

# FACT-SHEET ACTIVITIES UNDER CD-P-PH

**THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)** is a Directorate of the Council of Europe and 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 – currently 38 member states and the European Union (EU) – are committed to achieving harmonisation of the quality of medicines throughout the European continent and beyond.

The EDQM's mission 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 providing official standards which apply to the manufacture and quality control of medicines in all signatory States of the 'Convention on the Elaboration of a European Pharmacopoeia' and beyond;
- ✓ ensuring the application of these official standards to substances used in the production of medicines;
- ✓ co-ordinating a network of Official Medicines Control Laboratories (OMCLs) to collaborate and share expertise among member states and to effectively use limited resources;
- ✓ proposing ethical, safety and quality standards for the collection, preparation, storage, distribution and appropriate use of blood components in blood transfusion, and for the transplantation of organs, tissues and cells;
- ✓ collaborating with national, European and international organisations in efforts to combat 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;
- ✓ establishing standards and co-ordinating controls for cosmetics and food contact materials.

The EDQM is headed by Dr Susanne Keitel, Director, has approximately 350 staff and consists of the following:

## FIVE DEPARTMENTS

- 📖 European Pharmacopoeia Department (EPD)
- 💻 Information Technology and Publications Department (ITPD)
- 🔬 Laboratory Department (DLab)
- 🏥 Biological Standardisation, Official Medicines Control Laboratories (OMCL) Network and HealthCare Department (DBO)
- 📄 Certification of Substances Department (DCEP)

## FOUR DIVISIONS

- 📋 Reference Standards and Samples Division (DRS)
- 🗣️ Public Relations and Documentation Division (PRDD)
- 💰 Administration and Finance Division (DAF)
- 🔍 Quality, Safety and Environment Division (QSED)

## STATES PARTIES TO THE CONVENTION ON THE ELABORATION OF A EUROPEAN PHARMACOPOEIA (PH. EUR. CONVENTION):

### Members (38)

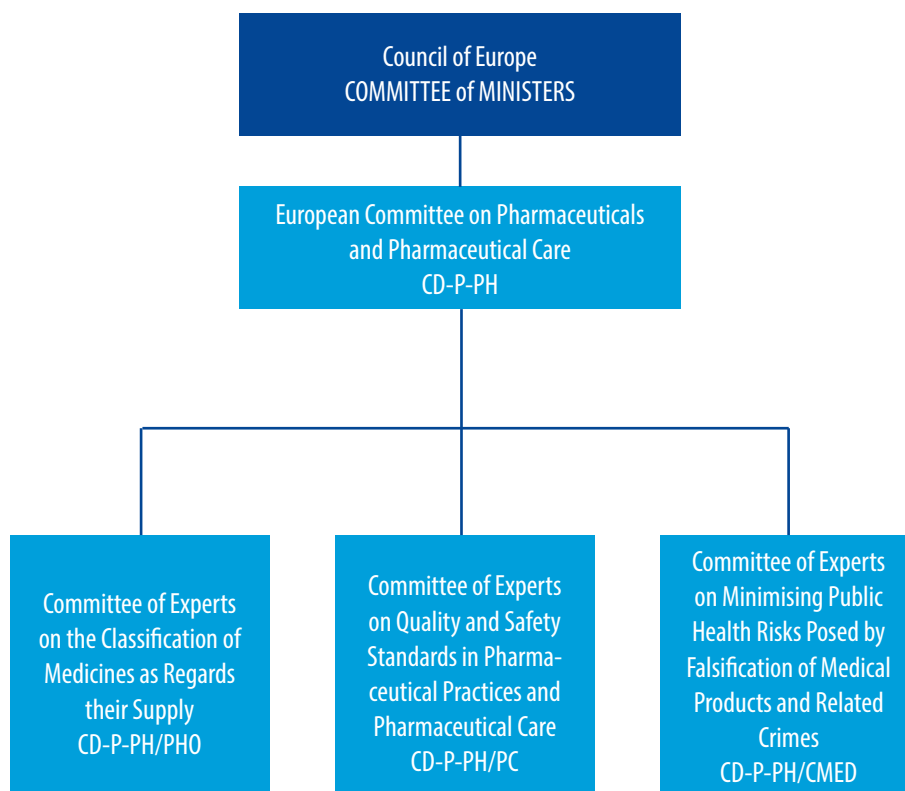
Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, 'The Former Yugoslav Republic of Macedonia', Turkey, Ukraine, United Kingdom and the European Union.

