



European Directorate for the Quality of Medicines & HealthCare

Council of Europe

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

EDQM Stakeholder Event on Plasma Supply Continuity

Opening Session - Welcome Addresses

26-27 March 2025

Strasbourg, France



EDQM Stakeholder Event on Plasma Supply Continuity

Petra Doerr, EDQM, Council of Europe

Laurent Mallet, EDQM, Council of Europe

Stefaan van der Spiegel, DG SANTE, European Commission

26-27 March 2025

Strasbourg, France



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Council of Europe

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



Committee
of Ministers



Parliamentary
Assembly



Congress of Local
and Regional
authorities



European Court of
Human Rights



Commissioner of
Human Rights



Conference
of INGOs



Blood Activities

COMMITTEE

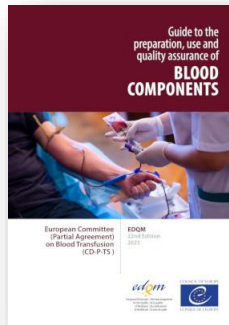
European Committee on Blood Transfusion (CD-P-TS)



Developing legal instruments,
technical standards, policies

Monitoring data and best practices

Operational activities supporting
SoHO establishments in
implementing CoE standards
& EU legislation



ACTIVITIES

PRINCIPLES

Voluntary non remunerated blood
donation

Mutual assistance

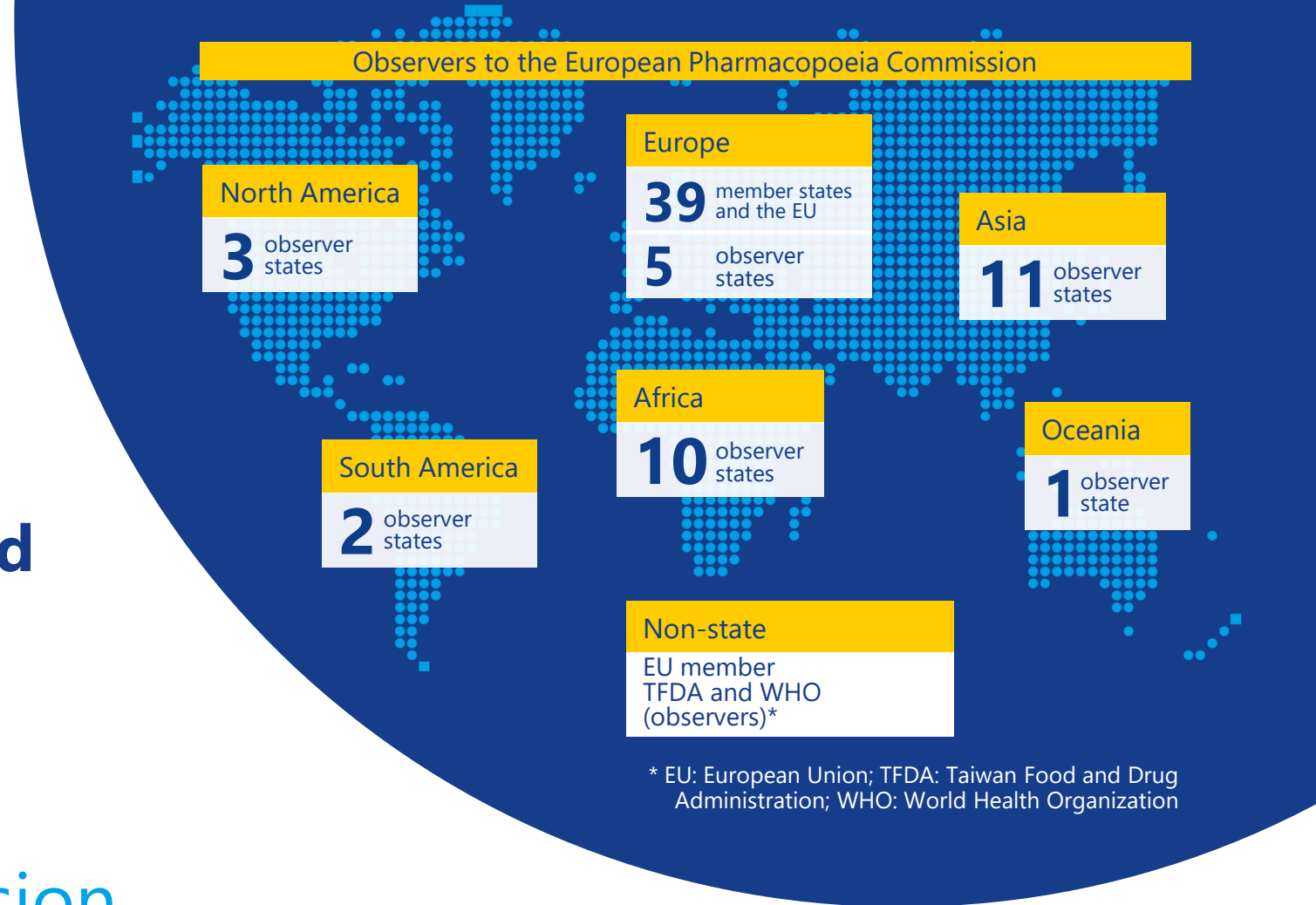
Protection of donors & recipients

EDQM

- ★ Founded in **1964**
- ★ Partial Agreement (39 members & the EU + 34 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



