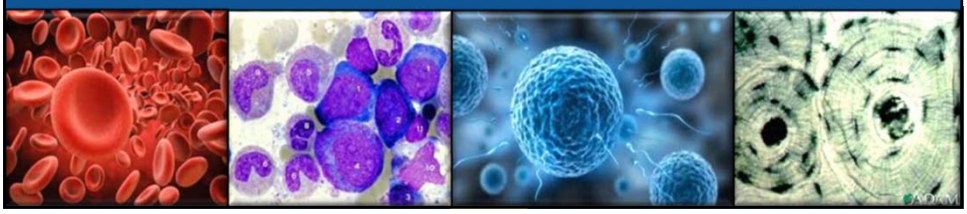
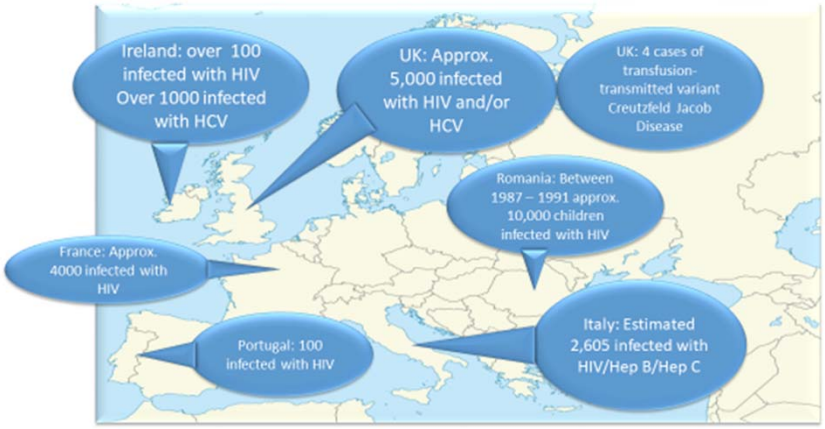
20years of Commission governance in the field of blood

Dr Andrzej Rys, European Commission

Celebrating the 10th anniversary of European Commission and EDQM/Council of Europe co-operation in the field of blood – 27 October 2020



Why the Member States asked the EU to legislate…



Infectious disease transmissions of HIV and hepatitis C by blood transfusion and plasma derived medicinal products in the 80s and 90s

Health

Legal Basis for SoHO Legislation

Amsterdam Treaty 1997

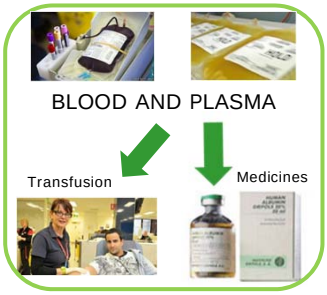
Treaty on the Functioning of the EU - Article 168 4(a)

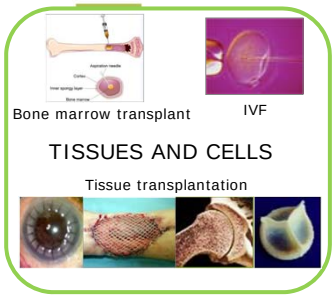
"Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures."

Clear Mandate for EU-level action to improve quality & safety of Substances of Human Origin

Health

EU Regulation of SOHO





EU legislation since 2002 (4 Directives)

EU legislation since 2004 (4 Directives)

EU legislation since 2010 (2 Directives)
+
EU Action Plan

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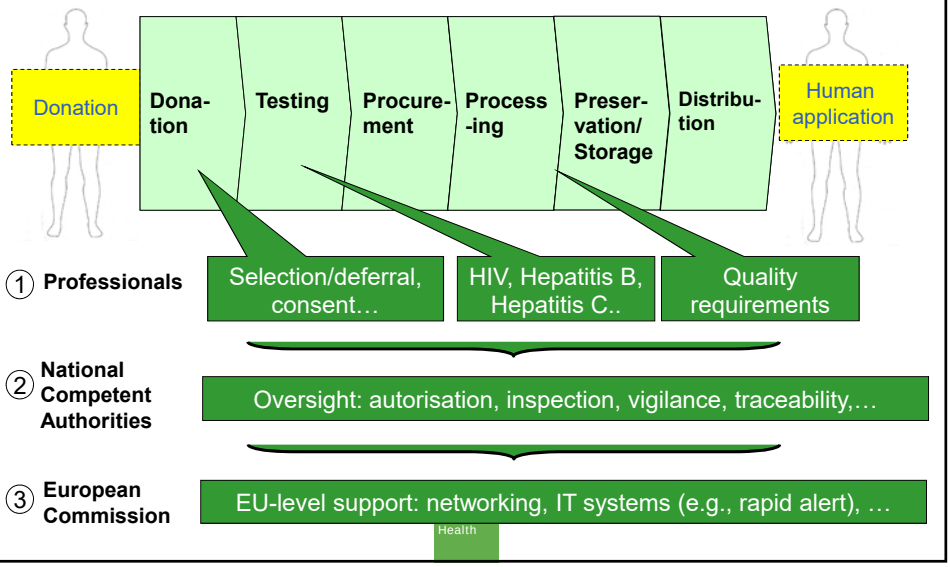
EU legal frameworks