### Observers (30)

Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, Georgia, Guinea, India, Israel, Japan, Kazakhstan, Republic of Korea, Madagascar, Malaysia, Morocco, Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, United States of America, Uzbekistan, Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).

## PHARMACEUTICALS AND PHARMACEUTICAL CARE

The Biological Standardisation, Network of Official Medicines Control Laboratories (OMCL) and HealthCare Department (DBO) is responsible for the Secretariat of the *European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH)* and its three subordinate committees of experts.



### MEETINGS

Meetings of the CD-P-PH and its subordinate committees are convened at the EDQM premises in Strasbourg (France).

Plenary meetings of the CD-P-PH take place once a year. Extraordinary meetings of the CD-P-PH can be convened upon motivated request by the Chair and Vice-Chair.

Plenary meetings of the subordinate committees take place twice a year.

### ROLE OF THE SECRETARIAT

The Secretariat draws up the meeting agenda based on the decisions taken at previous meetings and including additional topics proposed by representatives during the interval. The Chair and Vice-Chair of the committee are consulted in advance, they review and take part in the elaboration of the draft agenda. The draft agenda is adopted at the beginning of the meeting.

The Secretariat transmits to the committee members the working documents relating to the different agenda items well in advance of the meeting.

The Secretariat prepares the meeting report. The draft report is circulated to the delegates who attended the meeting for approval. The final report, as approved by the above delegates, is sent to the whole committee for information.

The Secretariat provides continuity and assures the follow-up of the committee's work programme, as well as of decisions taken, initiated projects, and required actions resulting from the committee meetings. It is also the contact point for any committee-related issues or questions.

### ROLE OF THE DELEGATES

The work of the CD-P-PH and its subordinate committees requires a certain commitment from the delegates. Delegates contribute on a voluntary basis having fully understood the commitment involved. A delegate should attend Committee meetings or inform the Secretariat in good time if he/she is unable to attend a meeting. If unable to attend, the delegate should provide whatever relevant information for the committee to the Secretariat. If an expert fails to attend three consecutive meetings, the Chair, Vice-Chair and the Secretariat may decide after further enquiry to stop sending documents and other written communications to this expert. It is expected of a delegate to actively contribute to the work programme of his/her committee.

Finally, a delegate should inform the Secretariat about any changes in his/her professional background, including conflicts of interest, affecting the position as delegate.

① A partial agreement allows member states of the Council of Europe to work together on an activity in spite of the abstention of other member states.

### MISSION

Its primary responsibilities, according to the terms of reference adopted by the Committee of Ministers are as follows:

- ✓ fulfil the tasks set out in Resolution [CM/Res\(2018\)1](#) – Resolution on the classification of medicines as regards their supply (superseding Resolution [ResAP\(2007\)1](#) on the classification of medicines as regards their supply);
- ✓ contribute to [improving public health](#) and access to good quality medicines and healthcare by developing harmonised provisions and practices for the rational use of medicines and promoting the implementation of the pharmaceutical care\* philosophy and working methods in Europe;
- ✓ [minimise public health risks](#) posed by falsification of medical products and similar crimes through:
  - a. support to the preparation, implementation and follow-up of relevant national legislation and international legal instruments, in particular the Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (Medicrime Convention) (ETS No. 211);
  - b. the preparation and implementation of specific multisectorial prevention and risk management policies and strategies based on co-ordinating competent health, police and customs authorities through the network of Single Points of Contact (SPOC) specified in Articles 17 and 22 of the Medicrime Convention;
  - c. contribution to the multisectorial follow-up mechanism maintained by the Committee of the Parties to the Medicrime Convention;
- ✓ ensure and follow up appropriate [implementation](#) of the results of the relevant activities in States Parties to the Convention on the Elaboration of a European Pharmacopoeia;
- ✓ draft legal instruments (e.g. resolutions), and define [policies](#) and [guidelines](#);
- ✓ while taking account of the progress of its work, prepare under its responsibility proposals for the programme of [activities](#) for the coming years.

\* 'Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life' (source: Hepler C.D. and Strand L.M. Opportunities and Responsibilities in Pharmaceutical Care. Am. J. Hosp. Pharm. 1990; 47: 533-543).

### GENERAL ROLE

The CD-P-PH

- ✓ carries out the technical and scientific programmes of activities forming part of its terms of reference with the support of its subordinate committees of experts;
- ✓ reviews on a regular basis the overall [progress of the work programme](#) of its subordinate bodies and, if necessary, revises it;
- ✓ has the ultimate [responsibility](#) for the progress, implementation and impact evaluation of the work that has been decided upon;
- ✓ evaluates and [approves](#) project proposals launched either by a CD-P-PH delegation or its subordinate bodies. Decisions on proposals that are presented to the CD-P-PH are taken at plenary or ad hoc meetings or, in exceptional cases, via written procedure;
- ✓ [adopts](#) the terms of reference of its subordinate bodies.

