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

Scientific Conference

28 / 29 April 2022

“The Supply of Plasma Derived Medicinal Products in the Future of Europe”

Rome, Italy

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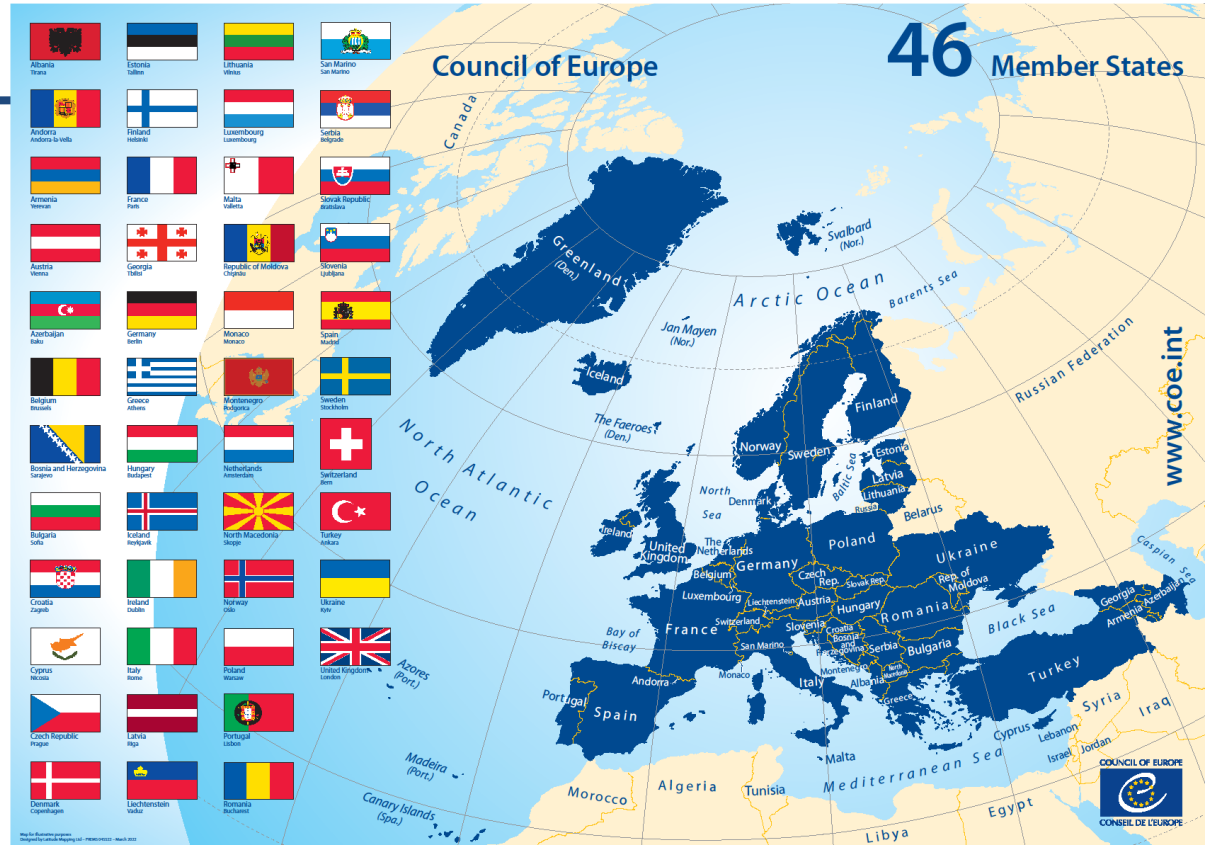
edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Council of Europe and EDQM

Council of Europe

- EDQM's parent organisation
- Founded in 1949, headquarters in Strasbourg (France)
- 46 Member states
- The oldest pan-European organisation dedicated to fostering co-operation in Europe
- Promotes democracy, protects the rule of law and human rights



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

- A council of Europe Directorate, based on the Convention on the Elaboration of a European Pharmacopoeia (partial agreement, 1964)
- **Mission:** to contribute to a basic human right: access to good quality medicines and healthcare

Council of Europe - Blood Activities

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

EDQM (technical secretariat since 2007)

