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.
HOW TO CONTACT THE EDQM?

Information and orders via the Internet:

www.edqm.eu
and
https://store.edqm.eu

Questions must be submitted through the HelpDesk, which is accessible on the EDQM Internet site:

www.edqm.eu/hd

Tel: +33 (0) 3 88 41 30 30
Fax: +33 (0) 3 88 41 27 71

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Council of Europe
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European Directorate for the Quality of Medicines & HealthCare

Protecting public health in Europe since 1964

Council of Europe, EDQM
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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 2018 – 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, including the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare and the World Health Organization (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;
The EDQM at a glance

THE EDQM IN BRIEF

► A Directorate of the Council of Europe
► Created in 1964
► Over 360 staff members, more than 25 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.

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.

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.

GLOBAL REACH

The pharmaceutical world has undergone dramatic changes over the past 50 years resulting in a truly globalised environment with a determining effect on the EDQM’s activities. This is the case for example of the increasing number of applications for CEPs and of requests for revision from India and China, reflecting the global trend in the 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).
The EDQM's cooperation with the European Union (EU) and its 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 EMA and national competent authorities on ensuring continued consistency in approaches between licensing authorities and the Ph. Eur. The EDQM also has observer status with a number of EMA bodies, e.g. the Committee for Advanced Therapies (CAT), the Herbal Medicinal Products Committee (HMPC), the joint CHMP/CVMP Quality Working Party (QWP), the Biologics Working Party (BWP), the GMDP Inspectors Working Group (GMDP IWG) 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), serving 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);
- participating as an observer in the WHO’s Programme on International Nonproprietary Names (INN) – since INN are used in Ph. Eur. monographs;
- participating 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;
- participating in WHO’s Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP);
- sharing data and information on joint inspections relating to the Certification procedure for APIs; and
- in the fields of blood transfusion and organ, tissue and cell transplantation.
To help the EDQM carry out its activities, the Ph. Eur. member states and Observers provide on a voluntary basis the services of their experts in pharmaceutical sciences, access to their equipment in medicines control laboratories, the services of their experts in blood transfusion, organ, tissue and cell transplantation, pharmaceuticals and pharmaceutical care, consumer protection, as well as the services of their experts involved in assessments and inspections in the context of the Certification procedure.

This is one of the reasons behind the success of the EDQM, which is well equipped to respond to the wide range of needs and adapt to the 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. and participate in all its other activities.
Chapter 2
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;
  ▶ elaborating quality standards for finished products in order to help Official Medicines Control Laboratories (OMCLs) in their market surveillance task, support the development of generic drugs that are vital for the sustainability of healthcare systems and facilitate the assessment of marketing authorisation applications by regulatory authorities;
  ▶ responding rapidly to new risks to public health by drawing up new methods of analysis and tests, as well as 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 in Europe 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), finished products monographs 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, the Ph. Eur. 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 30 Observers from around the world (as of April 2018)
- Nearly 2,400 quality standards (monographs) and 361 general texts
- Legally binding in 38 European countries and applied 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 30 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, as well as from some of its 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 9.5

- The diagram shows the distribution of different categories of medicinal products and dosage forms covered by the European Pharmacopoeia Monographs. The categories include:
  - Chemicals (50%)
  - Dosage forms (15%)
  - Biologicals (4%)
  - Homeopathy (1%)
  - Medical Devices (1%)
  - Gastro (1%)
  - Ant. Bact (1%)
  - Fats (6%)
  - Radiopharmaceuticals (3%)
  - Human Vaccines (4%)
  - Veterinary Vaccines (3%)
  - Plastics (0%)
  - Blood derivatives (1%)
  - Herbal products (13%)
  - Other (1%)

The European Pharmacopoeia » Page 9
The experts are nominated by the national delegations on the basis of their expertise and are appointed by the Ph. Eur. Commission to 20 permanent Groups of Experts, supplemented by some 38 ad hoc specialised Working Parties. 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. All the Group of Experts meetings take place in Strasbourg.

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 allows nominations from non-Ph. Eur. member states and Observers for membership of the Groups of Experts and Working Parties. This decision from 2015 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 has been effective since November 2016.

Ph. Eur. monographs are regularly updated in order to respond 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 Ph. Eur. Groups of Experts are issued for public consultation in the free online EDQM publication: Pharmeuropa¹. The respective Group of Experts then analyses the comments received, revises the texts, if necessary, and submits them for adoption to the Ph. Eur. Commission.

The 9th and latest Edition of the Ph. Eur. contains nearly 2,400 monographs, 361 general texts and more than 2,690 descriptions of reagents.

