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EDQM Stakeholder Event on Plasma Supply Continuity

Opening Session - Welcome Addresses

26-27 March 2025

Strasbourg, France

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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

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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

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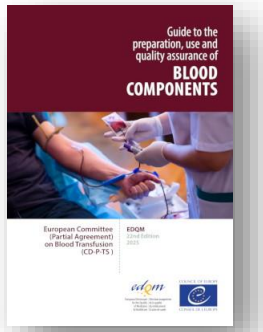
Blood Activities

COMMITTEE

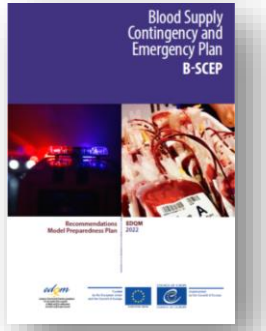
European Committee on Blood Transfusion (CD-P-TS)

ACTIVITIES

Developing legal instruments, technical standards, policies



Monitoring data and best practices



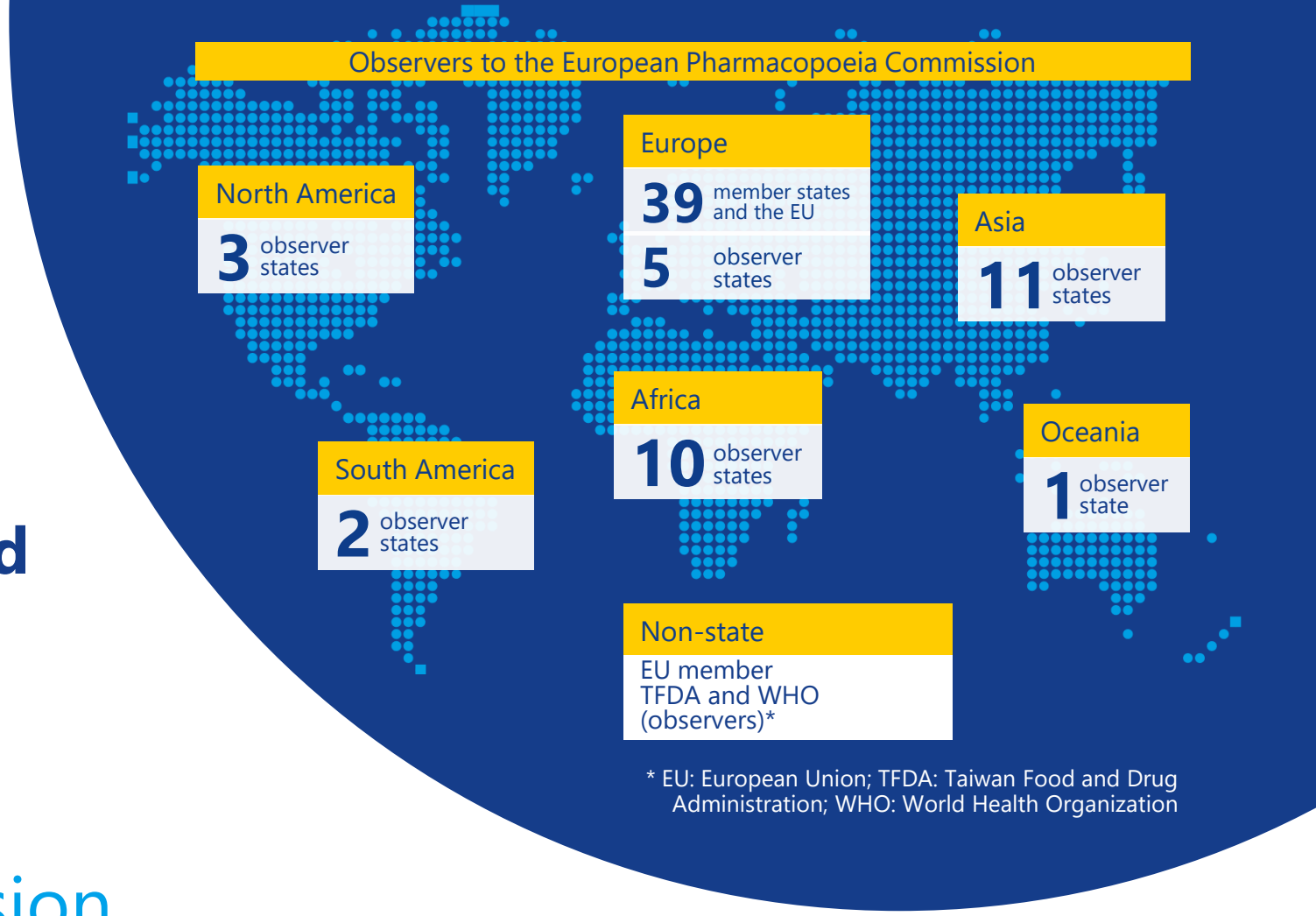
Operational activities supporting SoHO establishments in implementing CoE standards & EU legislation

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

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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