Four policy areas & a wide portfolio of activities



Medicinal
products

Official standards for manufacture
and quality control of
pharmaceuticals

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

Certificates of suitability
confirming compliance with
European Pharmacopoeia and
GMP
inspections

Certification of suitability

Control of medicines
**Network of Official Medicines
Control Laboratories (OMCL)**



Pharmaceutical
care

Policies & model
approaches for the
safe use of medicines

Co-operation
to combat
falsification of
medical products



Consumer
health

Safety standards
for cosmetics, tattoos
and food contact
materials

Control of cosmetics
**Network of Official
Cosmetics Control
Laboratories (OCCL)**



Substances
of human origin

Quality & safety
standards

Data collection

Improving quality
systems / capacity
building of blood
and tissues & cells
establishments

CD-P-TS

Blood transfusion

Main objective



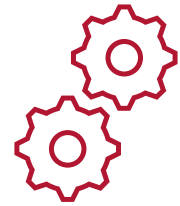
Ensures quality and safety of blood and blood components and application of ethical principles



Activities

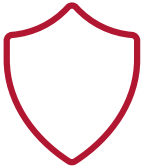
Standard setting

- Resolutions & recommendations
- Technical standards: Blood Guide



Blood Guide referred to in the new EU SoHO legislation

Monitoring data and practices: annual data collection on use of SoHO and vigilance



Capacity-building activities

- Blood Quality Management (B-QM)
- Blood Proficiency Testing Scheme (B-PTS)

PUBLIC HEALTH IMPACT

- Improves clinical outcomes
- Protects donors and patients

EDQM and EU today: a strategic **and** agile co-operation

The EDQM, a regulatory and technical partner of the EU

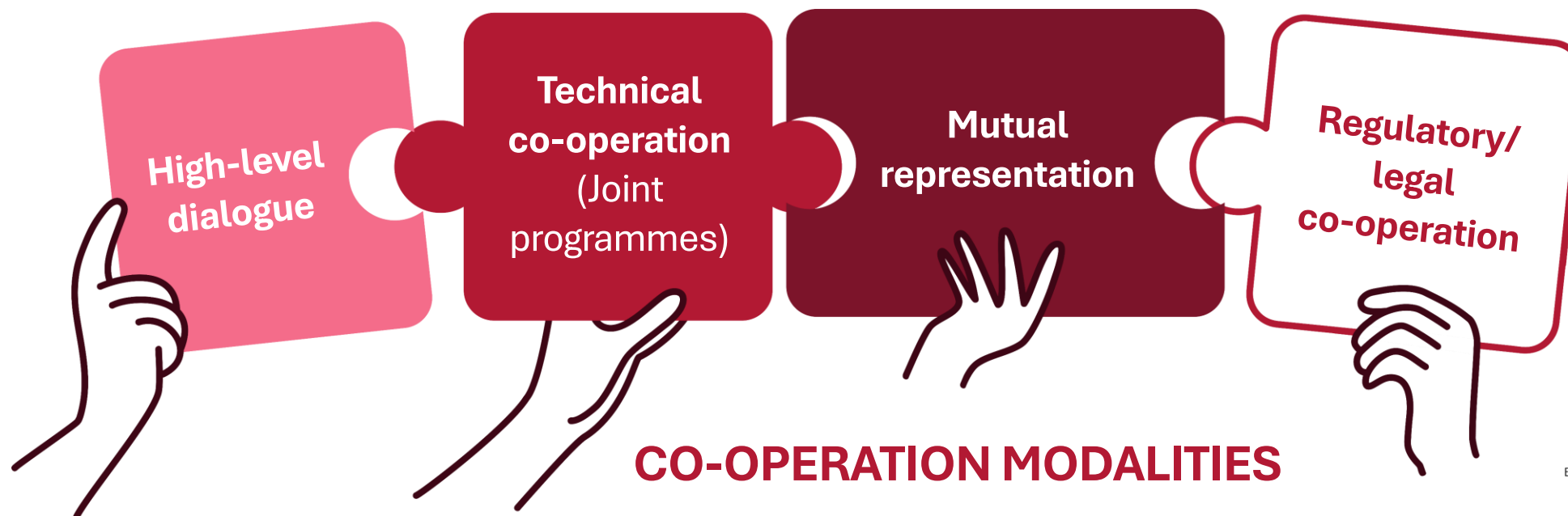
- 60 years of collaboration in the field of medicinal products
- 15 years of collaboration in the field of SoHO

Regular
meetings
since 2018

More than
40 agreements
signed since 1991

Representation
in respective
committees

A number of EDQM standards
and activities **referred**
into the EU legislation



EDQM Stakeholder Event - Plasma Supply Continuity

The Scientific Committee

Johanna Castrén

Vincenzo De Angelis

Fabio Candura

Piotr Radziwon

Stephen Thomas

Thank you to all speakers and moderators



EDQM Stakeholder Event on Plasma Supply Continuity

Thank you for your attention.

