



European Directorate for the **Quality of Medicines & HealthCare**



Serving public
health in Europe
since 1964

The EDQM is
a leading organisation
that protects public health

edqm.eu



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**European Directorate
for the Quality of Medicines
& HealthCare (EDQM)**

7, allée Kastner
CS 30026
F-67081 Strasbourg - France
Tel.: +33 (0)3 88 41 30 30
Fax: +33 (0)3 88 41 27 71
www.edqm.eu

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Chapter 1

The EDQM at a glance

WHO ARE WE?

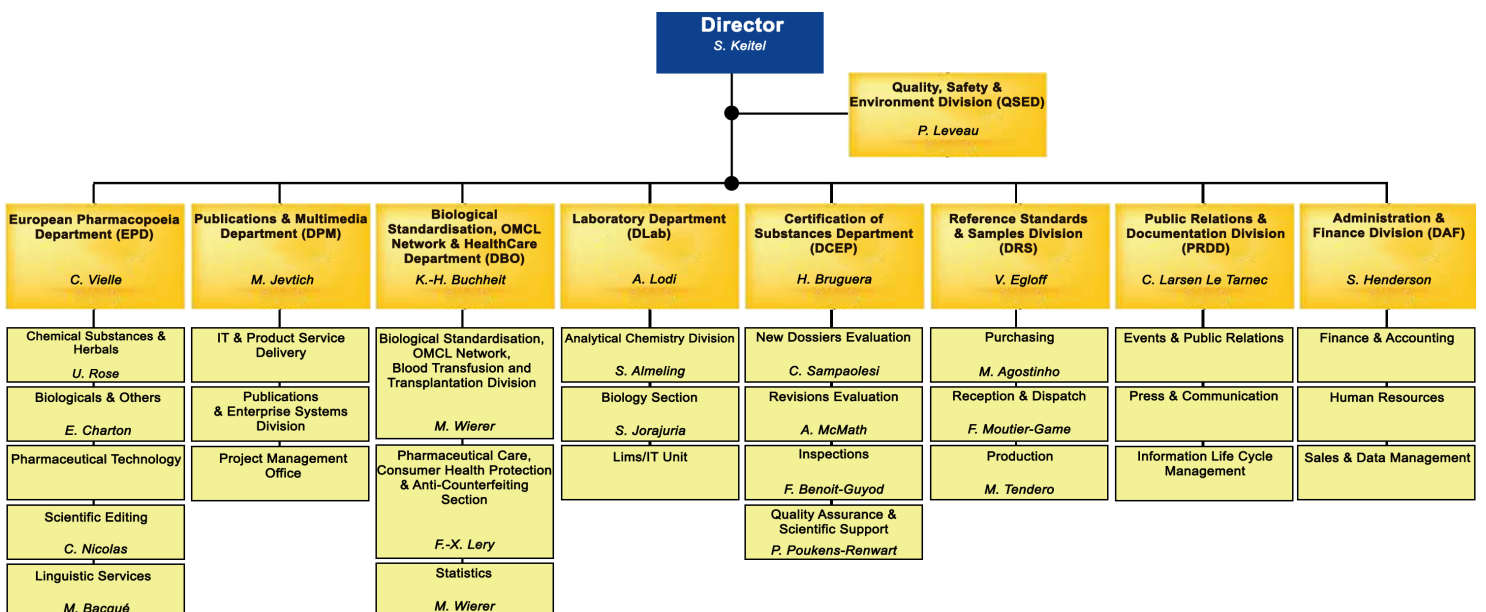
The European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe traces its origins and statutes to the *Convention on the Elaboration of a European Pharmacopoeia* (an international treaty adopted by the Council of Europe in 1964). The signatories to the Convention – 38 member states and the European Union (EU) as of April 2017 – 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 29 Observers, including WHO). The EDQM's standards are recognised as a scientific benchmark worldwide, and the European Pharmacopoeia (Ph. Eur.) is legally binding in member states.

OUR MISSION

The mission of the EDQM is to contribute to the basic human right of access to good quality medicines and healthcare, and to promote and protect human and animal health by:

- ▶ establishing and publishing official standards (named monographs) 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 components;
- ▶ coordinating a network of Official Medicines Control Laboratories (OMCLs) between member states to pool expertise and to use limited resources effectively with the aim of achieving effective public quality control of medicines in Europe and beyond;

EDQM ORGANISATIONAL CHART



THE EDQM IN BRIEF

- ▶ A Directorate of the **Council of Europe**
- ▶ Created in **1964**
- ▶ Over **320 staff members**, more than **29 nationalities**
- ▶ Dedicated to protecting and promoting human and animal health in Europe
- ▶ Central role in the quality of medicines and healthcare, including consumer health protection

- ▶ 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 coordinating controls for cosmetics and food contact materials.

INVESTING IN QUALITY MANAGEMENT

■ The EDQM has ISO 9001:2008 certification from the French accreditation body, AFNOR Certification (AFAQ), for the following activities:

- ▶ evaluation of applications for Certificates of Suitability to the monographs of the European Pharmacopoeia (CEPs) and management of the inspection programme for manufacturing sites and associated brokers;
- ▶ co-ordination of the OMCL Network, including: planning, implementation and coordination of post-marketing surveillance studies for medicinal products; audits; training sessions; meetings; the management of related databases; and the co-ordination of the elaboration and publication of guidelines related to the Official Control Authority Batch Release procedure (OCABR) for batches of human biological medicinal products (blood derivatives and vaccines);

- ▶ management of the elaboration, revision, correction and deletion of Ph. Eur. texts, their publication in printed and electronic format, and their distribution; and
- ▶ carrying out laboratory studies.

■ Since 2014, the EDQM also has ISO 17025:2005 accreditation from the Belgian accreditation body BELAC, covering all aspects of the laboratory quality management system, including: sample preparation; analytical testing competence; documentation control; premises and environmental conditions; equipment; traceability; and reporting.