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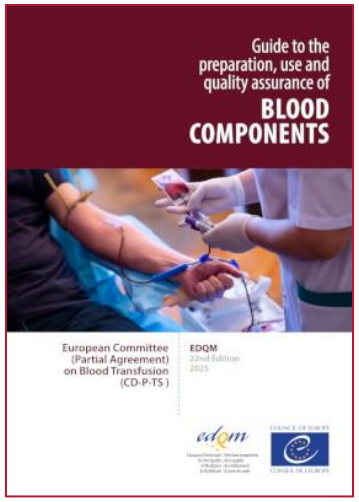
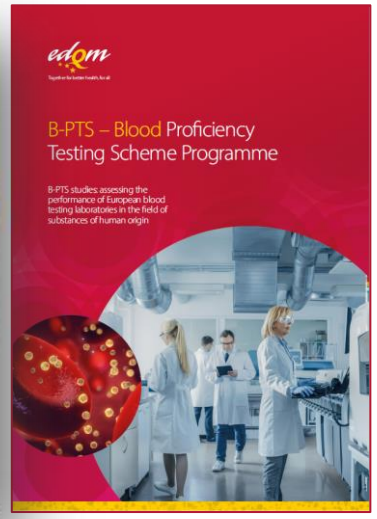
CD-P-TS
Blood transfusion

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

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

The EDQM, a regulatory and technical partner of the EU

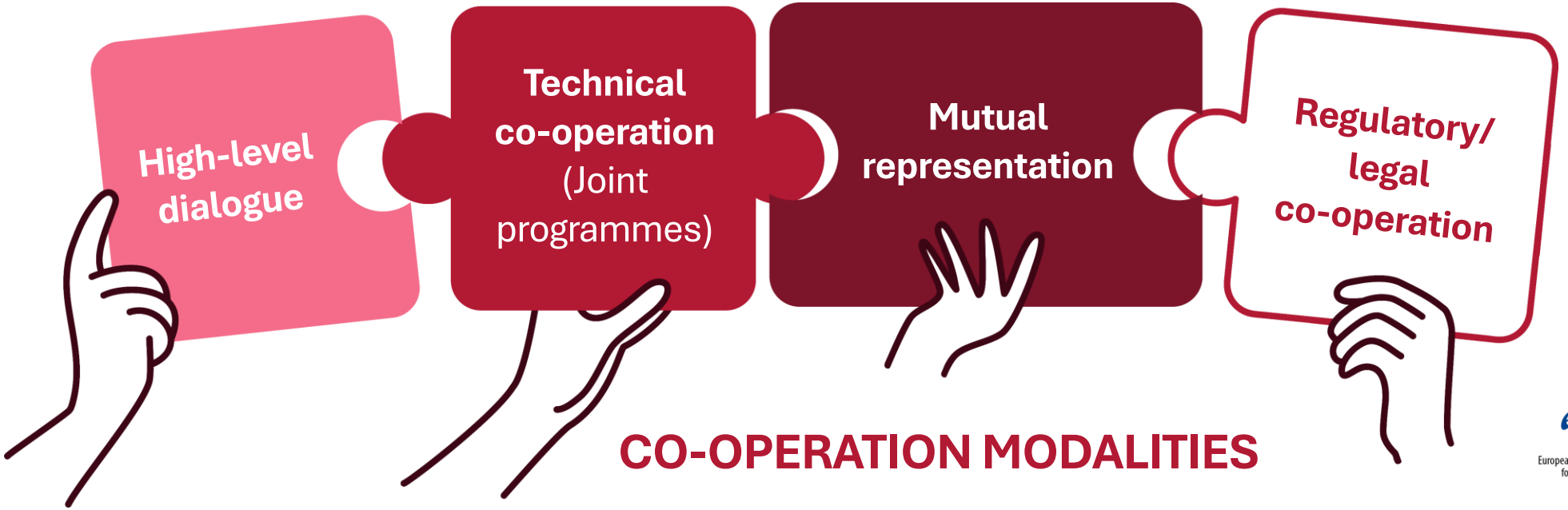
- 60 years of collaboration in the field of medicinal products
- 15 years of collaboration in the field of SoHO

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**



CO-OPERATION MODALITIES

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EDQM Stakeholder Event - Plasma Supply Continuity

The Scientific Committee

Johanna Castrén

Vincenzo De Angelis

Fabio Candura

Piotr Radziwon

Stephen Thomas

EDQM Stakeholder Event on Plasma Supply Continuity

Thank you for your attention.

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EDQM Stakeholder Event on Plasma Supply Continuity

Setting the scene - Objectives of the meeting

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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

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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.

SUPPLY

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eba EUROPEAN BLOOD ALLIANCE

PLASMA PROTEIN THERAPEUTICS ASSOCIATION

IPFA international plasma and fractionation association

European Commission

ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

EHA EUROPEAN HEMATOLOGY ASSOCIATION

IPOPI INTERNATIONAL PATIENT ORGANISATION FOR PRIMARY IMMUNODEFICIENCIES

FIDS

EPODIN

Critical Medicines Alliance

New EU rules on substances of human origin

Reform of the EU pharmaceutical legislation

INTERNATIONAL PLASMA PROTEIN CONGRESS (IPPC)

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

CENTRO NAZIONALE SANGUE

CHESSMEN

IPFA/EBA Symposium on

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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

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