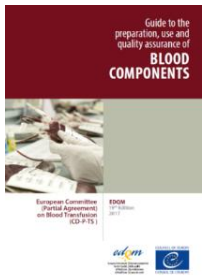
Department of Biological Standardisation, OMCL Network & HealthCare (DBO)

VNRBD

Mutual assistance

Protection of donors & the recipients

1. Developing legal instruments, technical standards, policies



2. Monitoring data and best practices

Working Groups

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

Funded by the European Union and the Council of Europe

EUROPEAN UNION

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Implemented by the Council of Europe

edqm European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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The Blood Guide

- **Appendix to Recommendation No. R(95)15 of CM of the CoE**
- **Comprehensive guidelines** to provide professionals with a useful overview of the most recent developments in the field
- Aimed at ensuring high level of **quality and safety standards**
- Contributing to the **harmonisation** of blood transfusion activities among European countries, facilitating uniform standards and practices
- **Continuous update** and maintenance – **GTS Working Group**
- **Consensus document** elaborated by experts nominated by Member States

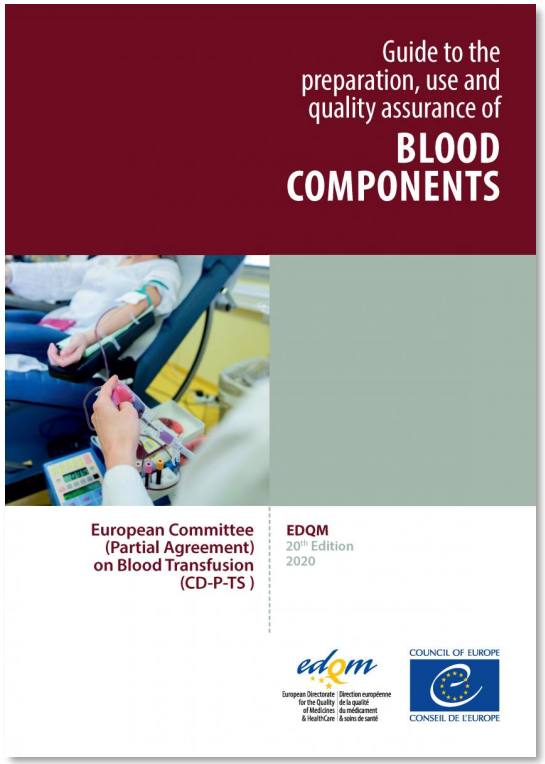
Current - 20th Edition

INCREASED QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

On-going work:

21st Ed Blood Guide (due 2023)

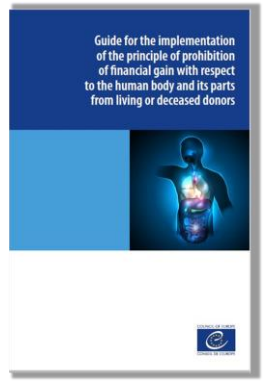
The Blood Guide and Plasma for Fractionation



CHAPTERS

- B-GPG
- Chapter 1 General notices
- Chapters 2-4 & 7-11
- Chapter 5 & 6 Monographs
- Appendices

Commission Directive (EU) 2016/1214, Member states shall ensure that blood establishments take fully into account the standards and specifications set out in those guidelines when implementing their quality system, The GPG are an integral part of the Blood Guide and revised/updated alongside.



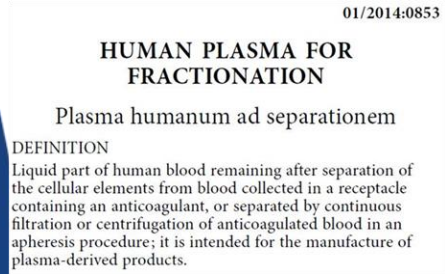
Chapter 2 - Donor Selection – VNRBD / Donor deferral / Plasmapheresis

Chapter 3 – Collection of Blood and Blood Components

Chapter 9 – Screening

36 monographs

5 appendices (SPC, data processing systems, tables for calculation of blood/collection volumes, etc.)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HUMAN PLASMA FOR FRACTIONATION

Plasma humanum ad separationem

DEFINITION

Liquid part of human blood remaining after separation of the cellular elements from blood collected in a receptacle containing an anticoagulant, or separated by continuous filtration or centrifugation of anticoagulated blood in an apheresis procedure; it is intended for the manufacture of plasma-derived products.

