

COUNCIL OF EUROPE INTERGOVERNMENTAL COMMITTEES

co-ordinated by the EDQM



European Directorate for the
Quality of Medicines & HealthCare

2023

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1. Mission of the EDQM and role as secretariat of intergovernmental committees

The European Directorate for the Quality of Medicines & HealthCare (EDQM) has responsibility for eight Council of Europe intergovernmental committees. In view of its mission to contribute to public health protection by engaging with an international community of experts and stakeholders, the EDQM enables the development, supports the implementation and monitors the application of quality standards for safe medicines, health products and consumer

products and their safe use, in addition to monitoring related practices in member states. Its standards are recognised as a scientific benchmark and are applied worldwide.

The EDQM's role as secretariat for intergovernmental committees is governed by Committee of Ministers Resolution [CM/Res\(2021\)3](#) on intergovernmental committees and subordinate bodies, their terms of reference and working methods.



2. Structure of intergovernmental committees

The EDQM provides the secretariat for eight intergovernmental committees. The following five steering committees report to the Committee of Ministers:

- ▶ European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH);
- ▶ the European Committee on Organ Transplantation (CD-P-TO);
- ▶ the European Committee on Blood Transfusion (CD-P-TS);
- ▶ the European Committee for Food Contact Materials and Articles (CD-P-MCA);
- ▶ the European Committee for Cosmetics and Consumer Health (CD-P-COS).

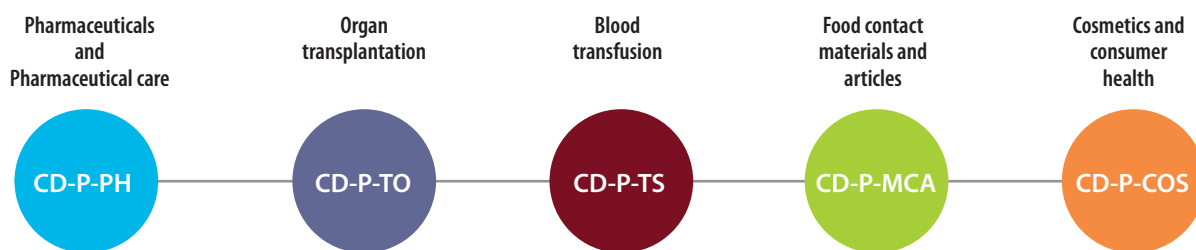
In addition, three subordinate bodies report to the CD-P-PH:

- ▶ the Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO);
- ▶ the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC);
- ▶ the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED).

The five steering committees oversee and co-ordinate intergovernmental activities in their respective areas of work, as defined in their terms of reference. The committees are composed of representatives from all Council of Europe member states having ratified the Partial Agreement on the European Pharmacopoeia (Ph. Eur.), including all European Union member states (see "[European Pharmacopoeia membership & observership](#)" under "Useful links", below).

Given the impact of the policy instruments and legal standards developed by these intergovernmental committees and the importance of protecting public health for all, the recommendations they issue may be proposed for adoption by the Committee of Ministers in its full composition, rather than in the restricted composition of Council of Europe member states having acceded to the Partial Agreement on the European Pharmacopoeia.

3. Work and examples of public health activities of intergovernmental committees



European Committee on Pharmaceuticals and Pharmaceutical Care



The CD-P-PH contributes to improving public health and access to good quality medicines and healthcare on the European continent by:

- ▶ promoting harmonisation of the classification of medicines for use with or without medical prescription through its Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO);
- ▶ developing harmonised standards for the appropriate use of medicines and promoting pharmaceutical care through its Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC);
- ▶ contributing to minimising falsification of medical products through its Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED);
- ▶ fulfilling the tasks of the Public Health Committee as set out in the Convention on the Elaboration of a European Pharmacopoeia (Ph. Eur. Convention).

