Contributions of the EDQM to European Regulations in the Field of Labile Blood Components and Blood Products

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Outline

- European Regulatory Institutions EDQM / EU Commission
- European Committee on Blood transfusion (CD-P-TS)
- European Pharmacopoeia
- EU Official Control Authority Batch Release (OCABR)
- Conclusion

European Institutions

Council of Europe (SXB) (CoE)

- 47 Member States
- 12 countries in 1949
- to promote democracy, human rights, rule of law
- Conventions, CM res/rec
- European Pharmacopoeia Convention in 1964 (38 MS & EU)
  - Public health by common quality standards

European Union (BRU) (EU)

- 28 Member States
- 6 countries in 1951,
- European Coal and Steel Community, EEC, EC, EU
- Treaties (Rome 1957, Maastricht 1993, ...)
- Single market, free movement people goods, incl. pharmaceuticals
- Directives
  - Minimum safety and quality requirements: blood & blood components & blood products

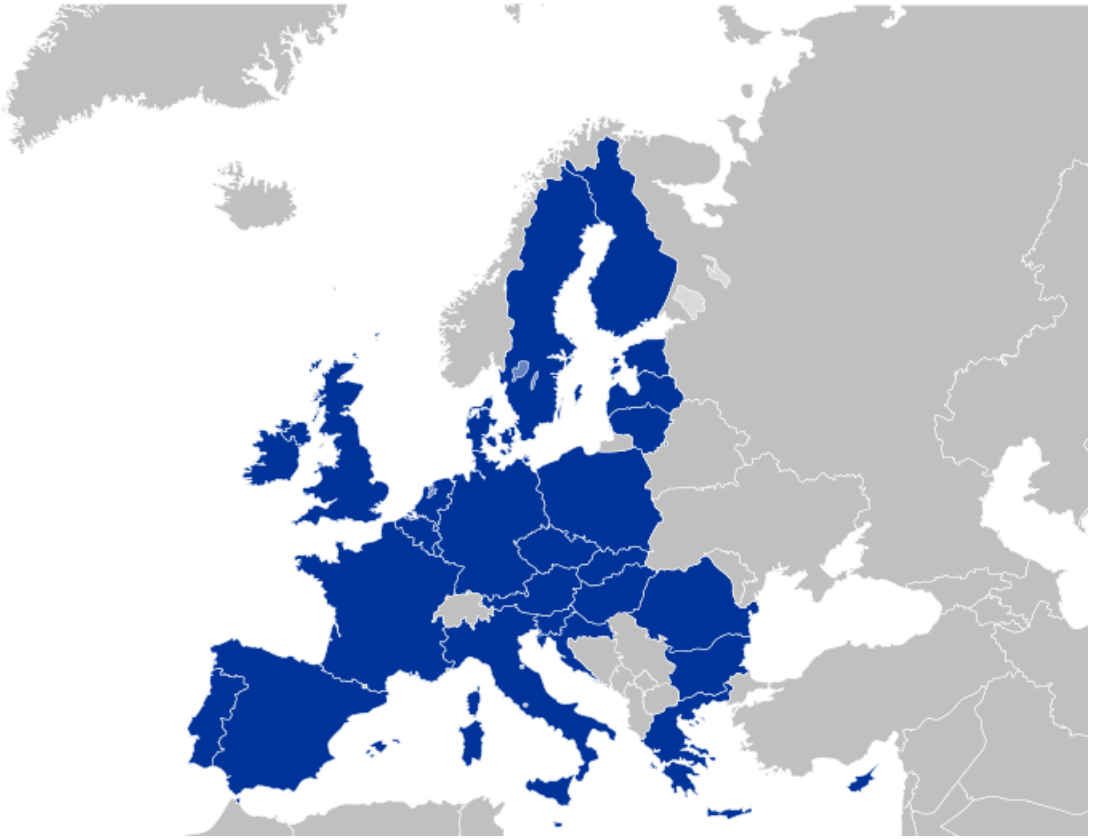
Membership

Council of Europe (SXB)

47 MS, 820 Million of Citizens

European Union (BRU)

28 MS, 500 Million of Citizens



Democracy – Human Rights – Rule of Law

Outline

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

- Created in 2007, under Art. 17 CoE Statute, Technical Secretariat EDQM
- Steering Committee directly answerable to Committee of Ministers CoE
- Composition (Partial Agreement)
  - Members (Parties to Ph Eur Convention), designated by governments
  - Observers (CoE MS, WHO, FDA, NZ, TGA, Health CDN, HSA Singapore,...)
- Role oversee and co-ordinate BT activities for CoE
  - ensure the periodic revision of the Blood Guide, setting common harmonised standards in the field of blood transfusion, organise international surveys, assess epidemiological risks, facilitate the implementation of quality management in TS

www.edqm.eu/en/blood-transfusion-work-programme-69.html

Blood Guide, legal status

Appendix to Recommendation No. R(95)15 of CM to MS

19th edition, June 2017

- Organised as Principles and Standards sections
- Good Practice Guidelines
  Mandatory in EU Dir2005/62/EC amended by Dir(EU)2016/1214