26-27 March 2025

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EDQM Stakeholder Event on Plasma Supply Continuity

Setting the scene - Objectives of the meeting

26-27 March 2025

Strasbourg, France



EDQM Stakeholder Event on Plasma Supply Continuity

**Johanna Castrén, Chair of the European Committee on Blood Transfusion,
Council of Europe**

Richard Forde, EDQM, Council of Europe

26-27 March 2025

Strasbourg, France



History / Starting Point

Plasma Supply Management Symposium 2019

- ★ **Jointly organised by EU Commission and EDQM (TS093 Plasma Working Group)**
- *Discuss obstacles in Europe to strategic independence of plasma for fractionation in Europe*
- *Discuss donor protection – safety, selection and management*
- *Presenting evidence-based data for revision of Blood Guide (20th Ed) plasmapheresis donors*
- **Recommendations to stakeholders**
 - EU Commission
 - EDQM/CD-P-TS
 - Member States National Competent Authorities
 - Blood Establishments
 - Plasma Fractionators
 - Patient Associations
 - Donor Associations
 - Professional Societies
- **Proceedings**
- <https://www.edqm.eu/en/plasma-supply-management>



Current Landscape

CD-P-TS working party

6.3. TS119 – Anti D Immunoglobulin

A kick off meeting of the working group on Anti-D Immunoglobulin was scheduled for 25th January 2023. An extended working group has been convened, including members nominated through the CD-P-TS and representatives from IPFA and PPTA and other Industry representatives.

TS119 aims to gain attention and a call for action on the growing shortage and lack of self-sufficiency in the supply of anti-D plasma. The working group will focus on the international cooperation on anti-D plasma collection, immunisation of donors; issues relating to the manufacture and access to polyclonal anti-D immunoglobulins and will explore the state of play in the development of alternative or complementary products to polyclonal anti-D immunoglobulins.



Securing commitment and control for the supply of plasma derivatives for public health systems. I: A short review of the global landscape

Leri von Borndorff¹ | Albert Farrugia^{1,2} | Fabio Candura³ | Peter O'Leary⁴ | Miguel A. Vesga^{5,6} | Vincenzo De Angelis⁷

Deliverable	Report
01.1	Crisis Situations - The impact on the plasma medicine patient chain: Analysis and Recommendations (Elements Evaluation Plan)
02.1	Plasma Donor recruitment and retention - Current Practice (Analysis Report)
02.2	Plasma Donor recruitment and retention strategies - Efficiency evaluation (Recommendations Report and Transfer Plan)
03.1	Setting up a Plasma Centre: Practical tools (Plasma Collection Recommendations and Support Tools)
03.2	The plasma journey from collection to transport to fractionator - Recommendations for Improvement
03.3	Opportunities to increase Plasma volumes: Recovered and via plasmapheresis: Analysis and Recommendations
03.4	Real-world experience: Implementation of the recommendations to increase Plasma volumes
03.6	Focus on quality: An assessment of plasma donor characteristics, immunoglobulins, and Total Protein in stored plasma
...	Member State steps on the European path to Strategic Independence for Plasma Medicines: A Position



INTERNATIONAL PLASMA PROTEIN CONGRESS (IPPC)

IPFA/EBA Symposium on

The supply of plasma-derived medicinal products in the future of Europe



Needs and Considerations - Continuity

Collaboration and Coordination

- Data
- Tools
- Benchmarking
- Networking

Role of the CD-P-TS

- The Blood Guide revision
- Data Collection and Reporting
- Plasma-specific Working Parties, Events, Symposia



Objectives

- ★ **Acknowledge** the significant **efforts and progress** that has been made across European countries in increasing and improving the supply of plasma and PDMP and recognizing the dedication and commitment of all who continue to support these efforts
- ★ Opportunity to **exchange on strategies** to improve and increase the **safe collection** and **adequate supply** of plasma and plasma-derived medicinal products (PDMP), addressing current challenges, key needs and actions
- ★ **Identify areas of priority and challenges**
 - Action plans – key areas for political support and investment
 - Tools and toolkits to develop
 - Next steps for concrete collaboration and coordination