TS093 Working Group – Plasma Supply Management

CD-P-TS nominated **TS093 – Plasma Supply Management** (Created 2013)

- Develop tools to assess self-sufficiency in member states leading to a clear landscape;
- Develop tools/give advice to achieve a higher degree of self-sufficiency;
- Use plasma of the required quality to its full potential;
- Achieve sustainable and safe plasmapheresis collection with a focus on donor protection;
- Provide evidence-based data to support the revision of the *Guide to the preparation, use and quality assurance of blood components*.

TS093 "extended" working group – comprised of the "core" group and representatives of key stakeholders involved in the field of blood transfusion and/or plasma-derived medicinal products, - **EBA, EPA, IPFA, PPTA, PLUS**

Meeting "Extended" TS093 (September 2016) - Main outcome: to organise a symposium with all stakeholders

Plasma Supply Management Symposium

Jointly organised by EU Commission and EDQM – 29th and 30th Jan 2019

Focus:

- *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 chapter 2 plasmapheresis donors;*

Attended by 150 participants from 33 countries

www.edqm.eu/en/projects

Proceedings

Recommendations to stakeholders

EU Commission
EDQM/CD-P-TS
Member States National Competent Authorities
Blood Establishments
Plasma Fractionators
Patient Associations
Donor Associations
Professional Societies

Recommendations to the EDQM / CD-P-TS / TS093

1. Data collection

- Collect data and publish reports and surveys on plasmapheresis, plasma and PDMPs

2. Guide revision (evidence-based criteria, transparency of updating)

- Adapt text of Blood Guide to highlight standards and allow a legal reference in the EU Directives
- Promote the use of the Good Practice Guidelines published in the Blood Guide
- Plan a new meeting with extended TS093 working party to look at 21st edition
- Promote individualised donor assessment methods for plasma collection

3. Stakeholder meeting concerning immunoglobulin (IgG) use and rare disease treatment

- Organise conference with the whole chain for rare diseases in collaboration with other stakeholders (EU Commission, industry, patient and donor associations)
- Organise Kreuth-like conferences to discuss optimal use of IgG (off-label use) and rare diseases

4. Plasma collection-targeted activities

- Promote strategic independence of plasma in the Council of Europe member states (wider Europe)
- Organise awareness campaigns on the need for plasma to produce PDMPs

TS100 Working Party – Sexual Risk Behaviours

CD-P-TS nominated **TS100 – Sexual Risk Behaviours** (Created 2013)

to monitor current practices, evaluate scientific data and define a harmonised approach for donor deferral, linked to the risks attributable to sexual behaviour;

- Survey on deferral policies – updated for 2022;
- Proposals for consideration in 22nd Edition of Blood Guide;

Annual Report

Data collection on the donors, collection, testing, use and quality aspects of blood and blood components in European Countries

