THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

edqm
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

60 Years of Council of Europe governance in the field of blood

Keeping up with Reality and Quality: A challenge for European Blood Establishments

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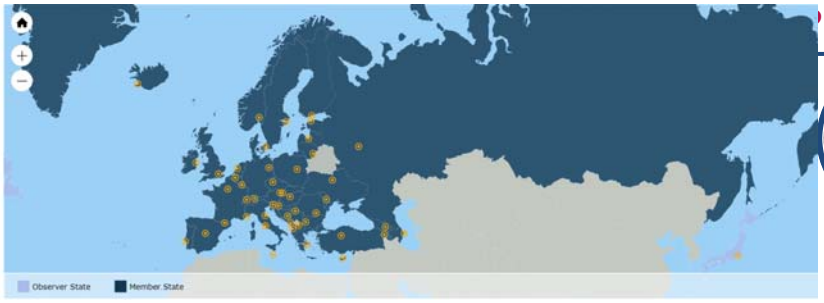


Parliamentary Assembly | **Congress of local & regional Authorities** | **Commitee of Ministers of Foreign Affairs**

COUNCIL OF EUROPE

HUMAN RIGHTS | **DEMOCRACY** | **RULE OF LAW**

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

Council of Europe (47)
≠
European Union (27)

PLEASE…DO NOT GET CONFUSED

Different roles but **shared values and common activities**

European Union (EU)
27 Member States
Approx. 448 Million of Citizens

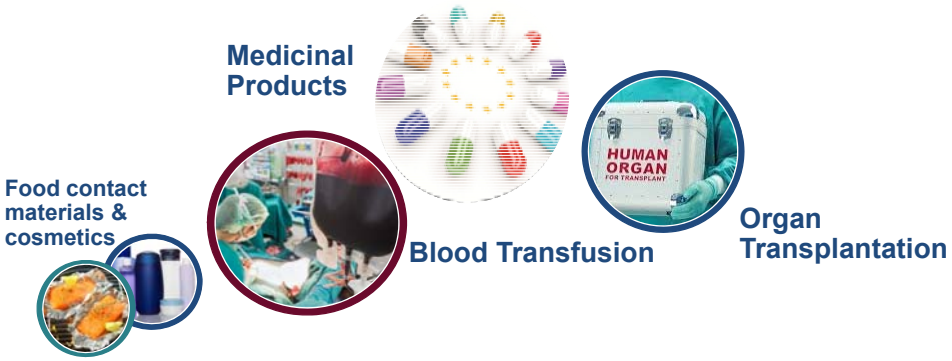
Deeper political and economic integration process

Council of Europe (CoE)
47 Member States
>820 Million of Europeans

Developing and spreading the awareness on these values

THE EDQM: WHO WE ARE & WHAT WE DO

- Contribute to the basic human right of access to good quality medicines and healthcare and to promote and protect human and animal health
- Based on the ***Convention on the elaboration of a European Pharmacopoeia,*** adopted in 1964



THE EDQM: .....AND HOW

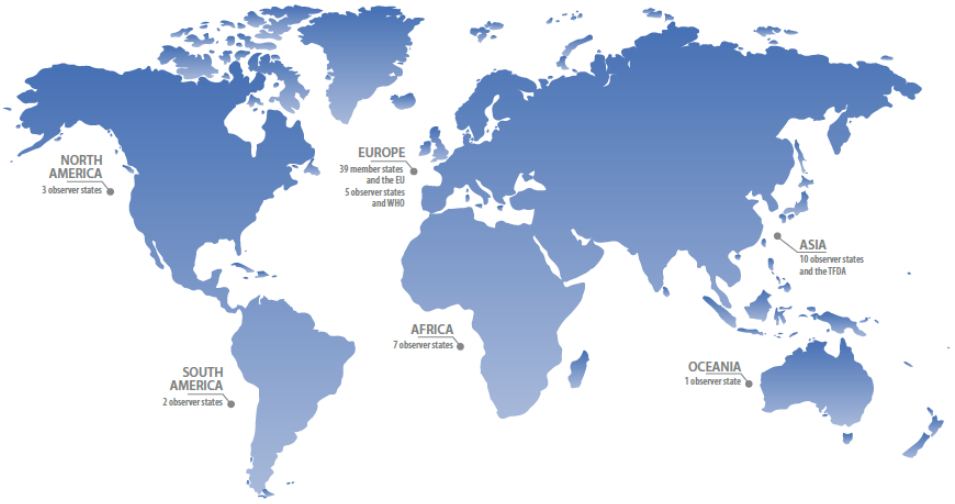
2 sites**: Strasbourg, main Building & contingency site in Metz, France**

A laboratory (chemistry and biology)
Production, distribution and storage areas for reference standards

>350 members of staff in 2020, organised in **9** administrative entities, representing **29** nationalities and a **dozens** different professions, working with a network of almost **2 000** experts from a variety of scientific disciplines from around the world.