Quality standards of the European Pharmacopoeia

The CD-P-PH ensures general oversight of the activities of the European Pharmacopoeia Commission (EPC):

- ▶ the Ph. Eur. and its governing body, the EPC, operate under the terms and conditions of the Ph. Eur. Convention and provide access to 3 000 relevant, up-to-date, legally binding and harmonised European standards to ensure medicines are safe and of good quality; these standards are used in more than 130 countries worldwide;
- ▶ the Ph. Eur. work programme focuses on the development of quality standards for new

substances and products, as well as the regular revision of existing standards in order to keep pace with the latest technical and scientific advances in the development, production and quality control of medicines;

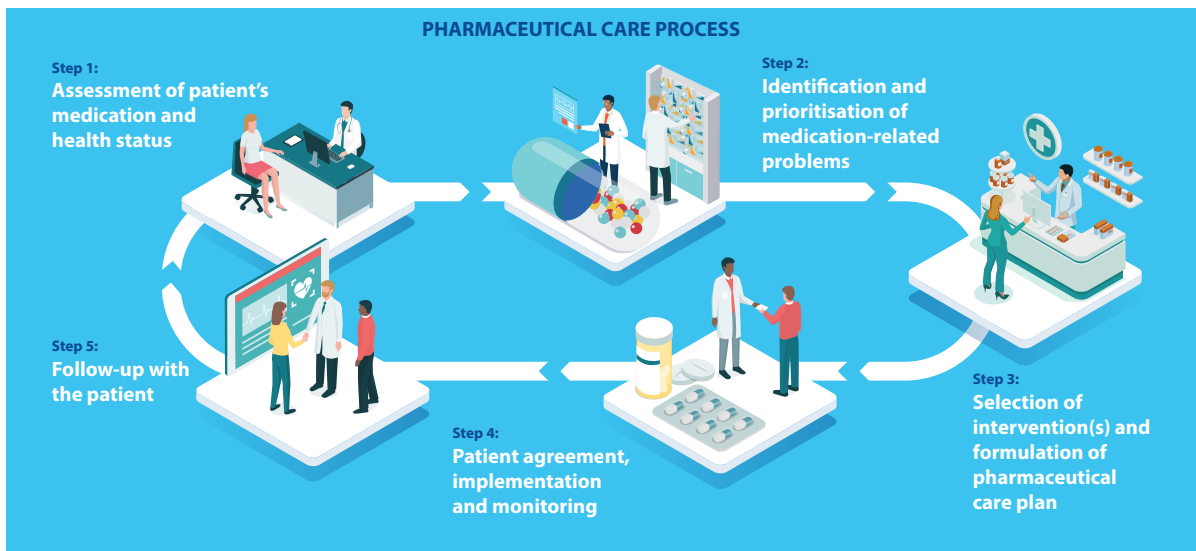
- ▶ the EPC is composed of representatives from all contracting parties to the Ph. Eur. Convention. The participation of observers from around the world confirms the importance of the EPC's work at international level;
- ▶ the CD-P-PH also supports the EPC in the elaboration of the European Paediatric Formulary, a pan-European collection of monographs for the preparation of extemporaneous formulations for paediatric medicines based on national or regional information.

TERMS OF REFERENCE:
<https://go.edqm.eu/ToRCDPPH>


Examples of activities

Implementation of pharmaceutical care for the benefit of patients and health services

Resolution CM/Res(2020)3 provides a framework for promoting and implementing the concept of pharmaceutical care in health systems at national level. Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. It involves the process through which a pharmacist co-operates with a patient and other professionals in designing, implementing and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. This resolution therefore enhances patient-centred care and promotes a responsible and rational use of medicines and healthcare resources and access to safe and good quality healthcare in Europe. Its implementation by member states is actively encouraged through activities such as:



- ▶ a mapping exercise on implementation of the pharmaceutical care process and related services in a selected number of member states in South-East Europe;
- ▶ a guidance document to harmonise the medication review process – a structured evaluation of all of a patient's medicines – in different care settings and for various target patient groups.

 **Recommendation on reporting of unaccounted disappearances of medicinal products for human and veterinary use from the legal supply chain**

- ▶ The goal of this draft instrument, scheduled for adoption in 2023, is to involve health regulatory authorities at the earliest possible stage by recommending they require stakeholders to report any theft, diversion or loss of medicines to the competent authority regulating medicines and pharmaceutical activities. The text further highlights the importance of sharing information and aims to facilitate

international co-operation. It is based on a Council of Europe-wide survey carried out in 2021 among health regulatory authorities to obtain their views on the situation.

 **Workshops for GDP, GMP and pharmacy inspectors on falsified medicines**

- ▶ The CD-P-PH/CMED committee organises regular practical workshops targeting inspectors from health authorities specialised in good manufacturing practice (GMP), good distribution practice (GDP) and pharmacy. These workshops aim to raise awareness among inspectors of cases involving falsified medicines. By enhancing their enforcement competencies, they will be able to detect signs of illegal activity and criminal acts which cannot be detected by standard procedures in the legal manufacturing or distribution chain. These workshops also shed light on the responsibilities and approaches of regulatory and enforcement officers to improve co-operation between health authorities and law-enforcement services.