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 RSs, which are then officially adopted by the Ph. Eur. Commission. These standards alone are authoritative in case of arbitration.

¹. https://go.edqm.eu/pharmeuropa

ACTIVITIES RELATED TO THE QUALITY OF MEDICINES

MAINTAINING STATE-OF-THE-ART QUALITY STANDARDS

THE NEED FOR REFERENCE STANDARDS
At the end of 2017, there were more than 2,800 RS in the Ph. Eur. catalogue; reflecting the globalised nature of the pharmaceutical industry, Ph. Eur. RSs were distributed in more than 115 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). ISAs 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 make the best uses of the resources of the participating laboratories and to add a worldwide dimension to biological standardisation.

2. https://go.edqm.eu/rs
3. https://go.edqm.eu/ISAen
4. https://go.edqm.eu/ICRSen

THE EUROPEAN PHARMACOPOEIA AND INTERNATIONAL HARMONISATION

The European Pharmacopoeia was one of the co-founders of the Pharmacopoeial Discussion Group (PDG) in 1989, together with the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (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).
Chapter 3

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

The Certification of Suitability to monographs of the European Pharmacopoeia procedure was established in 1994 and is based on a Resolution of the Council of Europe’s Public Health Committee. 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.

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 that 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. 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 GMPs are applied and that the information supplied under the Certification procedure is accurate.

5. Resolution AP-CSP (07) 1.

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 2017, more than 4,800 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 on the basis of 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) 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 now, the vast majority of inspected sites were based outside the EEA, as the production of substances for pharmaceutical use has largely shifted to non-European countries.

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.

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7. 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.
Chapter 4
The OMCL Network: Quality control of medicines on the market

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 appointed by the national authorities and responsible for the quality control of medicinal products for human and veterinary use. There are two levels of collaboration within the Network:

- 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.
OFFICIAL MEDICINES CONTROL LABORATORIES AND THE NETWORK IN BRIEF

- 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 6 countries outside of Europe participate in the various activities/programmes of the Network
- More than 70 laboratories provide human and technical resources to implement testing programmes
- About 70 individual counterfeit/illegal product testing reports were issued by the Network in 2017 via the Know-X database (the database contains 3,600 OMCL reports as of end 2017)

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.

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.8

- 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) studies9 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.

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8. https://go.edqm.eu/QAQMgl
9. https://go.edqm.eu/PTS
ACTIVITIES RELATED TO THE QUALITY OF MEDICINES

- 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 APIs and counterfeit/illegal medicines

- Responding to the globalisation of the manufacture and trading of active ingredients (APIs), the testing of APIs is nowadays a routine activity in many OMCLs. In order to react to these developments in the most efficient way, an OMCL working group dedicated to the testing of APIs was established in 2011. The task of this Working Group is to develop strategies and programmes for the OMCL Network that can contribute to the efforts of the European Health Authorities in ensuring the high quality and safety of APIs on the European market into the future.
- 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.
- A Working Group on counterfeit/illegal medicines testing was also created in 2011; its scope is not limited to medicines for human use which have a potential risk of falsification, it is also extended to veterinary medicines and designer drugs.
- Since 2012, the OMCL Network has been developing joint market surveillance programmes on suspected counterfeit and illegal products (MSSIP) to cover a large part of the European market in a co-ordinated campaign targeting specific product groups.
- 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.
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 that supports the exchange of information, encourages collaboration between health and law enforcement authorities and fosters the sharing of analytical information on the testing of counterfeit/falsified and other illegal medicines within the OMCL Network. Some 70 individual counterfeit/illegal product testing reports were issued by the Network in 2017 via the Know-X database; as of end 2017, the database contained about 3,600 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 controlling 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, which 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 550 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; 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.
- 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. At the end of 2017, the MRP/DCP Product Testing Database held some 9900 MRP and DCP product testing records, with contributions from 34 different OMCLs.

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.10
- 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.

10. https://go.edqm.eu/hOCABRgl
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 OBPR EU 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.11

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

11. https://go.edqm.eu/vOCA8R8q

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Chapter 5
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 inappropriately 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 annually updates its classification recommendations, which are published in the Melclass database of the EDQM. The medicines classified by the CD-P-PH/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. At the end of 2017, this database contained recommendations for about 2,319 substances.

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.

