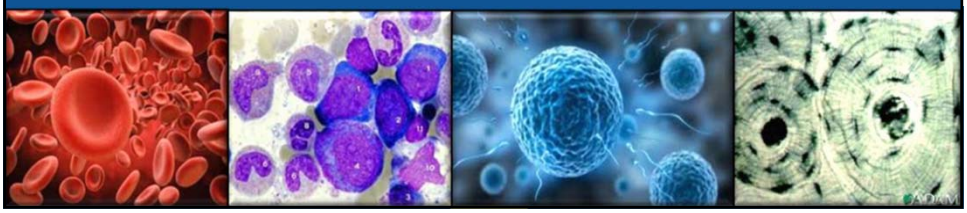
Update on the evaluation of the EU blood legislation (and beyond)

Dr Stefaan Van der Spiegel, European Commission

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



ORGANS, BLOOD, TISSUES & CELLS IN THE EU

- **BLOOD TRANSFUSION** 25 MILLION / YEAR
- **BONE MARROW TRANSPLANTS** 35 THOUSAND / YEAR
- **ASSISTED REPRODUCTION CYCLES** 777 THOUSAND IN 2014
- **OTHER TISSUES :** HEART VALVES | SKIN | BONE | CORNEA
- **PLASMA FOR MANUFACTURING MEDICINES** 8 MILLION LITRES / YEAR

ORGAN TRANSPLANTS

- 21 102 KIDNEY
- 7 984 LIVER
- 2 169 HEART
- 2013 LUNG

OTHERS: PANCREAS, SMALL BOWEL, HAND, FACE

TOTAL IN 2017 34 THOUSAND

MEDICAL CENTRES

- 1 400 BLOOD ESTABLISHMENTS
- 3 000 TISSUE ESTABLISHMENTS
- 800 ORGAN TRANSPLANT PROGRAMMES

Health

TYPE OF ACTORS

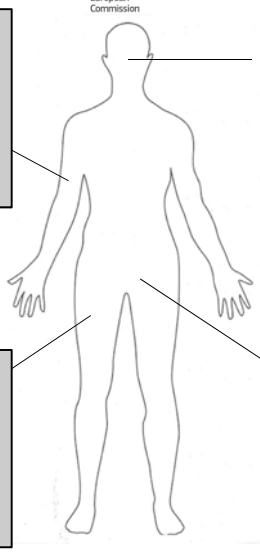
- ACADEMIC SETTING
- MAINLY PUBLIC ACTORS
- SOME FOR-PROFIT AREAS (IVF, bone, …)

Blood, tissue and cells in the EU

Blood components:

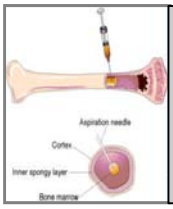
25 million units transfused/year

8 million liter/y of plasma for medicines



Replacement tissues:

Cornea, bone, skin, heart valves, …



Blood stem cells (bone marrow, cord blood)

35,000 transplants /year

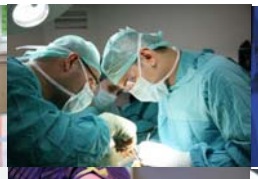
Medically Assisted Reproduction

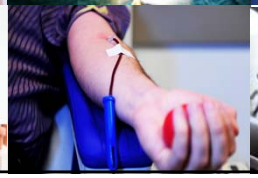
800,000 cycles/year

Health

EU law sets standards for safety and quality
(TFEU Art 168, 4 (a))

Donor → Donate → Test → Collect/ Procure → Process → Store → Ship → Recipient

Evaluation process

- Did the directives on blood (2002/98/EC) and on tissues and cells (2004/23/EC) **meet their purpose** to ensure safety and quality, and are they still **fit for purpose**?

