

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



European Directorate
for the Quality
of Medicines
& HealthCare

Direction européenne
de la qualité
du médicament
& soins de santé

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

The Council of Europe and its European Directorate for the Quality of Medicines & HealthCare (EDQM) at a Glance

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EDQM (Council of Europe)

Webinar - 20th May 2025, 14:30 to 16:30 CEST



European Directorate for the Quality of Medicines & HealthCare



Council of Europe

Council of Europe

- ★ Established in **1949**
- ★ **46 member states**
- ★ Based in **Strasbourg**
- ★ Founded on three main values:
**human rights, democracy
and the rule of law**



Council of
Europe



European
Council



Parliamentary
Assembly of the
Council of Europe



European Parliament

European
Parliament



European Court
of Human



Court
of Justice
of the EU

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Committee
of Ministers



Parliamentary
Assembly



Congress of Local
and Regional
authorities



European Court of
Human Rights



Commissioner of
Human Rights



Conference
of INGOs



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CONSEIL DE L'EUROPE

EDQM

- ★ Founded in **1964**
- ★ Partial agreement (39 member states & the EU + 33 observers)
- ★ Contributes to **public health and access to good quality medicines and healthcare in Europe**
- ★ Wide scope of activities

Our vision

Together for better health, for all

Our mission

To contribute to public health protection by engaging with an international community of experts and stakeholders

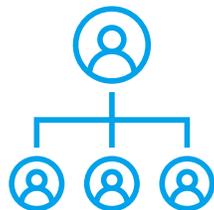


* EU: European Union; TFDA: Taiwan Food and Drug Administration; WHO: World Health Organization

Key figures

10

Administrative entities



More than **400 staff members** about **30 nationalities** and dozens of different professions

4

Areas of work

- ★ Medicinal products
- ★ Substances of Human Origin
- ★ Pharmaceutical care
- ★ Consumer health

Working with a global network of almost **2 000 experts** from a wide variety of scientific disciplines

3

sites



Strasbourg (2)



Metz

- ★ 5 intergovernmental committees
- ★ 1 treaty-based body, the European Pharmacopoeia Commission
- ★ 2 steering committees (BSP, CEP)
- ★ 2 networks (OMCL, OCCL)
- ★ More than **100** expert groups