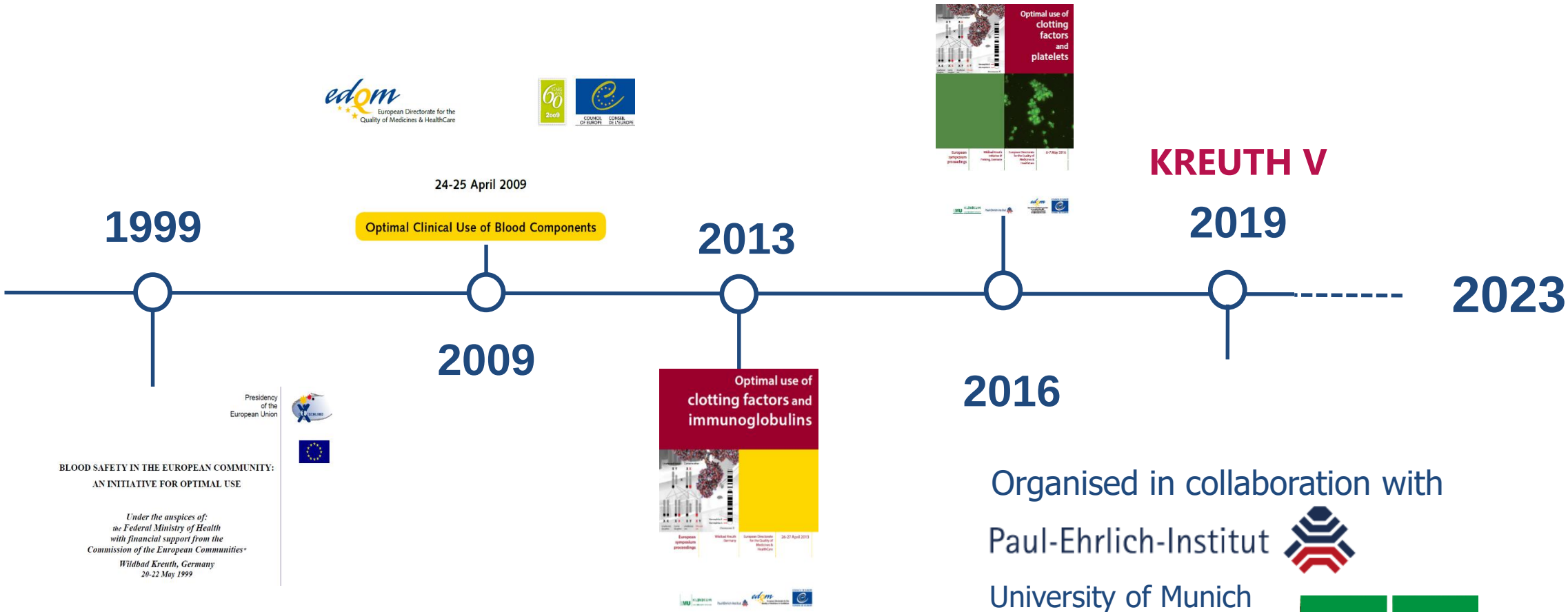
Ongoing Work:

- Report 2017 – 2019;
- 2020 – 2021 data collection survey;

- Review on approach to data collection and reporting;

THE WILDBAD KREUTH INITIATIVE

► Optimal Use of Blood Components and Plasma Derived Medicinal Products (PDMP)



Organised in collaboration with

Paul-Ehrlich-Institut

University of Munich

LMU LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN

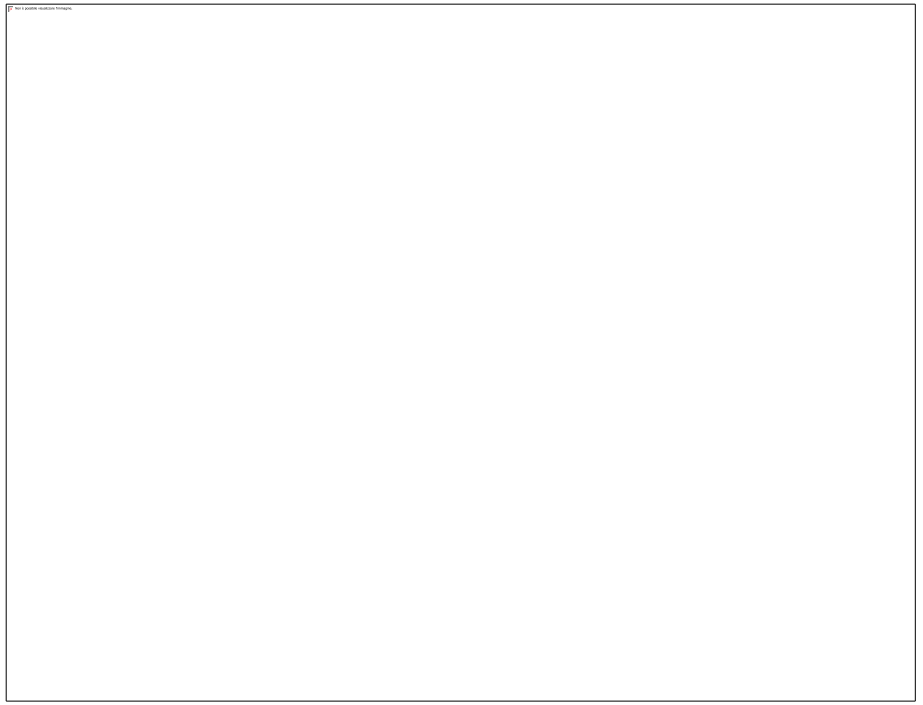
CD-P-TS – Supporting Safe Plasma Collection