### BACKGROUND

In 2007, the Council of Europe Committee of Ministers agreed to [transfer the activities](#) related to pharmaceutical issues from the Partial Agreement in the Social and Public Health field to the EDQM, as of [1 January 2008](#).

The European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) supports authorities in times of increasing social gaps and resource constraints to make the medication process safer, more responsible and accessible to all who need it.

The composition of the CD-P-PH includes senior officials in ministries and medicines agencies responsible for health policies and medical products that are safe and effective for use.

[The CD-P-PH accomplishes its tasks with the help of three subordinate committees of experts](#) related to the appropriate use of medicines and prevention of falsified medicines and similar crimes.


### SUBORDINATE BODIES

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



### WORK PROGRAMME

According to its terms of reference, the primary responsibilities of the Committee of Experts CD-P-PH/PHO are as follows:

- ✓ carry out **biannual revisions** of the appendices to Committee of Ministers (Partial Agreement) Resolution [CM/Res\(2018\)1](#) – Resolution on the classification of medicines as regards their supply (superseding Resolution [ResAP\(2007\)1](#) on the classification of medicines as regards their supply);
  - ✓ carry out evidence-based classification reviews of medicines, underlying rationale and national requirements for medicines of specific interest or concerns for public health and promote harmonisation of the classification of medicines across Europe;
  - ✓ **follow up** the national implementation of the appendices to the above Resolution [CM/Res\(2018\)1](#);
  - ✓ maintain and **develop links** with national, European authorities and international institutions and organisations active in the sphere of the classification of medicines as regards their supply;
  - ✓ develop further and co-ordinate the updates of an online database ([Melclass](#)) presenting the classification status of medicines in the member states and the biannually revised appendices of the above Resolution [CM/Res\(2018\)1](#).
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### BACKGROUND

The availability of medicines with or without a medical prescription has implications on patient safety, **accessibility of medicines** to patients and responsible management of healthcare expenditure.

The decision on prescription status and related supply conditions is a core competency of national health authorities. The conditions of the supply of medicines vary considerably in the member states, due to the fact that the provisions are differently interpreted and implemented by the member states, and that important additional classification criteria are not harmonised.

In continuing with the programme of activities carried out under the aegis of the former Partial Agreement in the Social and Public Health field, the Committee of Experts CD-P-PH/PHO **reviews the classification practice** at the national level and issues recommendations on the **classification of medicines** and their supply conditions to health authorities of the Council of Europe member states parties to the Ph. Eur. Convention. Its working programme is based on Committee of Ministers Resolution [CM/Res\(2018\)1](#) – Resolution on the classification of medicines as regards their supply (superseding Resolution [ResAP\(2007\)1](#) on the classification of medicines as regards their supply).

In its work, the CD-P-PH/PHO focuses on public health promotion and uses scientific approaches, and its recommendations are based on **dialogue and consensus**.

### WORK PROGRAMME

According to its terms of reference, the primary responsibilities of the Committee of Experts CD-P-PH/PC are as follows:

- ✓ develop and carry out a programme of activities aiming at improving public **healthcare** in Europe through promoting knowledge, skills, attitudes and values in care and practices involving **pharmaceuticals**. In particular, these activities comprise the promotion of the pharmaceutical care philosophy and working methods, and the provision of guidance documents on safe and good use of medicines (e.g. good reconstitution practices in healthcare establishments, guidance on automated dose dispensing);
- ✓ assist in monitoring the adequate implementation of the **results** of the relevant activities at national levels in States Parties to the Convention on the Elaboration of a European Pharmacopoeia;
- ✓ promote the further **development** of pharmaceutical professionals, **expertise**, roles and co-operation of all partners within the medication and care chain, in particular the pharmacist, the medical doctor and the nurse, and care-givers;
- ✓ maintain and **develop links** with national, European institutions and international organisations and professional bodies active in the fields of practice and care involving pharmaceuticals.

### BACKGROUND

Medication is a routine part of healthcare systems across the world. The primary aim of all stakeholders involved in the medication process should be to achieve the best possible improvement in quality of life for the patient. However, sometimes the potential benefits of medications are not fully realised or, even worse, inappropriate use of medicines can lead to increased morbidity or even mortality.