EDQM and its partners

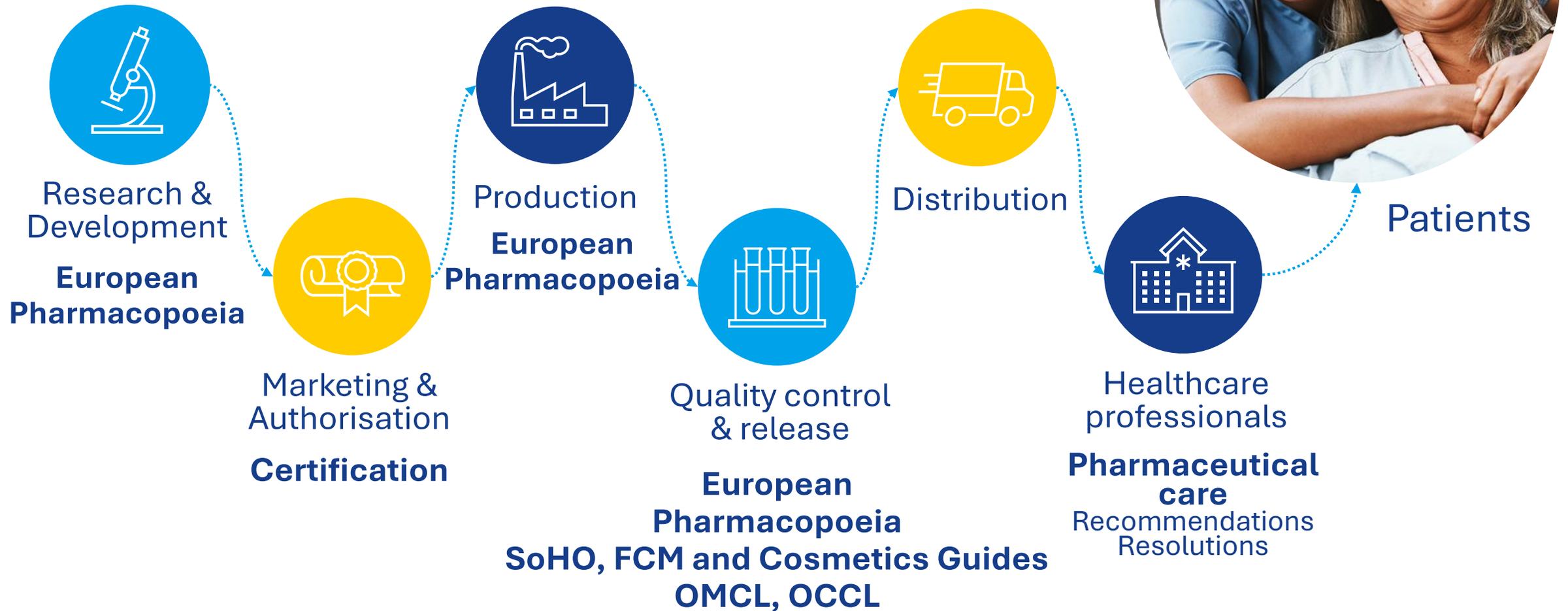


More than 60 years of collaboration in the field of medicinal products
More than 15 years of collaboration in the field of SoHO