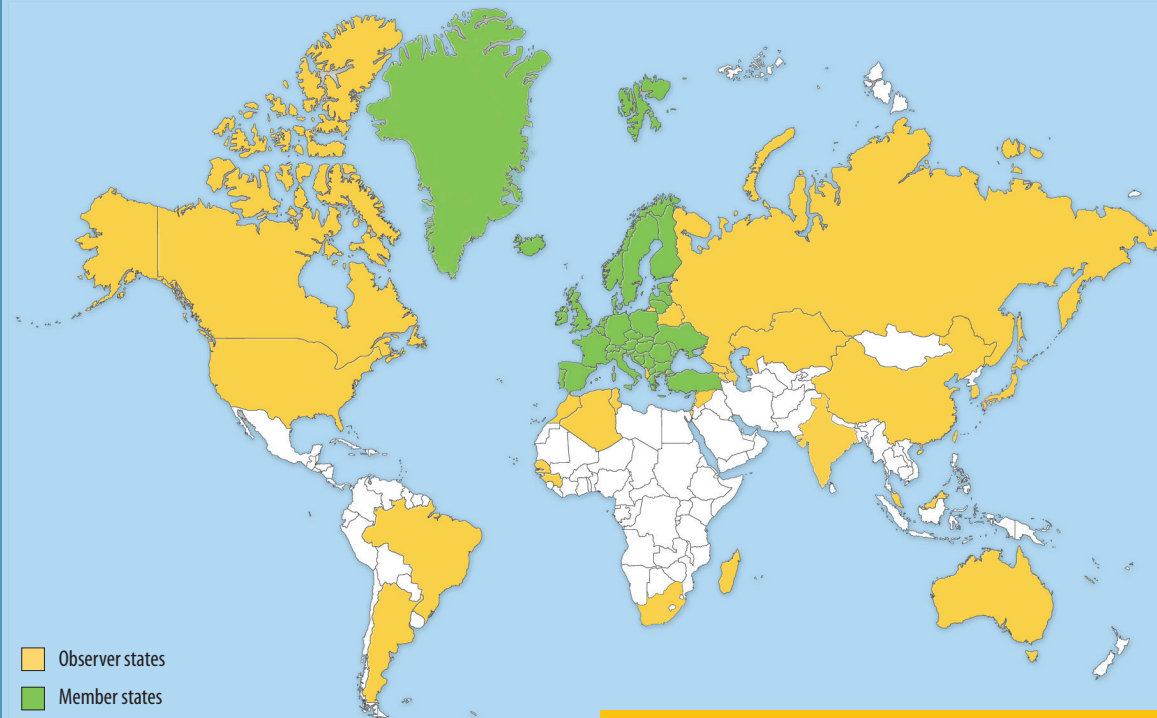


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GLOBAL REACH

■ The pharmaceutical world has undergone dramatic changes over the past 50 years which have resulted in a truly globalised environment, with a determining effect on the EDQM's activities. For example, an increasing number of applications for CEPs and requests for revision come from India and China, reflecting the global trend for production of active pharmaceutical ingredients (APIs).

■ The EDQM is involved in a number of international platforms for collaboration and harmonisation, such as the Pharmacopoeial Discussion Group (PDG) (see Chapter 2), the International Generic Drug Regulators Programme (IGDRP), the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the International API Inspection Programme (coordinated by the European Medicines Agency, or EMA) (see Chapter 3).



EUROPEAN PHARMACOPOEIA: INTERNATIONAL RELATIONS

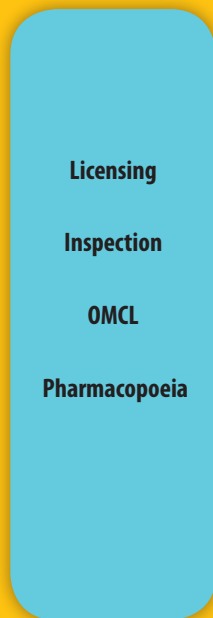
The EDQM's cooperation with the European Union (EU) and EMA includes membership of the European Union Network Data Board (EUNDB) and the International Standards on Identification of Medicinal Products in the EU (EU ISO IDMP) Task Force group. The EDQM also works closely with the EMA as well as national authorities to ensure continued consistency between the approaches of licensing authorities and the Ph. Eur. The EDQM has observer status with a number of EMA bodies, e.g. the Committee for Advanced Therapies (CAT), the joint CHMP/CVMP Quality Working Party (QWP), the Good Manufacturing and Distribution Practice Inspectors Working Group (GMDP IWG), the Biologics Working Party (BWP) and the Immunologicals Working Party (IWP). Members of EMA working groups (i.e. for which the EMA provides the Secretariat) or of the EMA Secretariat itself are observers to some of the Ph. Eur. Commission's Groups of Experts and Working Parties, e.g. 6B (human blood and blood products), 15 and 15V (vaccines and sera for human use and veterinary use), and are members of the Biological Standardisation Programme (BSP) Steering Committee and Certification Steering Committee

In addition to the PDG, the EDQM is actively involved in a number of other international harmonisation initiatives, such as the WHO initiative to draft "Good Pharmacopoeial Practices" (GPhP), which may serve as a basis for future work-sharing and collaboration amongst pharmacopoeias worldwide.

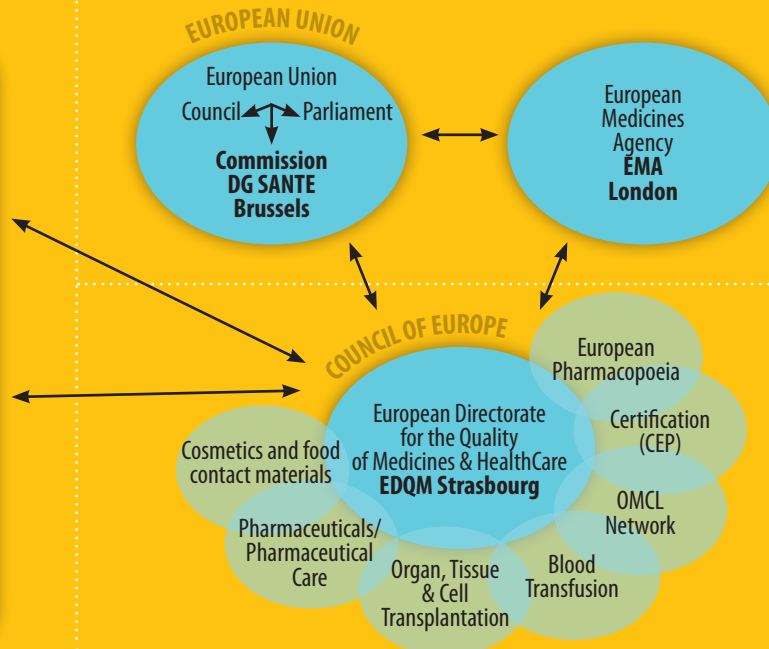
The EDQM collaborates with WHO in a number of other ways, including:

- ▶ establishing, monitoring and distributing WHO International Standards for Antibiotics (ISA) and WHO International Chemical Reference Substances (ICRS);
- ▶ as an observer to WHO's Programme on International Nonproprietary Names (INN), since INN are used in Ph. Eur. monographs;
- ▶ participation in WHO's Expert Committee on Biological Standardization (ECBS), with WHO participating as an observer in the meetings of the EDQM's BSP Steering Committee, thus guaranteeing a smooth exchange of information;
- ▶ participation in WHO's Expert Committee on Specifications for Pharmaceutical Preparations (ECSP);
- ▶ the sharing of data and joint inspections relating to the Certification procedure for APIs; and
- ▶ in the fields of blood transfusion and organ, tissue and cell transplantation.

NATIONAL AUTHORITIES



EUROPEAN AUTHORITIES



RELATIONS WITH EUROPEAN PARTNERS

MAINTAINING HIGH QUALITY STANDARDS IN A DYNAMIC GLOBAL ENVIRONMENT

— To help the EDQM carry out its activities, the Ph. Eur. member states and Observers volunteer not only the services of experts in the pharmaceutical sciences and access to equipment in national medicines control laboratories, but also the services of experts in blood transfusion, organ, tissue and cell transplantation, pharmaceuticals and pharmaceutical care, consumer protection, as well as those involved in assessments and inspections in the context of the Certification procedure.

— This is one of the reasons for the success of the organisation, which is thus able to respond to the needs and realities of public health in Europe and beyond.

— The EDQM salutes the dedication and enthusiasm of all those who contribute to the elaboration of the Ph. Eur. or participate in the organisation's other activities.

The European Pharmacopoeia: Establishing quality specifications and pharmaceutical reference standards

ACTIVITIES RELATED TO THE QUALITY OF MEDICINES

HOW DOES THE EUROPEAN PHARMACOPOEIA BENEFIT PATIENTS?

■ The mission of the Ph. Eur. is to provide common, harmonised quality standards in Europe for the development, manufacture and control of medicines for human and veterinary use and their components.

■ It does so by:

- ▶ elaborating individual quality standards (general and specific monographs) for substances and excipients used in the production of medicines; this also includes texts on dosage forms, homoeopathic preparations, biologicals, vaccines, blood and plasma derivatives, and radiopharmaceutical preparations as well as packaging materials/containers;
- ▶ responding rapidly to new risks to public health by drawing up new methods of analysis and tests and setting new specifications; and
- ▶ ensuring that the analytical methods described in the Ph. Eur. monographs are experimentally verified and validated.

