for pharmacopoeias worldwide to accept monographs. In addition, bilateral agreements signed with authorities worldwide allow the EDQM to collaborate and exchange experience at an international level and expand its reach globally for the benefit of all patients.

Contact information

For more information about the EDQM and its activities, please contact:

EDQM Council of Europe

7 Allée Kastner, CS 30026
F-67081 Strasbourg, France
Tel. +33 3 88 41 30 30

EDQM HelpDesk: <https://go.edqm.eu/hd>

Follow the EDQM on:

-  Twitter: @edqm_news
-  Facebook: @EDQMCouncilofEurope