CD-P-TS, under the coordination of the EDQM Secretariat will continue;

- The Blood Guide revision (evidence-based criteria)
- Data collection
- Support the coordination of meetings concerning immunoglobulin (IgG) use and rare disease treatment
- Plasma collection-targeted activities

Continue to help strengthen the implementation of measures to promote and support safe plasma donation and donor protection, and to ensure continued and safe access for patients to plasma-derived medicinal products for life-saving treatments

Thank you for your attention



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The Blood Guide – Key Dates

Stakeholder Consultation:

Launch 17th June 2022

Deadline for comments: 15th September 2022

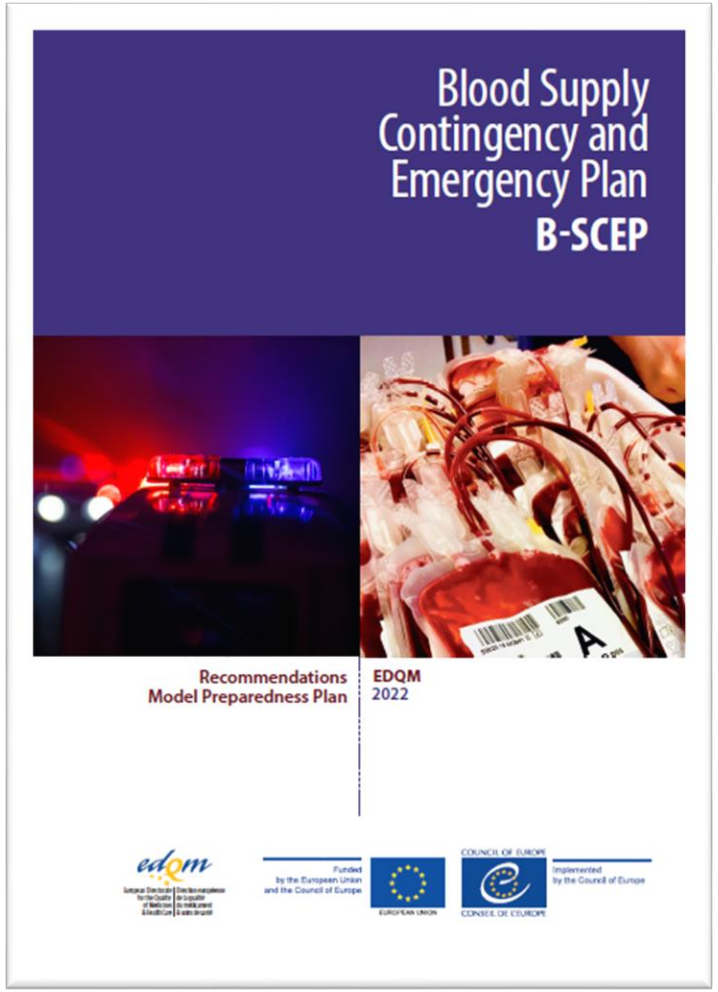
Adoption:

CD-P-TS Meeting: 15th and 16th November 2022

Publication:

Q1 of 2023

B-SCEP Project



The B-SCEP project aimed at strengthening national plans to ensure continuity of the blood supply in emergency situations, developing strategies to support European countries in this regard.

Survey Report, Recommendations and Model Preparedness Plan

https://www.edqm.eu/en/blood-supply-contingency-and-emergency-plan-b-scep-

B-SCEP Webinar - 5th May 2022, 13:00 – 15:30 CET

https://www.edqm.eu/en/web/edqm/webinar-supporting-contingency-and-emergency-planning-for-blood