■ The Ph. Eur.'s legally binding character and quality control methods ensure that everyone has access to high quality medicines. 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 strict specifications on their composition, manufacturing processes and quality. This means that a patient can buy a medicine (such as paracetamol tablets) in a pharmacy in any European country and obtain the same quality regardless of the brand or type of medicine (original product or generic).

WHAT IS THE EUROPEAN PHARMACOPOEIA AND HOW IS IT USED?

■ The Ph. Eur. consists of monographs describing individual quality standards (specifications and sets of controlled tests applicable to a substance or ingredient) and general quality standards applicable to families of ingredients (such as fermentation products) or to dosage forms, as well as general methods of analysis, e.g. dissolution test for solid dosage forms, uniformity of mass of single-dose preparations, etc. The Ph. Eur. covers all therapeutic areas.

■ Published and regularly updated in English and French, the two official languages of the Council of Europe, it is a single reference work for official European quality standards and helps define the requirements to obtain a marketing authorisation of a medicinal product in Europe. Ph. Eur. quality standards apply throughout the entire life cycle of a product. They are legally binding – as expressly laid down in the Council of Europe's *Convention on the elaboration of a European Pharmacopoeia* and in European Union pharmaceutical legislation – and become mandatory on the same date in all 38 member states of the Convention.

■ The EDQM regularly organises seminars and training sessions on subjects related to the Ph. Eur., as well as symposia on new scientific and technical subjects.

THE EUROPEAN PHARMACOPOEIA IN BRIEF

- ▶ Main objective: to provide common quality standards for the control of medicines for human and veterinary use and the substances used to manufacture them
- ▶ In existence since 1964
- ▶ 39 members (including the EU) and 29 Observers from around the world (as of April 2017)
- ▶ Over 2,700 quality standards
- ▶ Used in more than 100 countries worldwide
- ▶ Published and regularly updated by the EDQM in English and French, the two official languages of the Council of Europe, and made available in other languages by member states
- ▶ 9th Edition Ph. Eur. is officially binding from 1 January 2017 to 31 December 2019

HOW IS THE EUROPEAN PHARMACOPOEIA MANAGED?

The governing body is the Ph. Eur. Commission. All 38 member states and the European Union are represented and have the right to vote, while the 29 Observers are welcome to attend its sessions. Meeting at the EDQM's headquarters in Strasbourg three times a year, the Ph. Eur. Commission determines the general principles applicable to the elaboration of the Ph. Eur. It decides the work programme, establishes specialised groups responsible for preparing monographs and appoints experts to those groups. It adopts the monographs and recommends the time limits within which its decisions shall be implemented within the territories of the contracting parties.

Items are added to the work programme in response to requests received from the member

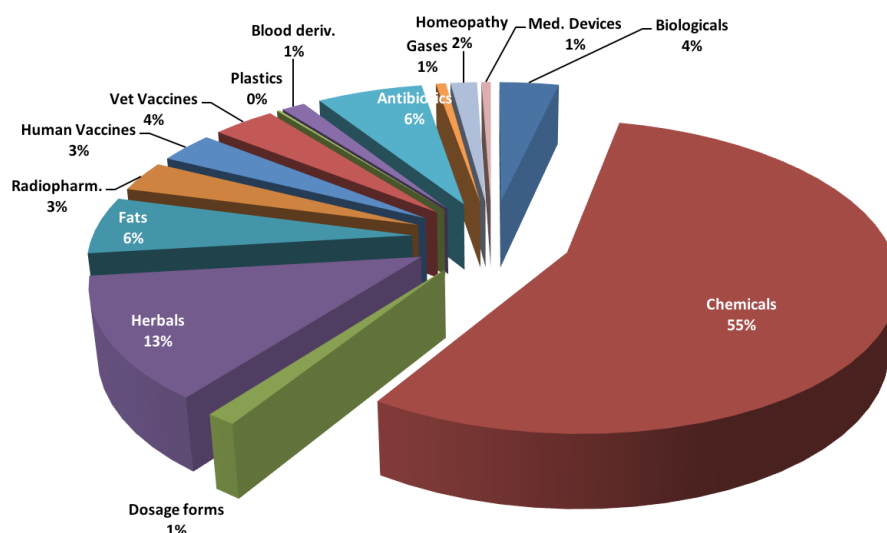
states, the EU and its agencies, based on current scientific evidence and health issues in Europe. Each delegation has one vote. In all technical questions, decisions of the Ph. Eur. Commission are taken by a unanimous vote among the national delegations that can cast votes.

HOW IS THE EUROPEAN PHARMACOPOEIA ELABORATED?

The Ph. Eur. is elaborated collectively by more than 700 experts who volunteer from all the member states plus some Observers. They come from a wide variety of backgrounds and sectors, including national competent authorities responsible for medicines, official medicines control laboratories, inspectorates, universities as well as the pharmaceutical and chemical industries.

SCOPE OF EUROPEAN PHARMACOPOEIA MONOGRAPHS (VOLUMES 1-3, PUBLISHED IN JULY 2016)

Classification of the monographs of the 9th Edition of the European Pharmacopoeia





ACTIVITIES RELATED TO THE QUALITY OF MEDICINES

■ The experts are nominated by the national delegations and are appointed by the Ph. Eur. Commission to 20 permanent Groups of Experts, supplemented by some 50 *ad hoc* specialised Working Parties, on the basis of their expertise. All of the Group of Experts meetings take place in Strasbourg. These expert groups and working parties – which enable the Ph. Eur. to respond to new scientific and technical developments, public health issues or changes in regulatory processes – meet as required by the work programme.

■ In recent years, the Ph. Eur. Commission has created several new Working Parties, for example:

- ▶ the General Methods Working Party to work on the update and revision of the Ph. Eur. general methods monographs;
- ▶ the Raw Materials for the Production of Cellular and Gene Transfer Products Working Party, which will draft text(s) on such raw materials including antibodies, basal media (for cell culture), serum/serum replacements, growth factors and cytokines; and
- ▶ the Host-Cell Proteins Working Party, which will draft recommendations with regard to the development, validation and use of in-house or commercial kits or test methods for the detection and quantification of host-cell derived proteins.

■ Recognising the impact of globalisation on the pharmaceutical world, the Ph. Eur. Commission decided in 2015 to revise its working procedures to allow nominations from non-Ph. Eur. member states and Observers for membership of the Groups of Experts and Working Parties. This decision is part of a deliberate policy to further involve both observer states and manufacturers from outside Europe in the work of the Ph. Eur., and is effective since November 2016.

MAINTAINING STATE-OF-THE-ART QUALITY STANDARDS

■ There is a continuous need to update monographs in response to scientific/technological advances, developments in manufacturing (especially due to the impact of globalisation), increasing demand for generic and biosimilar products, developments in the regulatory environment, or a new risk to public health.

■ Draft texts prepared by the Groups of Experts are published in the free online EDQM publication *Pharmeuropa* for public consultation. The respective Group of Experts then analyses the comments, revises the text if necessary and submits it to the Ph. Eur. Commission for adoption.

■ Over the course of the three-year life cycle of the 8th Edition, which has been used in more than 100 countries worldwide, the Ph. Eur. Commission approved 109 new monographs, 12 new general chapters and 1,403 revised texts. Some 57 percent of the content of the 9th Edition, published in July 2016, is new or updated. In addition to over 350 general texts, the 9th Edition contains some 2,300 monographs.