Pharmaceutical care (PC) is a **quality** concept and working method for the responsible provision of **drug therapy**, with the purpose of achieving definite outcomes that improve a patient's quality of life (source: *Hepler C.D. and Strand L.M. Opportunities and Responsibilities in Pharmaceutical Care. Am. J. Hosp. Pharm. 1990; 47: 533-543*). PC plays a crucial role in the promotion of the **safety and quality** of medication use and, therefore, its implementation in national healthcare systems could help achieve the benefits of responsible use of medicines, promote rational use of healthcare resources, and reduce inequalities in healthcare.

The EDQM's activities in the field of pharmaceutical care are performed in line with Hepler and Strand's definition of pharmaceutical care, and carried out by the Committee of Experts CD-P-PH/PC. This latter, subordinate body of the CD-P-PH, improves pharmaceutical care and practices in community care homes and in ambulatory and hospital care services through specific programmes and **policies**.

### WORK PROGRAMME

According to its terms of reference, the primary responsibilities of the Committee of Experts CD-P-PH/CMED are as follows:

- ✓ provide a platform for constructive **exchange** of information, experience and knowledge for professionals who are active in combating falsification of medical products and similar crimes;
- ✓ develop and promote the **implementation** of multi-sectorial approaches in the field of public health protection from falsified medical products and similar crimes, e.g. risk management and prevention, training, knowledge transfer programs and publications;
- ✓ facilitate **networking** and co-operation among member states with focus on protecting the general public from falsified medical products and similar crimes through activities promoting recognised networks, e.g. the network of Single Points of Contact (SPOCs);
- ✓ provide public health authorities with strategies for **risk** communication on falsification of medical products and similar crimes;
- ✓ as provided for in the Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Convention) (ETS No. 211), make available scientific **expertise** to the Committee of the Parties to the convention (e.g. supporting the preparation, implementation and follow-up of the Convention);
- ✓ establish and maintain **links** with national, European and international institutions and organisations that are active in combating falsification of medical products and similar crimes;
- ✓ develop supportive **tools** for information exchange on management, prevention and follow-up of the risks posed by falsification of medical products and similar crimes.

### BACKGROUND

In continuity with the programme of activities carried out by the former Ad hoc Group on Counterfeit Medicines under the aegis of the Partial Agreement in the Social and Public Health field, the Committee of Experts CD-P-PH/CMED focuses on public health protection from **falsification of medicines** and related crimes through risk management and prevention, and improved co-operation of member states and other stakeholders in Europe and beyond.

The composition and project approach of the Committee of Experts CD-P-PH/CMED is multi-sectorial, bringing together **healthcare and law enforcement officials** from Council of Europe member states, European institutions, pharmaceutical industries and trade, and international organisations.



## CONVENTIONS AND RESOLUTIONS IN THE FIELD OF PHARMACEUTICALS AND PHARMACEUTICAL CARE

**Medicrime Convention:** Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health.

**CM/Res(2018)1** – Resolution on the classification of medicines as regards their supply (superseding Resolution **ResAP(2007)1** on the classification of medicines as regards their supply).

Resolution **CM/Res(2016)1** on good reconstitution practices in health care establishments for medicinal products for parenteral use.

Resolution **CM/Res(2016)1** on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients (succeeding Resolution **CM/ResAP(2011)1** on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients).

**Resolution ResAP(2007)2** on good practices for distributing medicines via mail order which protect patient safety and the quality of the delivered medicine.

**Recommendation Rec(2006)7** on management of patient safety and prevention of adverse events in health care.

**Resolution ResAP(2001)2** on the role of the pharmacist in the framework of health security.

**Resolution ResAP(2000)1** on the classification of medicines which are obtainable only on medical prescription.

**Resolution ResAP(97)2** on the development of the function of pharmacists and adaptation of their initial training.

**Resolution ResAP(94)1** on the rational use of medicines.

**Resolution ResAP(93)1** on the role and training of the community pharmacists.

## EVENTS AND PUBLICATIONS

Delegates in the CD-P-PH and its subordinate committees develop and promote programmes and projects aimed at disseminating best practices in the field of pharmaceuticals, pharmaceutical care and the fight against falsified medical products. Among others, they actively participate in or organise training events and workshops, and prepare scientific and technical publications. An overview of such events and publications can be found on our web pages, listed here below.

### WEB PAGES

Council of Europe

[www.coe.int](http://www.coe.int)

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

[www.edqm.eu](http://www.edqm.eu)

European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH)

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

Committee of Experts (CD-P-PH/PHO)

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

Committee of Experts (CD-P-PH/PC)

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

Committee of Experts (CD-P-PH/CMED)

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

Medicrime Convention

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

### CONTACTS

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