

The European Directorate for the Quality of Medicines & HealthCare

What is the EDQM?

The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a directorate of the Council of Europe. Its origins date back to 1964, when the international Convention on the Elaboration of a European Pharmacopoeia was adopted by the Council of Europe with the vision of creating a common European Pharmacopoeia.

The creation of a technical Secretariat was foreseen in the Convention, and over the years it has become a directorate, with successive name changes reflecting the new missions assigned to it. In 2020 the EDQM employs nearly 400 staff from 25 nationalities and is structured in nine entities.

What is the impact of the activities of the EDQM?

Compliance with the quality requirements of the European Pharmacopoeia (Ph. Eur.) is a prerequisite for medicines to be authorised for the markets of the 39 Member States. The signatories to the Convention – 39 member states and the European Union as of May 2020 – 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 30 Observers: 28 countries from all continents, the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare and the World Health Organization (WHO).

The Impact of EDQM activities spans beyond Europe and across the whole world, reflecting today's global nature of medicines' markets, highlighted by the acceptance of Ph. Eur. standards in more than 120 countries worldwide. Signing the Convention or becoming an observer to the Ph. Eur. Commission is the gateway to all EDQM activities. Experts from all over the world contribute to the scientific and technical excellence of the EDQM's products and services.

Why is EDQM part of the Council of Europe, which is primarily a human rights organisation?

The mission of the EDQM is to contribute to the basic human right of access to good quality medicines and healthcare, and to contribute to promoting and protecting human and animal health.

All the EDQM activities are geared to protecting public health overall and ensuring that the same quality standards are applied throughout the continent, in line with this mission.

The EDQM' contribution to promote and protect human and animal health comprises:

- establishing and publishing official documentary standards (named monographs) as well as physical reference standards for the manufacture and quality control of medicines in all the signatory states of the Convention on the Elaboration of a European Pharmacopoeia and beyond;
- ensuring that these official standards are applied to medicines and their ingredients;
- co-ordinating a network of Official Medicines Control Laboratories (OMCLs) between member states to pool expertise and to use limited resources efficiently with the aim of achieving effective public quality control of medicines in Europe and beyond;

- proposing ethical, safety and quality standards:
 - for the collection, preparation, storage, distribution and appropriate use of blood and blood components for transfusions;
 - for the transplantation of organs, tissues and cells;
- collaborating with national, European and international organisations in efforts to combat counterfeiting/falsification of medical products and similar crimes;
- providing policies and model approaches for the safe use of medicines in Europe, including guidelines on pharmaceutical care; and
- establishing standards and co-ordinating controls for cosmetics and food contact materials.

What is the European Pharmacopoeia?

The Ph. Eur. is an official reference work used by professionals involved in the manufacture and control of medicines. Its objective is to define legally binding quality requirements for medicines and their ingredients. This means that a patient can buy a medicine in a pharmacy in any European country and obtain the same quality regardless of the brand or type of medicine (original product or generic). From a simple tablet taken with a glass of water to the most complex types of treatments, all medicines on the European market must comply with the specifications detailed in the European Pharmacopoeia.

How does the EDQM contribute to the good quality of medicines and their ingredients?

The Ph. Eur. is the indispensable standardisation tool that allows a harmonised quality standard to be applied. This tool can serve its users only if it is kept abreast of scientific and technological developments and changes in medical practice – therefore, collaboration with national competent authorities, the European Commission and the European Medicines Agency and also with manufacturers and industries is crucial. To remain “state of the art” the European Pharmacopoeia has a continuous process for adding and revising quality specifications

Items are added to the Ph. Eur. Commission work programme in response to requests received from licensing authorities of member states, experts and stakeholders such as the pharmaceutical industry. Public consultations are organised during the elaboration of quality standards to ensure a transparent and scientifically sound outcome, with robust, validated and affordable testing methods and specifications that help to protect public health.