- **Robust** evidence collection in **2-year process**:
  - Open Public Consultation with over 200 responses
  - Bilateral meetings with patient, professional and industry associations, (inter-)national authorities and experts
  - Multilateral meetings with key stakeholders and national authorities on key issues like supply continuity or donor protection
  - External study (literature, interviews, surveys)
  - Inputs from literature, COM reports, complaint, infringements, questions, …
  - Stakeholder events: 2017 (consult), Oct 2019 (results)

Health

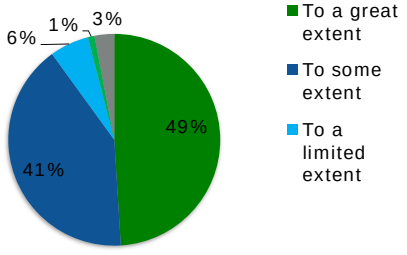
Key outcome — *Overall increased safety and quality*

Serious adverse reaction (2016)
1/12.040 blood transfusions
1/9.650 tissue/cells distributed

OPC: 80% of individual citizens, 74% of Blood stakeholders, 64% of Tissues and Cells stakeholders believe that:

- this could not have been achieved at national level, or
- might have happened but EU legislation sped up the process

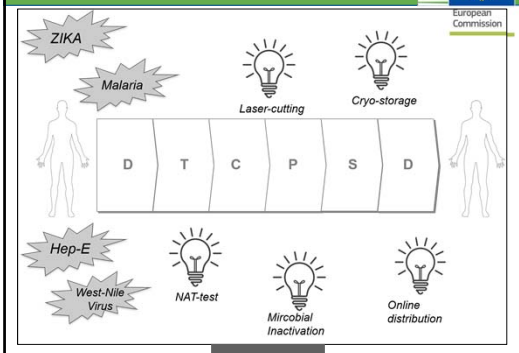
Question OPC: In your opinion, to what extent has the legislation increased the quality and safety of blood and blood components? (n=88)



Health

Cross-cutting themes emerging

1. Out-of-date technical provisions



Limited use of Articles 28 and 29 in both basic Acts ➔

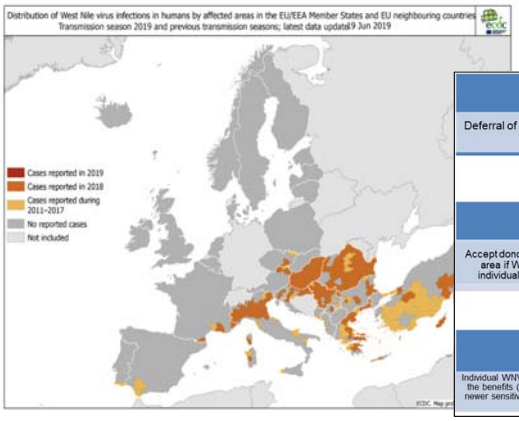
- Amendments: Directives 2011/38/EU, 2012/39/EU, 2014/110/EU, (EU) 2015/565, (EU) 2016/1214
- Urgency: Directive 2009/135/EC

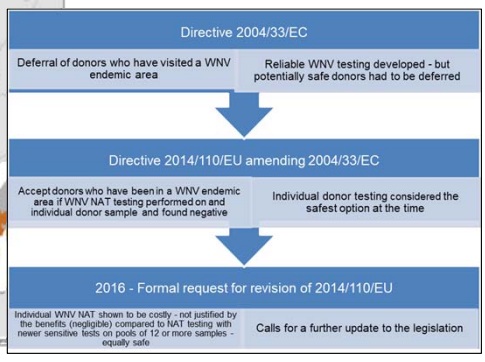
Risk of ZIKV transmission via substances of human origin (SoHO)

Data, though limited, indicate that there is a risk of ZIKV transmission through SoHO, especially through blood transfusion [51,52]. The high proportion of asymptomatic cases [53-56], the documented occurrence of Zika RN positive blood donations [57-59], and the reports of probable transfusion-transmitted (TT) cases [60,61] indicat that Zika-positive blood, donated by an asymptomatic infectious donor, may enter the blood supply and could b

Cross-cutting themes emerging

1. Out-of-date technical provisions

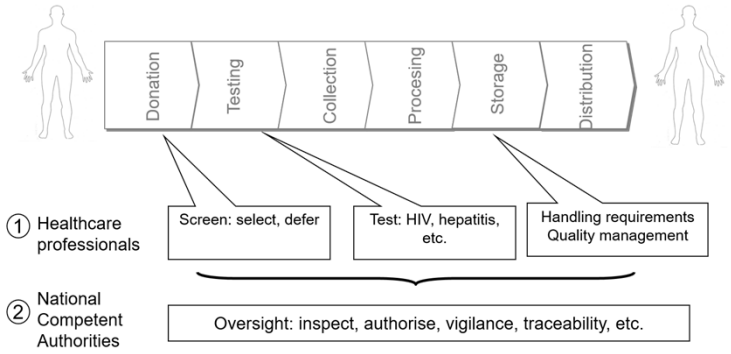




- Technological changes, new risks, societal changes
- Legislation detailed and difficult to change in a timely manner
- Gaps for new SoHO that do not meet T&C definitions (e.g. FMT, breast milk)