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Need for technical complements

1 Directive 2002/98/EC
- Setting safety and quality standards (Mother Directive)

2 COM Directive 2004/33/EC
- Technical requirements blood establishments

COM Directive 2005/61/EC
- Vigilance and traceability

COM Directive 2005/62/EC
- Quality Specs blood establishments

3 Technical Guidance to complement/specify

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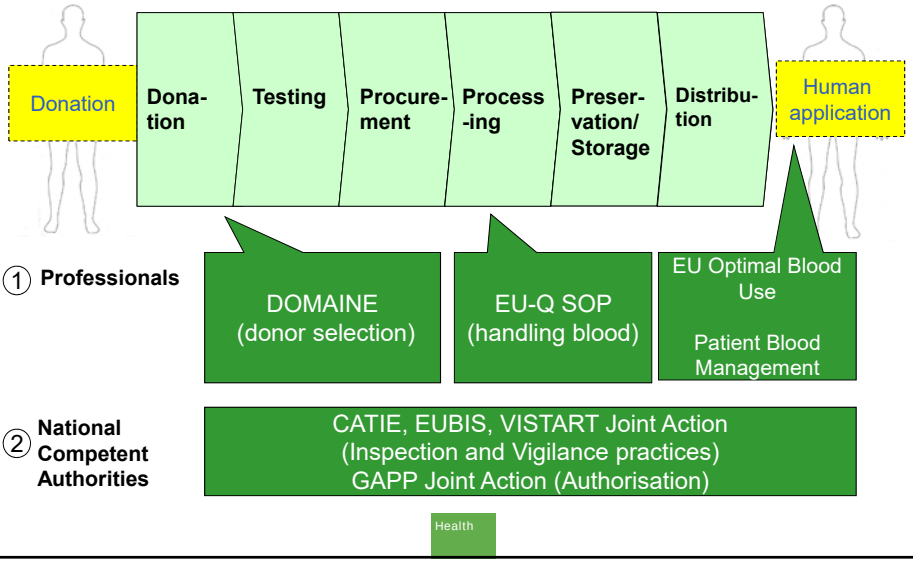
And support from Health Programme



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With a growing role for EDQM

First agreement (2010)

- Guidelines for Quality Systems for blood establishments
- Basis for later GPG (Directive 2016/1214)

Current Agreement

- Biovigilance, SARE reporting and training
- Blood Supply continuity
- Country Assessments
- Post-mortem blood tests
- Activity data collection (TC)
- Quality Standards (TC)
- Quality Management (TC)

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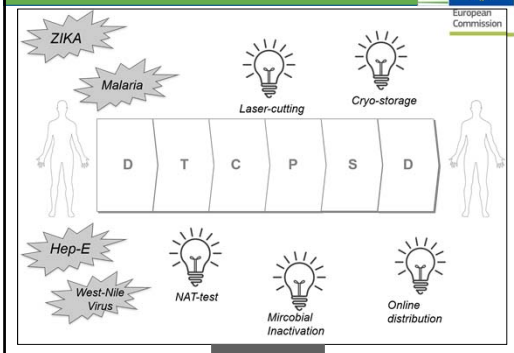
Key concern Evaluation BTC

1. Out-of-date technical provisions



EU legislation: limited use of amendments or urgency procedures in EU blood legislation.
(adoption procedures are difficult to keep track of developments)

Detailed sector guidance, regularly aligned to developments and science

Health

Commission WorkPlan 2021

(Annex II REFIT, entry 37)

Revision of blood, tissues and cells legislation

- Update the current legislation to allow for more flexible alignment to scientific and technological developments.
- Address the (re-)emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic.
- Address increasing commercialisation and globalisation of the sector.
- Removal from legislation of many technical provisions, which will allow faster updating of standards.
- Possibility to merge the basic acts into a single instrument.

Planned adoption date: Q4/2021

Health


European
Commission
Looking forward to continue and strenghten our collaboration…
https://ec.europa.eu/health/blood_tissues_organs/
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