European Committee on Organ Transplantation



The CD-P-TO oversees and coordinates the Council of Europe's work in the field of transplantation and human application of organs, tissues and cells of human origin. This includes:

- ▶ preparing quality and safety standards and providing guidance for their implementation;
- ▶ monitoring practices;
- ▶ studying emerging challenges;

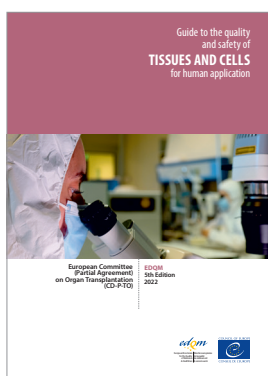
- ▶ promoting the principle of voluntary, non-remunerated donation;
- ▶ contributing to the fight against organ trafficking;
- ▶ supporting member states in the development of ethical, safe and efficient donation and transplantation services.

TERMS OF REFERENCE:
<https://go.edqm.eu/ToRCDPTO>

Examples of activities

Technical guidance to improve the quality and safety of organs, tissues and cells

The Council of Europe Recommendations CM/Rec(2020)4 and CM/Rec(2020)5 call on member states to take all necessary measures and steps to ensure that quality and safety standards for the donation and clinical application of organs, tissues and cells are applied in accordance with the EDQM *Guide to the quality and safety of organs for transplantation* and *Guide to the quality and safety of tissues and cells for human application*. They are regularly updated to provide healthcare professionals and relevant health authorities with the most recent advances in the field, as well as technical guidance to ensure the quality and safety of organs, tissues and cells. They ultimately improve the rate of successful and safe use of these substances of human origin and ensure the protection of living donors. They have become the generally accepted standards in Europe and beyond.



Network of National Focal Points on Travel for Transplantation (NETTA)

Legal transplantation frameworks provide for the referral of patients for a transplant abroad, for medical, organisational or social reasons. Travel for transplantation may become unethical, however, when it involves trafficking in persons for the purpose of organ removal or organ trafficking, or where devoting resources (including organs) to providing transplants to non-resident patients undermines a country's ability to provide transplant services for its own population.


A network of officially designated reference persons, or National Focal Points (NFPs), has been established to regularly collect data on patients travelling abroad for transplantation, within the framework of Resolutions CM/Res(2013)55 and CM/Res(2017)2. This information is compiled in the Registry of International Travel for Transplantation Activity (RITTA) for analysis. Ultimately, this contributes to

improving practices and identifying needs for tools and resources at national and international level to promote ethical travel for transplantation and combat illicit practices.



Newsletter Transplant

The need to monitor practices in the member states for the sake of transparency and international benchmarking has increased in recent decades. The *Newsletter Transplant*, co-ordinated by the Spanish National Transplant Organisation and published by the EDQM/Council of Europe since 1996, is designed to meet this need. It summarises comprehensive data – currently from 79 countries worldwide – on donation and transplantation activities, management of waiting lists, organ donation refusals and authorised centres for transplantation activities. This publication has evolved into a unique official source of information that continues to inform and inspire policies and strategic plans globally.

 **Expanding the donor pool, supporting self-sufficiency and ensuring donor protection and the respect of ethical principles**

The CD-P-TO has had a profound impact on national legislation, ethical frameworks, strategic plans on organisational aspects of donation and transplantation, and professional practices over the years through its legal instruments and position papers. Some recent documents include:

- ▶ Recommendation [CM/Rec\(2022\)19](#) on establishing measures for the harmonised collection of activity data related to the availability and use of tissues and cells of human origin with a view to supporting self-sufficiency and facilitating international data sharing;
- ▶ Recommendation [CM/Rec\(2022\)3](#) on the development and optimisation of programmes for the donation of organs after the circulatory determination of death;
- ▶ Recommendation [CM/Rec\(2020\)6](#) on establishing harmonised measures for the protection of haematopoietic progenitor cell donors;
- ▶ **Risk of commodification of substances of human origin** – A position statement of the European Committee on Organ Transplantation of the Council of Europe (2022).

 **European Donation Day**

With the aim of increasing public outreach on organ donation and transplantation, the Council of Europe organises the European Day for Organ, Tissue and Cell Donation (EDD) in a different member state each year, on the second Saturday of October. Over the years, the concept of accompanying satellite

celebrations, happening simultaneously in different European cities, has become increasingly popular.