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;\(^\text{14}\)

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14. Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. at https://go.edqm.eu/MedicrimeEDQM
ACTIVITIES RELATED TO THE QUALITY OF MEDICINES

PHARMACEUTICAL CARE AND ANTI-COUNTERFEIT ACTIVITIES IN BRIEF

- Establishing common policies related to the appropriate use of medicines and the prevention of counterfeit medicines and similar crimes
- Over 2,319 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

- 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 EU Falsified Medicines Directive (Directive 2011/62/EU) 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 the end of 2017, it has been ratified by 11 countries and signed by 16 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-P-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-dimensional 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 is involved in the organisation of periodic conformity assessments of the pan-European system called EMVO (European Medicines Verification Organisation). In 2017, the EDQM started verifying that the system is designed, managed and operated in accordance with the standards in the delegated regulation on the Unique Identifier15 (EU 2016/161) which implements the EU Falsified Medicine Directive (Directive 2011/62/EU). This initiative will help establish member states in their role as supervisors of traceability systems.

EUROPEAN PAEDIATRIC FORMULARY: A PAN-EUROPEAN FREE ONLINE PLATFORM TO IMPROVE THE HEALTH OF CHILDREN PATIENTS

The European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and the Ph. Eur. Commission have launched a programme for developing a European paediatric formulary. With authorised medicines not always suitable for the treatment of children, national or regional formularies on pharmacy preparations still play an important role in this field and the European paediatric formulary project aims at improving the availability of extemporaneous formulations of quality paediatric medicines across Europe.

15. https://go.edqm.eu/2016161requ
Chapter 6
Transfusion, Transplantation, Cosmetics and Food contact materials

BLOOD TRANSFUSION

The EDQM is responsible for the Council of Europe’s activities in the area of blood transfusion. These are built around three major principles: promoting voluntary and non-remunerated donation, optimal use of blood and protecting both donors and recipients of labile blood components. The EDQM addresses ethical, legal and organisational aspects of blood transfusion to ensure the safety, quality and optimal use of blood supplies, increasing their availability and avoiding wastage.

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.16

The CD-P-TS, which is composed of 46 experts from 39 Council of Europe member states and 12 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 resolutions17 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.18

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.

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.

16. https://rarebloods.edqm.eu
17. https://go.edqm.eu/BTrec
18. https://go.edqm.eu/BTrep
ACTIVITIES RELATED TO PATIENT AND CONSUMER PROTECTION

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, 36 studies (as of end 2017) have been organised in the fields of nucleic acid amplification techniques (NAT), serology and immunohematology. In 2017, 7 B-PTS study were carried out. An average of 72 laboratories participated in each B-PTS study, covering 33 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

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.

In 2017, the 3rd edition of the Tissues and Cells Guide was published. The EU Commission has partially funded its elaboration and was involved in the drafting process, thus ensuring that the standards set out under EU Directives are compatible with and complemented by the Council of Europe’s guidance.

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.

Other brochures such as “Umbilical Cord Blood Banking - A Guide for Parents” and “Exercise your way to better post-transplant health”.

19. The EDQM publications are available here: https://register.edqm.eu/freepub
20. https://go.edqm.eu/OTrec
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

The EDQM is engaged in strengthening consumer health protection in Europe and defining common policies related to the quality and safety of cosmetics and food contact materials.

In 2017, the Steering Committee (CD-P-SC) was responsible for managing work programmes and decision-making processes in the areas of cosmetics and food contact materials. The Committee examined health-related issues, evaluated their risks and drafted reports and recommendations for regulatory approaches. Two sub-committees supported the work: the Committee of Experts on Food Contact Materials (P-SC-EMB) and the Committee of Experts on Cosmetic Products (P-SC-COS). At the end of term, the CD-P-SC was dissolved and separate committees established for the two activity areas, based on the corresponding decision of the Committee of Ministers. The work programme of the subordinate Committees of Experts will be pursued under the new structure.

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 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.

21. The EDQM publications are available here:
https://register.edqm.eu/freepub
22. www.coe.int/organ-donation
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.

**FOOD CONTACT MATERIALS**

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. aluminium 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”).

**TATTOOS AND PERMANENT MAKE-UP**

In order to implement the recommendations of Council of Europe Resolution AP(2008)1, the EDQM compiled safety and documentation requirements for tattoos and permanent make-up in a guide published in 2017.

The guide “Safer tattooing” provides an overview of current knowledge and challenges of toxicological assessment.

The EDQM work on the safety of tattoos and permanent make-up provided input for the preparation of related restriction proposals by the Chemicals Agency of the European Union (ECHA).
HOW TO CONTACT THE EDQM?

Information and orders via the Internet:
www.edqm.eu
and
https://store.edqm.eu

Questions must be submitted through the HelpDesk, which is accessible on the EDQM Internet site:
www.edqm.eu/hd

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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.