The global impact of the EDQM's activities in 2020

Member and observer states of the Ph. Eur. (2020)



Legally binding and non legally binding CoE instruments

Legally binding
International agreements
>>> Signature, ratification and adherence

- **Conventions**
- **Treaties**
- **Agreements**

Non legally binding
Provide MSs with a given course of action
No signature and ratification required

- **Recommendations**
- **Resolutions**

Genesis of the CoE's Governance in the field of Blood (1)

- **1950s - Governance of blood systems, nationally based**
- **1953 - Major event** *the North Sea Flood, affecting Belgium, the Netherlands and the UK*
  - >>> Major consequence in the NL: 1800 deaths, material damage
  - >>> Supply of blood from European countries to the Netherlands
  - >>> Identified the need for harmonised standards
- **1954** – the CoE Committee of Ministers set up the European Health Committee (CDSP)
- **April 1955** – Seeds for the CoE to start working in the area of blood transfusion
  - >>> Experts recommended to have measures enabling exemption of custom duty
- **October 1955 -** Committee of Ministers took note of this recommandation
- As of **1956 - creation of Committees of Experts under the CDSP**
  - >>> Committee on Blood Transfusion and Immunohematology (SP-HM)
  - >>> Committee on Quality assurance in Blood transfusion Service (SP-R-GS)

Genesis of the CoE's Governance in the field of Blood (2)

3 Fundamental European Agreements

- **1958 – ETS N°26 -** ***European Agreement on the Exchange of Therapeutic Substances of Human origin :*** Mutual assistance between Parties in the supply of therapeutic substances of human origin (human blood and its derivatives) should the need arise.
- **1962 – ETS N°39 -** ***European Agreement on the Exchange of Blood-Grouping Reagents:*** allows the Parties to make blood-grouping reagents available to other Parties who are in urgent need of them and to charge only those costs of collection, processing and carriage of such substances and the cost (if any) of their purchase.
- **1974 – ETS N°84 -** ***European Agreement on the Exchange of Tissue-Typing Reagents:*** make tissue-typing reagents available to other Parties who are in need of them, by the most direct route, subject to the condition that no profit is made on them and that they shall be used solely for medical and scientific purposes and free of import duties

Signed & ratified by: Belgium, Cyprus, Denmark; Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Netherlands, Norway, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom and the **European Union**

Genesis of the CoE's Governance in the field of Blood (3)

'*From the general to the particular*', Prof. Bernard Genetet - Recommendations and Resolutions

- **1968 – Resolution No R(68) 32 -** Establishment of the European Bank of rare blood groups
- **1979 – Recommendation No R (79) 5 -** Concerning international exchange and transportation of human substances
- **1980 – Recommendation No R (80) 5-** Concerning blood products for the treatment of haemophiliacs

.....

- **1994 – Recommendation No R (95) 14-** On the protection of health of donors and recipients in the area of blood transfusion >>>lays down ethical principles, including the principle of **Voluntary Non remunerated Blood Donation**
- **1995– Recommendation No R (95) 15 -** On the preparation, use and quality assurance of blood components
  >>> Annex: Guide to the preparation, use and quality assurance of blood components
- **2013 - Resolution CM/Res(2013)3** - On sexual behaviours of blood donors that have an impact on transfusion safety
- **2017 - Resolution CM/Res(2017)43** - on principles concerning haemophilia therapies (replacing Resolution CM/Res(2015)3)

TOTAL number of recommendations/resolutions: 29

Genesis of the CoE's Governance in the field of Blood (4)

Council of Europe cooperation with

Central & Eastern countries

- **1990's** – Cooperation with central and Eastern European countries: survey used to prepare a working document to support countries to further develop their blood system and organisation of country assessments
- **2000** – technical support targeting specific countries, *e.g. Moldova* – in collaboration with the Council of Europe Development Bank (CEB) and cooperation with SEE and WHO

European Community: the first seed

- **Directive 89/381/EEC** – laying down special provisions for proprietary medicinal products derived from human blood or human plasma
- **1990's** - European Community & Council of Europe joint surveys to assess extent of transposition and implementation of the Directive
- **1990's** – Council of Europe experts involved in the elaboration of technical requirements of the EU Blood legislation. EU blood legislation built on requirements laid down in the Blood guide

Current Governance of CoE's Blood activities

EDQM (responsible for the CoE's blood activities since 2007)

Department of Biological Standardisation, OMCL Network & HealthCare (DBO)

European Committee on Blood Transfusion (CD-P-TS)

Non-commercialisation of substances of human origin

Mutual assistance

Protection of donors & the recipients

1. Developing legal instruments, technical standards, policies

2. Monitoring data and best practices

3. Operational activities supporting BEs implementing technical standards & EU legislation

Subordinate bodies

Developing legal instruments, technical standards, policies

POLICIES/ LEGAL INSTRUMENTS

- **Resolutions/ Recommendations**
  - *e.g. Risk behaviours having an impact on blood safety*

TECHNICAL GUIDANCE

- **Guide to the preparation, use and quality assurance of blood components (the 'CoE Blood Guide')**
- **Good Practice Guidelines (the GPG)**

POLICIES/ RECOMMENDATIONS

- **Evidence based policies**
  - *e.g. Increasing plasma collection, protecting donors*

Monitoring data and best practices

DATA COLLECTION

- **Annual Surveys (*e.g. usage of blood components*) & Trend Analysis**
- **Haemoviligance (Serious Adverse Reactions & Events - SARE)** on behalf of the European Commission

IMPLEMENTING *Technical Standards & EU Legislation*

EXTERNAL QUALITY ASSESSMENTS

- **Blood Proficiency Testing Scheme (B-PTS) Programme**

QUALITY MANAGEMENT PROGRAMME

Blood Quality Management (B-QM) Programme

- **On-site Audits & Visits**
- **Training Courses & Conferences**
- **Practical Guidance**

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Thank you for your attention

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