The main objectives of EDD are to raise public awareness and establish trust among the general public towards responsible, ethical, non-commercial and professional organ, tissue and cell donation and transplantation, to engage policy makers and the medical community, and to encourage public debate and provide information so that each person can decide on donation and make their wishes known to their family. EDD is also an opportunity to honour all organ donors and their families and to thank transplantation professionals throughout Europe, whose hard work helps save lives and improve the quality of life for many people.



European Committee on Blood Transfusion

CD-P-TS

The CD-P-TS oversees and coordinates the Council of Europe's work in the field of blood transfusion. It addresses ethical, legal and organisational issues promoting voluntary, non-remunerated blood donation, mutual assistance, optimal use of blood and blood components and the protection of donors and recipients. Its activities include:

- ▶ developing technical standards aimed at ensuring the quality, safety and efficacy of blood and blood components and providing guiding principles which underpin blood donation;

- ▶ collecting international data and monitoring practices in Europe;
- ▶ enabling the transfer of knowledge and expertise between organisations and experts through training and networking and the preparation of reports, surveys and recommendations.

TERMS OF REFERENCE:
<https://go.edqm.eu/ToRCDPTS>

Examples of activities

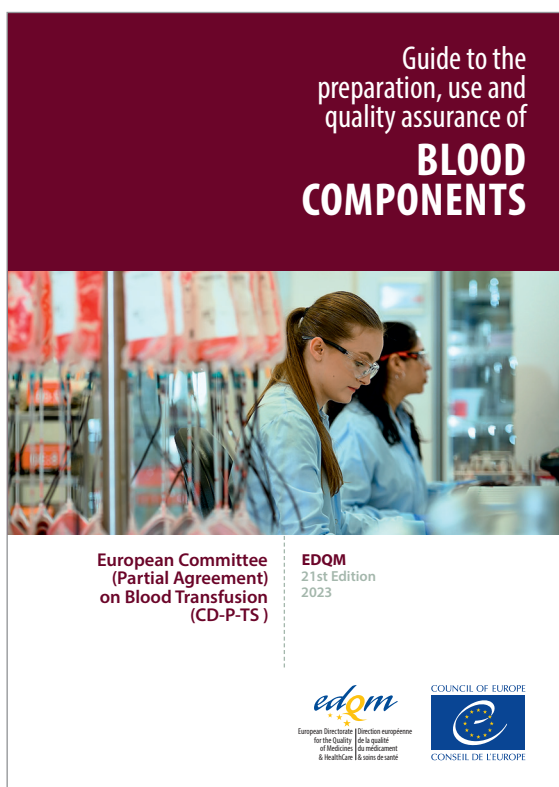
Guide to the preparation, use and quality assurance of blood components

This work, also known as the Blood Guide, is a compendium of widely accepted, harmonised European standards. It provides safety, efficacy and quality requirements for blood components in Europe and beyond.

The Blood Guide is a technical appendix to Committee of Ministers [Recommendation No. R \(95\) 15](#) on the preparation, use and quality assurance of blood components, which requires that the guide be updated to keep it in line with scientific progress and regulatory change.

In addition, the Blood Guide provides guiding principles to be considered for the donation of blood and blood components and includes the Good Practice Guidelines (GPGs), which provide standards for the implementation of quality systems in blood establishments and, where applicable, hospital blood banks.

In accordance with European Commission Directive (EU) 2016/1214, the GPGs should be taken into account by EU member states in the implementation of quality systems in blood establishments.



Reports on the collection, testing and use of blood and blood components

Based on data collected every year since 1989 and co-ordinated at CD-P-TS level, these annual reports provide information for the monitoring of best practice and activity data on the donation, collection, testing and use of blood and blood components in Europe. The goals are to provide further insights on advancements in the blood transfusion chain, to contribute to the development of evidence-based technical guidelines, the optimisation of transfusion practices and measures to ensure the protection of donors and recipients.

The Blood Quality Management (B-QM) Programme

The B-QM Programme is an assistance and educational programme aimed at supporting European blood establishments (BEs) in developing, implementing and improving their quality management systems. It includes the provision of auditing schemes and the organisation of training courses or events. The programme provides an opportunity for European experts to share knowledge and experience with their peers and helps European BEs implement technical standards in practice and develop risk-based and cost-effective quality management systems.