20th edition stakeholder consultation, May-August 2019

- Principles merged with Standards

CD-P-TS, subordinate working parties

- GTS Working Party,
  - Periodic revision of the Blood Guide
  - Collect evidence based for setting (revising) recommendations
- TS093 Plasma Supply Management Working Party
  - Organise Surveys
  - Symposium January 2019
  - Revision Blood Guide Chapter 2 for 20th edition
- TS100 Risk Behaviours of Donors Impacting the Safety of Blood Transfusion
  - Organise Surveys
  - Mapping of deferral policies

TS093 Plasma Supply Management Symposium

- Europe depends on USA collected plasma for treating patients

- Organised jointly by EDQM/DG Health EU Commission (January 2019)
- Identify obstacles in Europe to strategic independence of plasma
- Ensure donor protection

- Evidence base for Blood Guide chapter 2 plasmapheresis donors
- Recommendations to stakeholders

Donor protection

Recommendations from Symposium

- Debriefing meeting
- Disclaimer
  - EU Commission
  - EDQM/CD-P-TS
  - Member States National Competent Authorities
  - Blood establishments
  - Plasma fractionators
  - Patient associations
  - Donor associations
  - Professional societies
- To be fine tuned and published (soon)

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European Pharmacopoeia, legal status

- Convention Council of Europe, ETS No. 50, 1964

  Founder Countries: Belgium, France, Italy, Luxembourg, Switzerland, United Kingdom

- Protocol ETS No. 134, 1992 EEC
- Dir 2003/63/EC amending 2001/83/EC

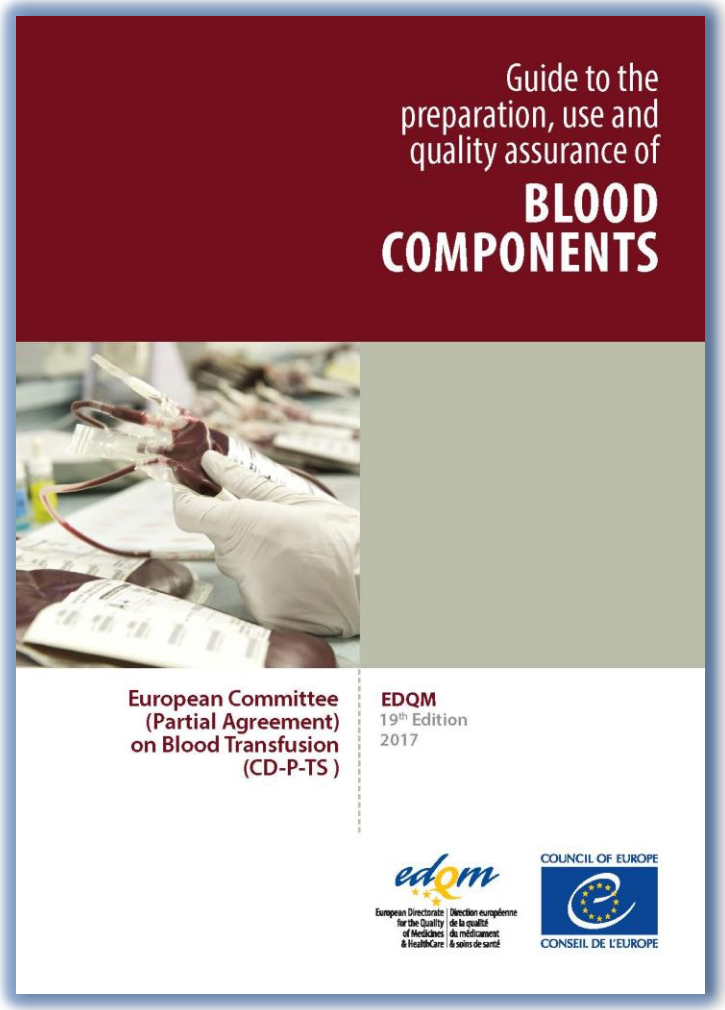
  provision legal enforcement of Ph. Eur. @ EU MS

- Composition (2020) 38 Member States + EU + 30 Obs.

www.edqm.eu/en/european-pharmacopoeia-background-50.html

Blood Guide and European Pharmacopoeia

Blood Legislation



Pharmaceutical Legislation

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.

PRODUCTION

DONORS

Only a carefully selected, healthy donor who, as far as can be ascertained after medical examination, laboratory blood tests and a study of the donor's medical history, is free from detectable agents of infection transmissible by plasma-derived products may be used. Recommendations in this field are made by the Council of Europe [*Recommendation No. R (95) 15 on the preparation, use and quality assurance of blood components,* or subsequent revision]; a directive of the European Union also deals with the matter: *Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.*

Monographs F-H

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EU Official Control Authority Batch Release (OCABR)

- Legal framework

  Dir 2001/83/EC amended by
  Dir 2004/27/EC formely
  Dir 89/381/EEC

- Each batch of plasma derived medicinal product retested independently before release, mutual recognition
- Official Medicines Control Laboratory Network, created in 1994, contractual agreement between CoE and EU commission, coordinated by EDQM, financial contribution from the EU
- Protocol review, independent testing, EU OCABR certificates

www.edqm.eu/en/batch-release-human-biologicals-vaccines-blood-and-plasma-derivatives

Conclusion

European regulatory landscape

- EDQM/CoE
  - European Committee on Blood Transfusion (CD-P-TS) — Blood Guide
  - European Pharmacopoeia Commision — Monographs
  - OMCL Network for human biologicals — Guidelines and Procedures
- EU Commission
  - DG SANTE — Directives

Thank you for your attention

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