THE NEED FOR REFERENCE STANDARDS

■ Official reference standards (RS) are an essential component of most texts of the Ph. Eur. They include Chemical Reference Substances (CRS), Herbal Reference Standards (HRS), Biological Reference Preparations (BRP), Biological Reference Reagents (BRR) and reference spectra. The EDQM's Laboratory Department and the Biological Standardisation Programme (BSP) are responsible for establishing RS, and once established the latter are officially adopted by the Ph. Eur. Commission. These standards alone are authoritative in case of arbitration.



■ In 2017, there were near to 2770 RS in the Ph. Eur. catalogue; as a result of globalisation of the pharmaceutical industry, Ph. Eur. RS were distributed in more than 100 countries worldwide.

■ The EDQM is also responsible for the establishment, monitoring and distribution of WHO International Standards for Antibiotics (ISA) and for WHO International Chemical Reference Substances (ICRS). ISA are supplied worldwide for use in microbiological assays performed for quality control of antibiotics, and are essential for the standardisation and quality control of antibiotic drug substances and medicinal products. ICRS are prescribed by the International Pharmacopoeia, which is published and maintained by WHO and used worldwide.

■ The Biological Standardisation Programme is a joint EDQM-European Commission initiative whose mandate is to establish BRP and BRR, develop and validate new analytical methods, and validate alternative methods based on the 3Rs principles (i.e. Replacement, Refinement and Reduction of the use of animals in research) for the quality control of biologicals. To this end, collaborative studies are performed involving all interested partners, such as OMCLs and manufacturers, both European and non-European. Whenever possible, these studies are run jointly with WHO in order to economise the resources of the participating laboratories and to add a worldwide dimension to biological standardisation.

THE EUROPEAN PHARMACOPOEIA AND INTERNATIONAL HARMONISATION

■ The European Pharmacopoeia was one of the co-founders in 1989 of the Pharmacopoeial Discussion Group (PDG) together with the Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP). This group meets twice a year to discuss the harmonisation of pharmacopoeial standards, with WHO participating as an observer. Excipient manufacturers' associations play an active role in identifying the priorities for the PDG's work programme.

■ In line with the goals of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the main objective of this work programme is to provide common standards, harmonised between the three regions and beyond. This means that for a product manufactured at the same site but marketed in different countries, the manufacturer does not have to repeat testing according to different individual specifications in each region (Europe, Japan and United States).

■ The Ph. Eur. is also actively involved in a number of other international harmonisation initiatives, such as the WHO initiative to draft "Good Pharmacopoeial Practices" (GPhP).

The Certification Procedure: Evaluating quality dossiers on the manufacture of substances for pharmaceutical use and the related inspections programme

ACTIVITIES RELATED TO THE QUALITY OF MEDICINES

■ The *Certification of Suitability to monographs of the European Pharmacopoeia* procedure was established in 1994 and is based on a Resolution¹ of the Council of Europe's Public Health Committee (Partial Agreement), which is revised regularly to address new risks to public health.

■ The aim of the Certification procedure is to evaluate the capacity of Ph. Eur. monograph(s) to control the quality and impurity profile of a given source of an API or excipient. If the tests specified in a monograph are not sufficient, appropriate supplementary tests are annexed to the certificate granted after evaluation of the dossier, for example to control additional impurities linked to the specific synthesis or residues of the solvents used in production.

■ The Certification procedure centralises the evaluation of data for the benefit of regulatory authorities and industry and also provides the Ph. Eur. with information on the quality of substances on the European market, thus helping to identify whether or not a revision of specific monographs is needed.

■ CEPs – which are referred to in EU pharmaceutical legislation – are recognised by the Ph. Eur. member states and by a number of other countries, such as Australia, Canada, Singapore, Saudi Arabia, South Africa and Tunisia. An increasing number of licensing authorities worldwide accept CEPs to support (fully or partially) the data related to the quality of APIs used in medicinal products.

■ The EDQM is responsible for managing the Certification procedure and the applications. By the end of 2016, more than 4400 valid certificates were granted to manufacturers in 50 countries from every continent, for about 1,000 substances or preparations used in the manufacture of medicines.

■ For a manufacturer to be granted a CEP, a detailed dossier is submitted to the EDQM describing the manufacturing process, the tests performed on the materials and on the substance produced. The dossier must demonstrate that the product complies with the quality standards of the Ph. Eur. and European Union legislation and, in particular, the monograph can be used to control impurities. The applicant must also agree to comply with Good Manufacturing Practice (GMP) as defined in Part II of the EU GMP Guide.

■ The procedure used to evaluate a dossier guarantees the confidentiality of intellectual property. The dossier is evaluated by experts nominated by the national competent authorities of participating countries and appointed by the Steering Committee of the Certification procedure. Scientific administrators working within the EDQM's Certification Division are also involved in performing scientific assessments of applications and in the preparation of evaluation reports. They also provide administrative support, propose amendments or new policies if necessary and ensure adherence to the procedure.

THE INSPECTION PROGRAMME

■ The EDQM inspection programme is an integral part of the Certification procedure and is carried out under the mandate given to the EDQM by the European Commission in application of Directives 2001/83/EC and 2001/82/EC as amended.² Inspections of manufacturing and/or distribution sites of active substances covered by CEPs are scheduled on the basis of a risk assessment; they ensure that GMP is applied and that the information supplied under the Certification procedure is accurate.

1. Resolution AP-CSP (07) 1.

2. Directive 2001/83/EC sets out the EU code relating to medicinal products for human use. Directive 2001/82/EC sets out the EU code relating to veterinary medicinal products.

THE CERTIFICATION PROCEDURE IN BRIEF

- ▶ Main objective: to ensure that the quality of substances used in the production of medicines meets the standards set in the Ph. Eur. and that the quality therefore complies with legal requirements
- ▶ Established in 1994 as a routine procedure
- ▶ As of the end of 2016, more than 4,400 valid certificates (CEP) granted to manufacturers from more than 50 countries covering more than 1,000 substances
- ▶ A network of around 100 assessors and 30 inspectors from 24 different national competent authorities and the EDQM

■ The EDQM is responsible for organising the inspections and their follow-up; this includes taking any subsequent action in relation to CEPs and communicating with the authorities concerned.

■ The inspection programme is drawn up based on priorities recommended by the competent authorities of member states and is adopted by the Certification Steering Committee. The inspections are jointly carried out by:

- ▶ GMP inspectors from the competent authorities in the European Economic Area (EEA)³ or in countries which have a Mutual Recognition Agreement (MRA) with the EU in the GMP sector.
- ▶ EDQM inspectors having the same qualification.

■ About 40 on-site inspections are carried out each year, mainly in Asia – for several years, the vast majority of inspected sites have been outside the EEA, as the production of substances for pharmaceutical use has largely shifted to non-European countries.

3. The European Economic Area (EEA) 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.

■ The EDQM's Certification Division is also involved in a number of international platforms, such as:

- ▶ the International Generic Drug Regulators Programme (IGDRP), a forum for devising concrete measures and arrangements for sharing information and regulatory work at the international level regarding generic drugs;
- ▶ the International API Inspection Programme, which aims to foster greater international collaboration and information-sharing on API inspections, allowing more sites to be monitored and reducing unnecessary duplication; and
- ▶ the Pharmaceutical Inspection Co-operation Scheme (PIC/S), which develops and promotes harmonised GMP standards and guidance documents, trains competent authorities (in particular inspectors), and assesses (and reassesses) inspectorates.

■ Such international projects for collaboration and sharing information related to the inspection of APIs have made it possible to cover a higher number of inspection sites worldwide and make best use of limited resources.