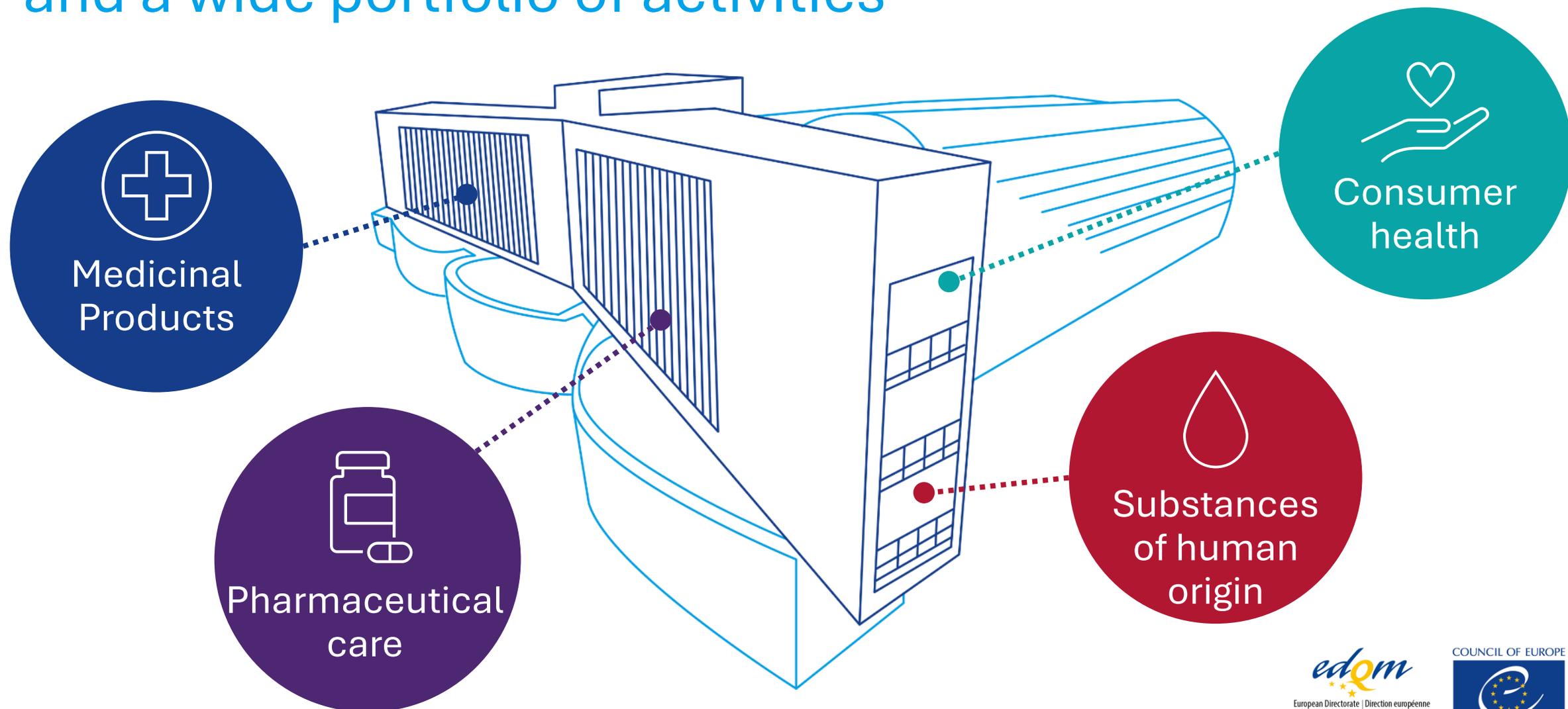


- ★ European Commission
- ★ European Medicines Agency
- ★ European Centre for Disease Prevention and Control

Contributing all along the pathway to access



Four policy areas and a wide portfolio of activities



Four policy areas and a wide portfolio of activities



Medicinal
products

Official standards for manufacture and quality control of pharmaceuticals

European Pharmacopoeia (documentary & reference standards), Biological Standardisation Programme (BSP)

Certificates of Suitability confirming compliance with European Pharmacopoeia and inspections
Certification of suitability

Control of medicines
Network of Official Medicines Control Laboratories (OMCLs)



Substances
of human origin

Quality & safety standards

Biovigilance, data collection and harmonisation

Improving quality system / capacity building of Blood and Tissues & Cells Establishments