The Blood Proficiency Testing Scheme (B-PTS) Programme

The EDQM B-PTS Programme is a form of external quality assessment, measuring the performance of BE laboratories responsible for the testing of individual blood donations. Participation is free of charge. It enables laboratories to objectively assess

their performance and demonstrate the accuracy and reliability of their test results by reviewing the integrity of their entire testing process to identify potential sources of error. In participating, BEs gain further insight into their testing practices and state-of-the-art assays used in Europe in the field of blood transfusion.

European Committee for Food Contact Materials and Articles



The CD-P-MCA contributes to consumer health protection by setting standards and developing policies for the safety and quality of food contact materials and articles. It also:

- ▶ focuses on harmonised measures that supplement EU and national legislation;
- ▶ publishes technical guides which are used as reference documents by manufacturers and other business operators, safety evaluators and control laboratories.

TERMS OF REFERENCE:

<https://go.edqm.eu/ToRCDPMCA>

Example of activities

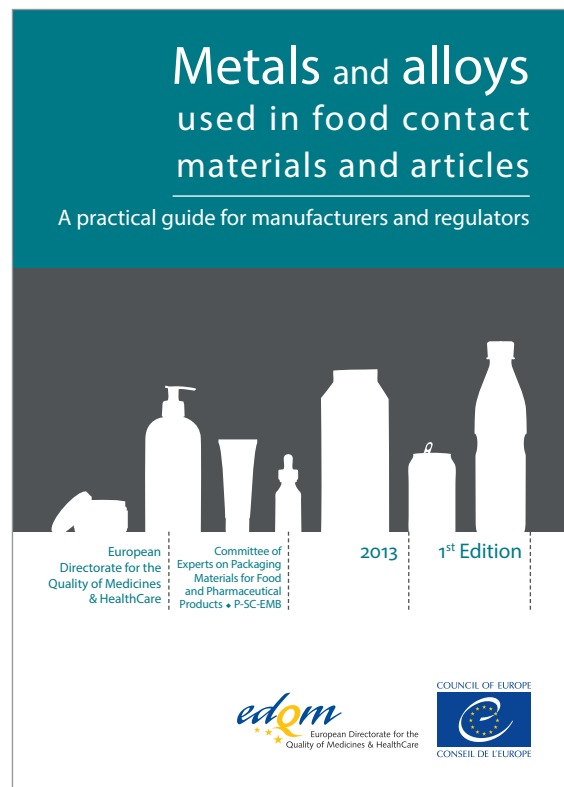
Safety and quality of materials and articles for contact with food

Resolution [CM/Res\(2020\)9](#) aims to improve the protection of consumers from contaminants (metals, antioxidants, stabilisers, colorants, plasticisers, etc.) potentially released by material in contact with food, such as containers, work surfaces or packaging. It harmonises regulatory approaches to consumer health protection across Europe and includes in its annex guiding principles for the implementation of suitable policies and technical guidance for specific materials, such as paper and board, metals and alloys, coatings and silicones.

Technical Guide on metals and alloys for food contact materials and articles

Metals and alloys are often used in contact with food: stainless steel and cast iron for food preparation, metal containers to store or transport food and aluminium foil for packaging. Supplementing Resolution [CM/Res\(2020\)9](#), this guide is intended

to ensure the safety and suitable quality of food contact materials and articles made from metals and alloys. Experts from competent authorities, official control laboratories and industry participate in the drafting and updating of the different chapters of this practical guide for manufacturers and regulators. The second edition is scheduled for publication in 2023.



European Committee for Cosmetics and Consumer Health



The CD-P-COS contributes to protecting human health across Europe through common product quality and safety requirements for cosmetic products. It responds to health risks posed by the use of specific ingredients with pharmacological or toxic effects in cosmetics. It also:

- ▶ proposes appropriate harmonised measures, sets standards and defines relevant policies;
- ▶ promotes technical collaboration in the field of market surveillance by the Network of Official Cosmetics Control Laboratories (OCCLs).

TERMS OF REFERENCE:

<https://go.edqm.eu/ToRCDPCOS>

Examples of activities

Safety criteria for cosmetic products intended for infants

Resolution [CM/ResAP\(2012\)1](#) recommends that Council of Europe member states implement measures to reduce health risks arising from the exposure of infants to cosmetic products and their ingredients. Infants are more sensitive to certain toxic effects of chemicals and special attention should therefore be paid to the safety of cosmetic products intended for them.