The OMCL Network: Quality control of medicines on the market

ACTIVITIES RELATED TO THE QUALITY OF MEDICINES

As part of its surveillance activities for marketed medicines, the EDQM co-ordinates the General European Network of Official Medicines Control Laboratories (GEON). This activity was established in 1995, following a joint decision in May 1994 by the European Commission and the Council of Europe to promote co-ordination and so avoid duplication between EEA member states in terms of the quality control of identical medicinal products on the market. The Official Medicines Control Laboratories (OMCL) Network, which is open to Ph. Eur. member states and Observers, thus ensures that patients receive the same quality of pharmaceutical products throughout Europe.

This international collaboration reduces public health expenses by sharing resources, and also influences future development through harmonised common standards. The sharing of workloads, resources and expertise among the OMCLs makes it possible to avoid duplication of work and gives them access to the latest technologies and selective methods of analyses. Special emphasis is placed on the establishment and maintenance of 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.

LEVELS OF COLLABORATION

The OMCL Network consists of independent public laboratories that are appointed by the national authorities and are responsible for the quality control of medicinal products for human and veterinary use. There are two levels of collaboration:

- ▶ General activities, which are open to all of the member states of the Ph. Eur. Convention and the observer states (following an auditing and acceptance process). All official control laboratories are invited to participate in meetings and in collaborative studies in all the areas of general interest;

- ▶ Activities restricted to the EU/EEA and its regulatory framework, notably those connected to the Community Marketing Authorisation process, the Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) and to the OCABR system for biological products (human and veterinary). With respect to the latter, the restricted network also includes non-EU countries that have entered into specific agreements with the EU in relation to batch release, e.g. Switzerland and Israel (the latter for human vaccines only).

This approach means that know-how can be shared and all parties can progressively attain the same level of quality assurance, while respecting each party's constraints.

THE SURVEILLANCE PROGRAMMES

The main areas covered by the surveillance programmes are:

- ▶ market surveillance, according to a work programme set by the EMA, of pharmaceutical products that have received a Community Marketing Authorisation (Centrally Authorised Products, or CAP) which is valid throughout the EU/EEA, or have been authorised through the MRP/DCP;
- ▶ general Market Surveillance Studies (MSS) on products marketed throughout Europe, for example generics and herbal preparations;
- ▶ specific control of a number of biological products (blood derivatives and vaccines for human or veterinary use) prior to their release to the market;
- ▶ quality monitoring of stockpiled medicines;
- ▶ testing of counterfeit/illegal medicines;
- ▶ testing of APIs;
- ▶ testing of unlicensed pharmacy preparations.

- ▶ 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
- ▶ Independent public laboratories, established by the national authorities
- ▶ 36 European and 5 countries outside of Europe participate in the various activities/programmes of the Network
- ▶ About 70 laboratories provide human and technical resources to implement testing programmes
- ▶ About 210 individual counterfeit/illegal product testing reports were issued by the Network in 2016 via the Know-X database (the database contains 3,500 OMCL reports as of December 2016)

GENERAL NETWORK ACTIVITIES

Quality Management Programme

■ The OMCL Network has developed and implemented a common approach for QM systems. The pace of work in this area has intensified over the years and has resulted in the adoption of:

- ▶ a harmonisation programme for the QM policies of all Network members;
- ▶ a specific assistance and maintenance programme for QM systems in the Network;
- ▶ guidelines on validation of analytical procedures used in testing programmes, evaluation and reporting of results, qualification of equipment and management and handling of reagents and reference standards.

■ By agreement, the OMCL Network applies the quality standards of ISO/IEC 17025, and audits are performed based on Ph. Eur. and OMCL Guidelines. An annual programme of audits and visits of the various OMCL laboratories is performed routinely.

Proficiency Testing Scheme Studies

■ To ensure that the results obtained by the various laboratories in the Network are comparable, proficiency testing scheme (PTS) studies are regularly carried out on basic methods of analysis. These studies provide laboratories with an objective means for assessing and demonstrating the reliability of their data, and thus help to build mutual trust between OMCLs. They constitute an important component of an effective common system for QM and the measurement of performance.

■ Every year, studies are organised in the physico-chemical and biological areas and these studies are open to members of the Network, to manufacturers and other laboratories working in the field.

■ A PTS programme on specific topics is also set up jointly with the WHO and is open to governmental control laboratories worldwide.

Collaborative Market Surveillance Studies (MSS)

■ These studies are designed to compare the quality of medicinal products in the different member states, and thus provide a panoramic view of the quality of medicinal products available on the European market in a given therapeutic class. They are developed in close collaboration with inspectors and national authorities in the various countries.

■ Usually, several studies are organised each year, with the participation of national control laboratories of various countries of the Network. The results provide valuable information on the potential need to revise the relevant Ph. Eur. monographs, general chapters and methods.

Studies on counterfeit/illegal medicines

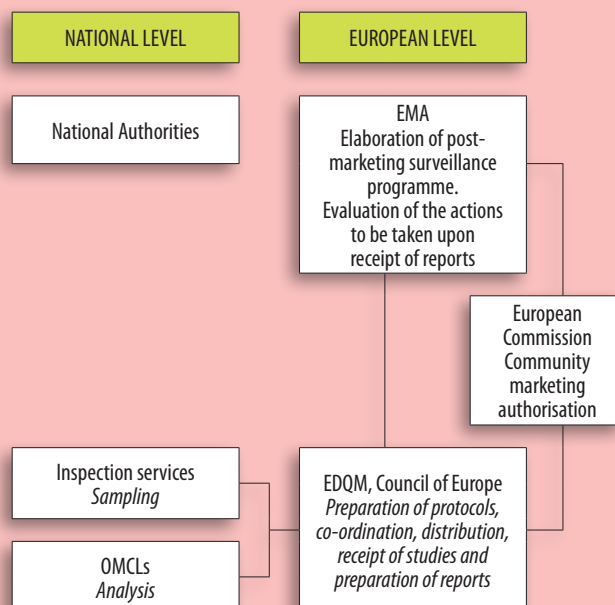
■ Over the last decade, the laboratories in the Network have been increasingly involved in testing activities related to counterfeit/illegal medicines. OMCLs have initiated close collaboration with forensic laboratories in order to share their expertise in the quality control of medicines.

■ Responding to the globalisation of the manufacture and trading of active ingredients, the Network decided in 2011 to set up a Working Group on API testing; a Working Group on counterfeit/illegal medicines testing was also set up.

■ In 2012, the first Market Surveillance Study on Suspected Illegal Products (MSSIP) was performed involving dietary supplements with a purported slimming effect. After initial testing, it was proposed that this programme would continue to be developed and expanded in the coming years.

■ The performance of OMCLs in identifying (and, where possible, quantifying) unknown active pharmaceutical ingredients is checked on a regular basis in a specifically-developed programme called the Suspicious Unknown Products (SUP) programme.

ACTIVITIES RELATED TO THE QUALITY OF MEDICINES



■ In 2014, the EDQM launched a database called Know-X, which collates reports on counterfeit/falsified medical products that have been detected in Council of Europe member states. It aims to provide a user-friendly tool to assist the exchange of information, to highlight and encourage collaboration between health and law enforcement authorities, and to foster the sharing of analytical information on the testing of counterfeit/falsified and other illegal medicines within the OMCL Network. Some 210 individual counterfeit/illegal product testing reports were issued by the Network in 2016 via the Know-X database; as of December 2016, the database contains about 3,500 OMCL reports. Access to the Know-X database is restricted to members of the Network.