Addressing SoHO supply



Pharmaceutical
care

Policies and model approaches for the safe use of medicines

Cooperation to combat falsification of medical products

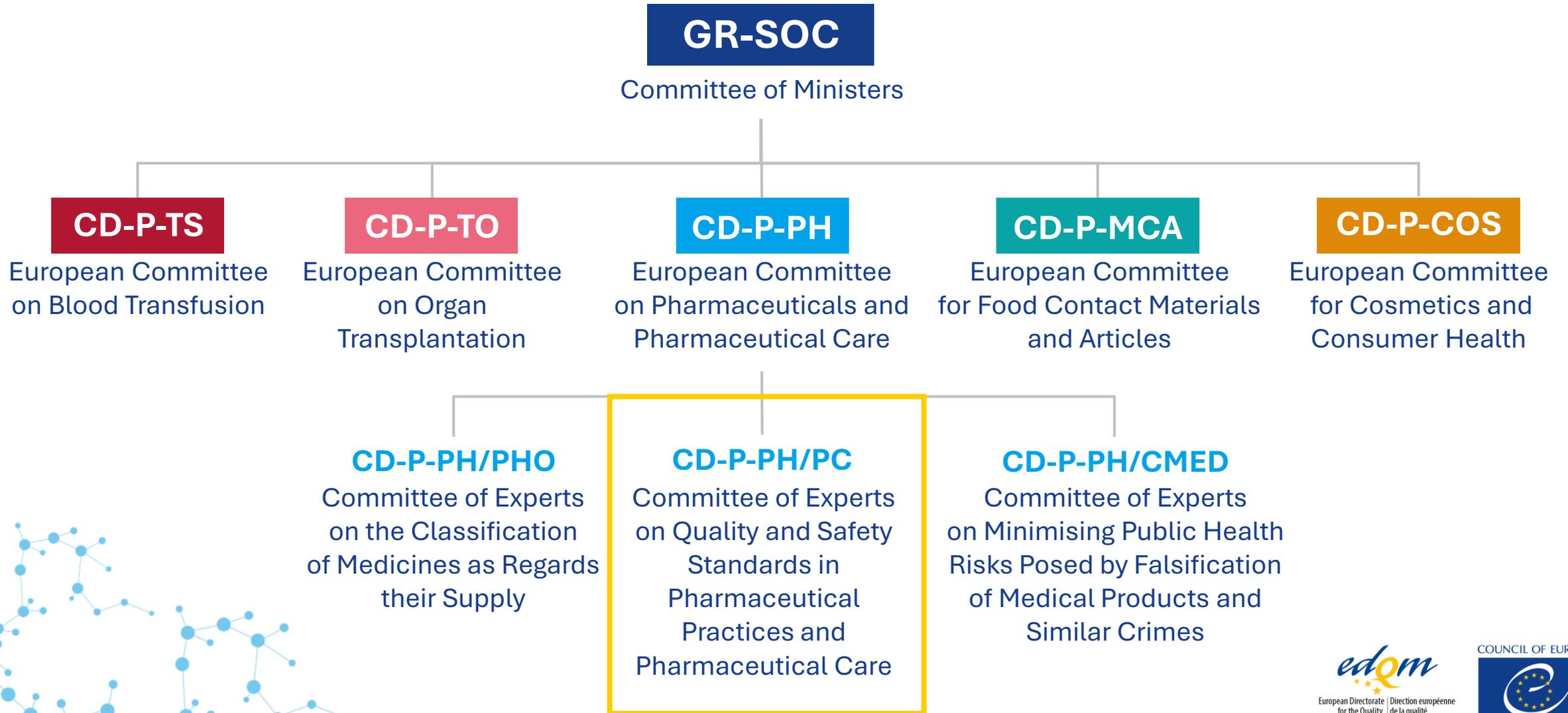


Consumer
health

Safety standards for cosmetics, tattoo inks and food contact materials

Control of cosmetics
Network of Official Cosmetics Control Laboratories (OCCLs)

Intergovernmental Committees coordinated by EDQM



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

Main objective



To ensure appropriate use of medicines and minimise the falsification of medical products

Activities

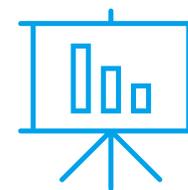
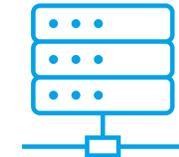


Standard setting

- Resolutions and recommendations
- Guidance documents and good practices

Data collection

E.g. classifications status of medicines, reports on falsified medical products



Workshops and information sharing on issues related to the theft, loss and diversion of medicines from the legal supply chain from a public health perspective



PUBLIC HEALTH IMPACT

Medication process safer, more responsible and accessible to all

Committee of Experts on Quality and Safety Standards for Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC)

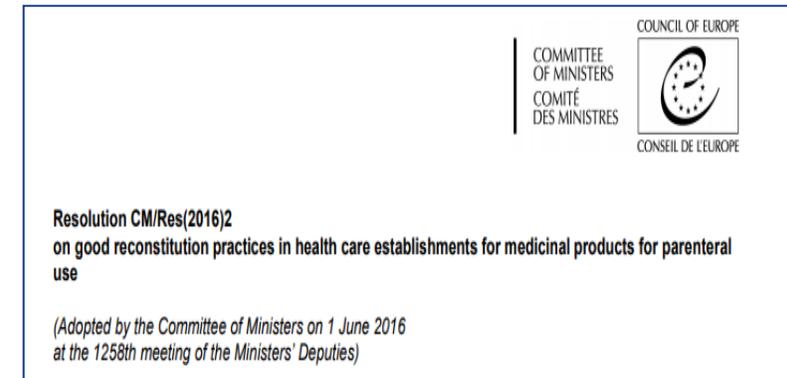
- **Mission:** standard setting in the domain of safe and appropriate use of medicines in hospital and community pharmacy settings

- **2 main focus areas:**

Pharmaceutical practices: operational/ technical activities (Resolution CM/Res(2016)2 on Good **Reconstitution** Practices in Health Care Establishments for Medicinal Products for Parenteral Use and Guidelines for Best Practices for **Automated Dose Dispensing**)

Pharmaceutical care (PC): activities related to **clinical pharmacy** practice (e.g. PC quality indicators; pharmaceutical care resolution)

- **Members:** representatives from competent health authorities of states parties to the Convention on the Elaboration of a European Pharmacopoeia (Ph. Eur.)
- **Observers/participants** (including institutions such as EU, WHO)
- EDQM is responsible for the **Secretariat** of the CD-P-PH/PC



More information

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