Safe cosmetics for young children

This guide compiles a set of safety criteria for cosmetic formulations that should be taken into account when placing a product on the market. It also provides guidance and support for manufacturers and safety assessors and emphasises the importance of the safety evaluation of cosmetic products for infants. The fully revised second edition is scheduled for publication in 2023.



Guidance on essential oils in cosmetic products

Essential oils are used in a variety of ways – from flavouring agents to providing the essence and aroma of cosmetic products. They are mixtures of typically liquid, volatile and fat-soluble plant ingredients with a characteristic fragrance. These natural essential oils may not be completely safe and this is why the CD-P-COS compiled specific quality requirements and recommendations for their risk assessment, for the attention of regulators, safety evaluators and manufacturers. Following a full review taking into account recent scientific publications and reflecting regulatory developments, the second edition of this guide is scheduled for release in 2023.

4. Intergovernmental committees: roles and working methods

Work in committees lies at the heart of the Council of Europe and allows the direct participation of governmental and independent experts in its work. It significantly contributes to the Organisation's core mission, which is "to achieve greater unity between its members for the purpose of safeguarding and realising the ideals and principles which are their common heritage and facilitating their economic and social progress", as stated in Article 1 of its Statute.

This intergovernmental structure is the framework for the development of common policy instruments and legal standards, such as treaties, recommendations and resolutions, thus supporting member states in building a common pan-European legal space, anticipating and addressing challenges in the field of human rights, democracy and the rule of law. It

enhances co-operation between member states through the exchange of knowledge, experience and good practice, and the analysis of common and emerging issues.

The first category of committee in this structure includes those directly answerable to the Committee of Ministers – steering committees composed of member states' representatives of the highest possible rank in the relevant field, with planning and steering functions.

A second category includes subordinate bodies, in general answerable to steering committees, with specific expertise on selected matters.

Intergovernmental committees involve relevant international and regional organisations, civil society and other partners in their work.

Useful links

Selected adopted texts

- ▶ Statute of the Council of Europe (ETS No. 1): <https://go.edqm.eu/ETS001>
- ▶ Convention on the Elaboration of a European Pharmacopoeia (ETS No. 50): <https://go.edqm.eu/ETS050>
- ▶ Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components: <https://go.edqm.eu/CMRec199515>
- ▶ Recommendation CM/Rec(2020)4 on the quality and safety of organs for transplantation: <https://go.edqm.eu/CMRec20204>
- ▶ Recommendation CM/Rec(2020)5 on the quality and safety of tissues and cells for human application: <https://go.edqm.eu/CMRec20205>
- ▶ Resolution CM/Res(2013)55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system: <https://go.edqm.eu/CMRes201355>
- ▶ Resolution CM/Res(2017)2 on establishing procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up care: <https://go.edqm.eu/CMRes20172>
- ▶ Resolution CM/Res(2020)3 on the implementation of pharmaceutical care for the benefit of patients and health services: <https://go.edqm.eu/CMRes20203>
- ▶ Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food: <https://go.edqm.eu/CMRes20209>
- ▶ Resolution CM/Res(2021)3 on intergovernmental committees and subordinate bodies, their terms of reference and working methods: <https://go.edqm.eu/CMRes20213>
- ▶ Resolution CM/ResAP(2012)1 on safety criteria for cosmetic products intended for infants: <https://go.edqm.eu/CMResAP20121>

Other resources

- ▶ Committee of Ministers web page on intergovernmental structures and other bodies: <https://www.coe.int/en/web/cm/intergovernmental-structures>
- ▶ Council of Europe website: <https://www.coe.int>
- ▶ EDQM website: <https://www.edqm.eu>
- ▶ European Pharmacopoeia membership & observership: <https://go.edqm.eu/membersobservers>
- ▶ European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH): <https://go.edqm.eu/CDPPH>


- ▶ European Committee on Organ Transplantation (CD-P-TO): <https://go.edqm.eu/CDPTO>
- ▶ European Committee on Blood Transfusion (CD-P-TS): <https://go.edqm.eu/CDPTS>
- ▶ European Committee for Food Contact Materials and Articles (CD-P-MCA): <https://go.edqm.eu/CDPMCA>
- ▶ European Committee for Cosmetics and Consumer Health (CD-P-COS): <https://go.edqm.eu/CDPCOS>

The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a directorate of the Council of Europe. Its mission is to contribute to public health protection by engaging with an international community of experts and stakeholders.

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The Council of Europe is the continent's leading human rights organisation. It comprises 46 member states, including all 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.