■ Finally, technical training programmes for Network members on the testing of counterfeit/illegal medicines have been offered by the EDQM in collaboration with volunteer OMCLs that have technical expertise in this field.

EU/EEA-SPECIFIC ACTIVITIES

Market surveillance of products with a Community Marketing Authorisation

■ Since 1995, Community Marketing Authorisations have been granted for innovative medicines that can then be marketed throughout the EU and the EEA. A co-ordinated approach to control their quality in the various markets was necessary, and since 1999 this activity involves the OMCL Network under an annual Centrally Authorised Products (CAP) Sampling & Testing Programme agreed between the EMA and the EDQM.

■ The EMA sponsors the programme and has overall responsibility for it, while the EDQM coordinates the sampling and testing operations. The list of medicinal products to be included in the annual

programme is prepared by the EMA Secretariat together with the EMA Scientific Committees (CHMP and CVMP) following an evaluation of the potential risk to public health. The procedure allows a common protocol for sampling and testing of products to be established in collaboration with the EMA, the EDQM and the national authorities.

■ Products to be tested are sampled in three EU/EEA member states. The collected samples are sent to the EDQM, who in turn allocates them to national control laboratories for testing in accordance with well-established protocols derived from Marketing Authorisation (MA) dossiers. The EDQM collects the analyses and results and establishes a report that includes the quality control results and proposals for follow-up action if necessary. This report is then sent to the EMA.

■ In all, OMCLs from 28 EU/EEA countries regularly participate in the testing phase of the programme. More than 500 products have been tested since 1999.

Mutual Recognition Procedure and Decentralised Procedure post-marketing surveillance

■ This specific testing programme was established for market surveillance of medicines that have received a marketing authorisation via the MRP or DCP.

■ The market surveillance scheme for these medicines was initiated on a voluntary basis by members of the OMCL Network from EU/EEA member states and the EDQM provides the secretariat services for the Network. After a four-year trial phase, it was decided in May 2005 to continue with an annual work programme.

■ Since then, more than 20 OMCLs have regularly participated in this programme. For example, in 2016, 25 OMCLs from 20 EU/EEA member states participated.



- The EDQM has established a collaborative database system to ensure communication between the participating OMCLs, as the programme is based on the principles of the sharing of work and test results.

- By avoiding duplicate testing of the same products in different member states, this system ensures a co-ordinated and economical approach to market surveillance. At present, about 1,000 medicines undergo quality control testing every year through this programme.

Official Control Authority Batch Release (OCABR) of Biologicals for Human Use

- The activities of the human OCABR Network ensure the harmonised application of Article 114 of EU Directive 2001/83/EC as amended by fostering the mandatory mutual recognition of batch release for human vaccines and medicinal products derived from human blood and plasma.

- This Network elaborates guidelines that define the testing requirements for each product and establishes administrative procedures and guidance for OCABR-related activity in order to facilitate mutual recognition. These guidelines are published exclusively on the EDQM's website.

- Through a review of manufacturers' protocols and targeted OMCL testing, the goal is to confirm that batches comply with the specifications defined in the relevant approved marketing authorisation dossier. It allows Official Control Authorities to test each batch of human vaccines and blood-derived medicinal products before they are placed on the market. Compliant batches receive an EU certificate which is accepted within the EU/EEA, Switzerland and Israel (the latter for human vaccines only), and is recognised as a sign of quality in other parts of the world.

- In 2012, the EDQM signed a Memorandum of Understanding (MoU) on behalf of the OCABR Network with the Biologics and Genetic Therapies Directorate (BGTD) of Health Canada, allowing the participation of Health Canada in numerous OCABR network activities in this area.

Batch Control for Immunological Veterinary Medicinal Products

- This activity focuses on the independent control of immunological veterinary medicinal products (IVMPs) according to Articles 81 and 82 of EU Directive 2001/82/EC, as amended.

- Article 82 of the Directive allows a member state, for human or animal health reasons, to request samples of each batch of a given IVMP to be submitted to a competent authority for control by an OMCL before it is placed on the market, and establishes conditions under which a restricted test scheme can be applied. This is referred to as the OCABR procedure.

- It involves the testing of samples and a review of the manufacturer's batch protocol to confirm compliance with the approved marketing authorisation. The results of the testing must be mutually recognised by all other competent authorities requiring OCABR for that product. The list of products eligible for OCABR testing is regularly reviewed by the Network.

- According to Article 81 of the Directive, IVMPs not eligible for OCABR can be controlled by checking the manufacturer's batch protocol; this is referred to as Official Batch Protocol Review (OBPR).

- In both cases, compliant batches receive either an OCABR or OPBREU certificate which is accepted within the EU/EEA and Switzerland and is also recognised as an indication of quality in other countries.

- A series of product-specific guidelines and administrative procedures have been developed by specialised OMCLs within the Network in close collaboration with the EU Commission, the EU Commission's Veterinary Pharmaceutical Committee and industry.

- The Network provides an effective platform for information exchange and work-sharing through mechanisms that include regular meetings and electronic data exchange.

Pharmaceutical care and combating counterfeit medicines

ACTIVITIES RELATED TO THE QUALITY OF MEDICINES

PHARMACEUTICALS AND PHARMACEUTICAL CARE

Worldwide, it is estimated that half of all medicines are inappropriately⁴ prescribed or dispensed, and that half of all patients fail to take their medicines properly. Errors relating to medication use, lack of documentation on how medicines are prescribed, used and dispensed, as well as insufficient communication have a considerable impact on mortality and morbidity. The large amount of resources spent on the development and regulatory control of medicines are only reasonably invested if the medicine is used appropriately and the necessary information to ensure this is accessible to all.

The EDQM's European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) oversees the work of three committees of experts in three main areas:

1. The classification of medicines as regards their supply: The classification status of medicines authorised in Europe into prescription and non-prescription medicines remains a competency of the individual countries. The Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PC/PHO) annually updates its classification recommendations, which are published in the Melclass database of the EDQM.⁵ The medicines classified by the CD-P-PC/PHO may or may not be licensed for use in the EU. The Melclass database, also presents the classification status of medicines in Council of Europe member states. In January 2017, this database contained recommendations for about 2,700 substances.

4. WHO, *The World Medicines Situation*, 2011.

5. <https://melclass.edqm.eu/>.

2. Setting quality and safety standards in pharmaceutical practices and pharmaceutical care: Public authorities and the manufacturing and distribution sectors devote a lot of their resources to the quality, safety and efficacy of medicines. However, the safe and appropriate use of medicines is just as important as product quality to ensure a patient obtains the best possible outcome from their medicine. Pharmaceutical care is understood as a quality concept and working method for the responsible provision of medicine therapy for definite outcomes in the interest of patients' quality of life.

- ▶ The Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) develops scientific indicators for measuring the quality of pharmaceutical care in Europe. These indicators provide information that is of practical utility for policy-makers and professional associations.
- ▶ Regulations for medicinal products that are prepared in pharmacies for the special needs of patients are not harmonised among Europe countries. However, this activity is an important part of pharmacy practice and provides a valuable therapeutic service that is an integral part of the modern health care system. To respond to this gap, the CD-P-PH/PC supports the development of legal texts and best practices in this field.
- ▶ There is a growing demand for and promotion of foreign traditional therapies – such as traditional Chinese medicines – in Europe. With a view to supporting safe practices, the Committee of Experts developed models in 2012 for curricula for therapists and health professionals in Europe and for balanced information for the European public.

- ▶ Establishing common policies related to the **appropriate use of medicines and the prevention of counterfeit medicines and similar crimes**
- ▶ Over **2,700 substances** are published in the Melclass database on the classification of medicines hosted by the EDQM at <https://melclass.edqm.eu>
- ▶ **MEDICRIME Convention**, entered into force on 1st January 2016, criminalising the counterfeiting of medical products

3. Preventing and managing risks posed by counterfeit medical products and related crimes:

Counterfeit medicines pose a growing and real threat to public health in Europe. These medicines may contain low quality ingredients or the wrong doses; they may be deliberately mislabelled or have fake packaging or ingredients.

- ▶ For this activity, the Council of Europe and its EDQM have adopted a multi-level, anti-counterfeiting strategy with various aspects, such as: legislative actions against pharmaceutical crime by means of the MEDICRIME Convention;⁶ awareness campaigns against illegal internet pharmacies; multi-sectorial training for officials from member- and observer states; increased testing activities, e.g. through the network of OMCL; and, in the performance of conformity assessments of medicines mass serialisation tools, to support member states in their supervisory responsibilities under the Falsified Medicines Directive 2011/62/EU (Delegated Act) in order to prevent falsified medicines from reaching patients.
- ▶ The MEDICRIME Convention is the first international treaty that criminalises the counterfeiting of medical products and similar crimes with a view to public health protection. The Convention entered into force on 1st January 2016; as of February 2017, it has been signed by 18 countries and ratified by a further 9 countries. Part of the holistic anti-counterfeiting strategy of the Council of Europe/EDQM is to provide international support for the implementation of the Convention, focussing on prevention and inter-disciplinary co-operation and enforcement. The EDQM also

seeks to improve “know-how” among officials in terms of applying the provisions and best practice models described; to this end, the EDQM’s Committee of Experts on Minimising the Public Health Risks Posed by Counterfeiting of Medical Products and Related Crimes (CD-PH/CMED) has co-organised several regional training sessions with national authorities.

- ▶ The EU’s Falsified Medicines Directive (FMD) and Delegated Acts have been designed to prevent falsified medicines entering into the legal supply chain. From 2018, a unique identifier (a 2-dimension barcode) must be placed on the packaging of human medicines. This identifier will ensure full traceability and guarantee the authenticity of the medicine. The EDQM will be involved in the organisation of periodic conformity assessments of the pan-European system called the EMVS (European Medicines Verification System). The aim of these audits is to ensure compliance with the standard and they will also support the Member States in their future supervisory responsibilities under the Delegated Act on the Unique Identifier.⁷

6. *Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health.* at <https://go.edqm.eu/MedicrimeEDQM>.

7. See <https://go.edqm.eu/2016161regu>.

Transfusion, Transplantation, Cosmetics and Food contact materials

ACTIVITIES RELATED TO PATIENT AND CONSUMER PROTECTION

BLOOD TRANSFUSION

■ The work of the Council of Europe in the area of blood transfusion started in the 1950s, and has been based consistently on certain guiding principles:

- ▶ the promotion of voluntary and non-remunerated donation (non-commercialisation of substances of human origin);
- ▶ mutual assistance of member states (e.g. in the exchange of blood-typing reagents and access to rare blood group donations); and
- ▶ the protection of the health of blood donors and recipients.

■ Building on these major principles, the EDQM continues to focus on studying the ethical, legal and organisational aspects of blood transfusion with a view to ensuring quality, increasing availability, avoiding wastage, ensuring optimal use of blood and blood components and analysing the possible ethical and organisational impact of new scientific developments.

■ This work is the responsibility of the European Committee on Blood Transfusion (CD-P-TS), which also assists Council of Europe member states to improve their blood transfusion services, ensures the transfer of knowledge and expertise through training and networking, and monitors practices in Europe and assesses epidemiological risks, in particular those related to the emergence of new infectious agents transmissible by blood transfusion.

■ The CD-P-TS supervises the work of a number of individual activities, such as the European Database of Frozen Blood of Rare Groups, the Blood Proficiency Testing Scheme (B-PTS) and the Blood Quality Management (B-QM) Programme, as well as a number of Working Groups, including one on Plasma Supply Management and another on the *“Guide to the Preparation, Use and Quality Assurance of Blood Components”* (the Blood Guide).

Such projects contribute to the Steering Committee’s goals of defining and promoting the implementation of quality and safety standards in the collection, storage, distribution and use of blood and blood components, and of proposing ethical, safety and quality standards on professional practices and on blood component specifications.

■ In January 2016, the European Database of Frozen Blood of Rare Groups became operational. This database facilitates the search and access to units of frozen blood of rare blood groups within Europe.⁸

■ The CD-P-TS, which is composed of 65 experts from 35 Council of Europe member states and 10 observer countries, plus the EU Commission and WHO, meets at least once a year to discuss its work programme. This programme includes the elaboration of Council of Europe resolutions⁹ and the collation of annual reports and trend analyses from the Council of Europe’s member states on the collection, testing and use of blood and blood components.¹⁰

■ An important outcome of its activities is the Blood Guide, which is drafted by an expert Working Group (with members from Europe, Australia, New Zealand and the USA) and is published every two years. One significant benefit of the intergovernmental collaboration involved in publishing the Blood Guide is the promotion of quality and safety standards in transfusion in Europe and beyond, for example in Australia and New Zealand where some quality and safety requirements stipulated in the Guide are mandatory.

8. See <https://rarebloods.edqm.eu/>

9. See <https://go.edqm.eu/BTrec>

10. See <https://www.edqm.eu/en/blood-transfusion-reports-70.html>

BLOOD TRANSFUSION IN BRIEF

- ▶ 65 experts from 35 member and 10 observer states, plus the EU Commission and WHO, contribute to the work
- ▶ 19th Edition of the *Guide to the preparation, use and quality assurance of blood components* published in 2017
- ▶ Annual surveys on collection, testing and use of blood
- ▶ Support the implementation of a **Quality Management System** in blood establishments
- ▶ Coordination and management of a **Blood Proficiency Testing Scheme**

■ The EDQM has observer status at the International Society of Blood Transfusion (ISBT) Board of Directors and is also a member of two dedicated ISBT working parties, the Quality Management and the Code of Ethics Working Parties. In addition, there is a long-standing co-operation with the EU Commission in the field of blood transfusion.

BLOOD PROFICIENCY TESTING SCHEME (B-PTS) STUDIES

■ These studies are aimed at externally assessing the performance of laboratories with regard to tests used for the qualification of individual blood donations. They constitute an important component of an effective Quality Management System (QMS) and the measurement of testing capabilities of blood establishments' laboratories.

■ Since 2010, 24 studies (as of April 2016) have been organised in the fields of nucleic acid amplification techniques (NAT), serology and immuno-haematology.

In 2016, an average of 58 laboratories participated in each B-PTS study, covering 32 countries from the Council of Europe and EU.

BLOOD QUALITY MANAGEMENT (B-QM) PROGRAMME

■ This programme, which began in 2012 as a pilot, aims to help European blood establishments to develop, implement and improve their QMS.

■ Training visits, mutual joint visits and audits by peers as well as training sessions are organised for blood establishments. This joint effort should ultimately lead to the harmonisation of QM policies in Europe and improve mutual confidence between European countries in the context of exchange of blood components, especially for the sourcing of plasma used for the production of plasma-derived medicinal products.



ORGAN, TISSUE AND CELL TRANSPLANTATION IN BRIEF

- ▶ 91 experts representing 54 countries/organisations, including the EU Commission and WHO, contribute to the work
- ▶ 2nd Edition of the *Guide to the quality and safety of tissues and cells for human application* published in 2015; 6th Edition of the *Guide to the quality and safety of organs for transplantation* published in 2016
- ▶ Regular publication of the *Newsletter Transplant*
- ▶ Participation in the elaboration of legal instruments such as **Conventions, Recommendations and Resolutions**.
- ▶ Publication of brochures for the general public, for example the “*Parent’s guide on umbilical cord blood banking*” and “*Exercise your way to better post-transplant health*”.

ACTIVITIES RELATED TO PATIENT AND CONSUMER PROTECTION

ORGAN, TISSUE AND CELL TRANSPLANTATION

■ The work of the Council of Europe in the area of organ, tissue and cell transplantation began in 1987. The guiding principles for the EDQM’s activities in this area are to guarantee human rights and dignity and to protect donors and recipients. This latter principle means improving and promoting rigorous standards for quality and safety to protect not only the donor and recipient, but also the graft itself, which is a rare and precious resource.

■ The EDQM works to defend these major principles by elaborating guidelines on ethical, quality and safety standards and their implementation in collaboration with the EU, WHO and other international organisations. The non-commercial use of products of human origin is a core principle in this area and similarly the fight against organ trafficking is one of the priorities of the EDQM.



■ The Committee responsible for these activities is the European Committee on Organ Transplantation (CD-P-TO). It actively promotes the non-commercialisation of organ donation (anonymous, voluntary, non-remunerated donations), the fight against organ trafficking and the development of ethical, quality and safety standards in the field of organ, tissue and cell transplantation. Its activities include the collection of international data and monitoring of practices in Europe, the transfer of knowledge and expertise between organisations and experts through training and networking, the preparation of surveys and recommendations as well as the provision of guidance for healthcare professionals and the general public.

■ In addition, the CD-P-TO regularly works on the elaboration of the following publications:

- ▶ ***Guide to the quality and safety of organs for transplantation:*** This deals with different aspects of the organ transplantation process, from risk assessment to disease transmission, collating information to provide transplant professionals with a useful overview of the most recent advancements in the field;
- ▶ ***Guide to the quality and safety of tissues and cells for human application:*** This provides sound information and guidance for all professionals involved in donation, banking, transplantation and other clinical applications of tissues and cells as well as to those involved in inspecting tissue establishments. This Guide helps optimise the quality and minimises the risks of these complex procedures, ultimately helping improve the rate of successful clinical applications of human tissue cells; and
- ▶ ***Newsletter Transplant:*** This annually collates international figures on organ donation and transplantation.

CONSUMER HEALTH PROTECTION IN BRIEF

- ▶ Establishing common policies related to **quality and safety of cosmetics and food contact materials**
- ▶ More than **250 experts** from **34 Ph. Eur. member states** and **5 Observers** involved
- ▶ A network of **40 Official Cosmetics Control Laboratories (OCCL)** in **22 member states** (including 19 EU member states) are involved in the surveillance of cosmetics

■ The CD-P-TO also elaborates resolutions and recommendations in the field of organs, tissues and cells. These documents have a profound impact on national legislations, ethical frameworks, professional practices and strategic plans on organisational aspects of donation and transplantation.¹¹

■ Other brochures such as “*Umbilical Cord Blood Banking - A Guide for Parents*” and “*Exercise your way to better post-transplant health*” are aimed at providing guidance to the general public.

■ As part of its effort to promote the non-commercialisation of organ donation and the fight against organ trafficking, the CD-P-TO, together with the European Committee on Crime Problems and the Committee on Bioethics from the Council of Europe, was involved in the elaboration of the Council of Europe’s Convention against Trafficking in Human Organs, which was adopted in 2014 and opened for signature in 2015.

■ To raise awareness about organ donation, the Council of Europe organises, together with a hosting country, European Organ Donation Day (EODD). The idea behind this Day is to help a different member state each year to encourage debate and provide information on organ donation and transplantation, legal and medical measures so that each person can decide on donation and make their wishes known to their family.

CONSUMER HEALTH PROTECTION

■ Public health tasks and food safety were included in the Council of Europe’s agenda in 1959. Since 1 January 2009, the EDQM has been engaged in efforts to strengthen consumer health protection in Europe and to define common policies related to the quality and safety of cosmetics and food contact materials.

¹¹. See <https://go.edqm.eu/OTrec>

■ The EDQM’s Consumer Health Protection Committee (CD-P-SC), which is composed of representatives from national ministries with public health responsibilities, manages the work programme. In 2016, more than 250 experts from 34 member states and four Ph. Eur. observers followed or contributed actively to its work. The CD-P-SC also manages two subordinate expert groups: the Committee of Experts on Food Contact Materials (P-SC-EMB) and the Committee of Experts on Cosmetic Products (P-SC-COS). These expert groups examine health-related matters and prepare reports and make recommendations for improvements to policies and practices.

■ These committees enjoy close co-operation with equivalent bodies in other international institutions; in particular, the European Commission, the European Food Safety Authority (EFSA) and the Joint Research Centre (JRC). Contact is also maintained with manufacturers and European manufacturer associations in each sector, which may participate in *ad hoc* working groups or may be consulted during the drafting process concerning new requirements.

■ Guidelines are provided related to the use of natural or synthetic ingredients in response to health risks posed by substances with pharmacological or toxic effects. This work aims at assisting national authorities in their work and also other professionals in the area of health and safety.

■ In March 2012, a Resolution on safety criteria for cosmetic products intended for infants was adopted by the Council of Europe’s Committee of Ministers. Cosmetic products must be safe for the health of young children and should only contain ingredients that are non-toxic. For example, potent allergens or substances with endocrine disrupting activity should not be present and preservatives should be used at their lowest effective concentrations. To provide guidance and support to those working in

ACTIVITIES RELATED TO PATIENT AND CONSUMER PROTECTION

this field, a Guide entitled “*Safe Cosmetics for Young Children – A published Guide for Manufacturers and Safety Assessors*” (2012, 1st Edition) was published and it provides detailed recommendations for the risk assessment of baby creams and lotions.

■ A network of OCCL was established in 2010 to share the work linked to cosmetics surveillance by strengthening inter-laboratory collaboration and the sharing of resources among market surveillance authorities. This network is open to member states and observers of the Ph. Eur.; more than 40 European OCCLs participate in regular network activities, including laboratories in 19 EU member states. Several control laboratories in Asia also take part in the work programme.

■ Network activities include market-surveillance studies, analytical development, proficiency testing scheme studies and the implementation of harmonised QM systems. Priority is given to

testing products that may present a health risk for consumers, either linked to the presence of prohibited or restricted substances (according to EU legislation) or to trace metals. In addition, the Network also publishes test methods after performing inter-laboratory trials to confirm that these methods are fit for purpose.

■ In June 2013, the Council of Europe’s Committee of Ministers adopted a Resolution on metals and alloys used in food contact materials and articles (e.g. aluminum foil, kitchen utensils, coffee machines). The Resolution is supplemented by a *Technical Guide* containing practical guidelines for its implementation, which have been agreed amongst national authorities, manufacturers and control laboratories (private and public sector). The *Technical Guide* defines quality requirements for materials for which no specific EU regulations exist and sets out, for example, upper limits for the transfer of metals to food (“specific release limits”).



HOW TO CONTACT THE EDQM?

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and

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which is accessible on the EDQM Internet site:

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Fax : +33 (0)3 88 41 27 71

...

Postal address

European Directorate
for the Quality of Medicines & HealthCare (EDQM)
Council of Europe
7 allée Kastner, CS30026
F-67081 Strasbourg (France)

www.coe.int

The Council of Europe is the continent's leading human rights organisation. It comprises 47 member states, 28 of which are members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law. The European Court of Human Rights oversees the implementation of the Convention in the member states.

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