Cross-cutting themes emerging

2. Suboptimal oversight provisions

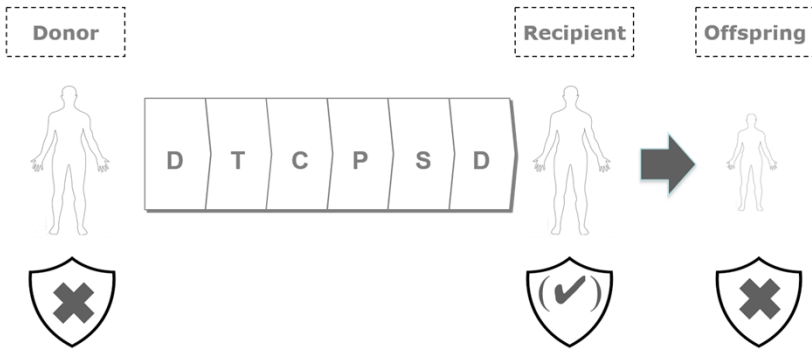


- Independence and effectiveness of inspections and vigilance – harmonisation - trust
- Capacity and skills of NCAs, particularly for novel therapy regulation

Health

Cross-cutting themes emerging

3. Incomplete protection citizens

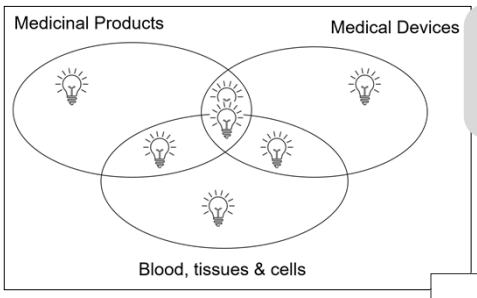


Many provisions to keep BTC and recipient safe, but not for

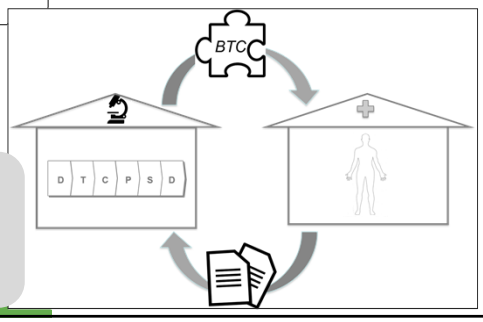
- Donors – increased demand, commercial interest, limited provisions for protection or follow up
- Children born from IVF – vigilance and outcome.

Cross-cutting themes emerging

4. Sub-optimal for innovation



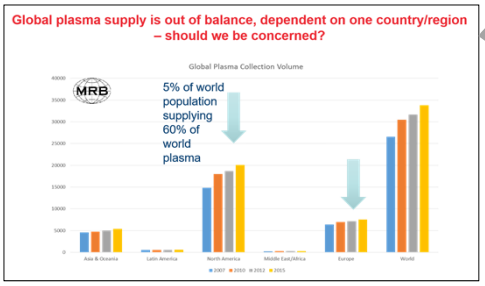
Many innovations cross EU-regulatory borders ➔ requiring more clarity and interplay



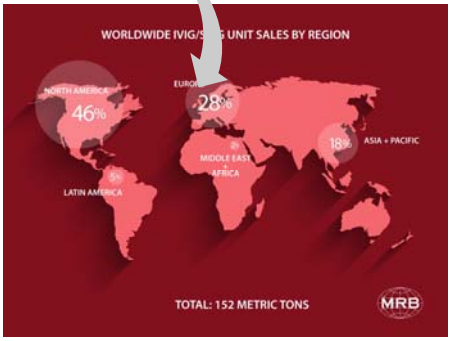
Innovations bring benefit (and risks) for patients ➔ requiring more clinical information (as part of autorisation)

Cross-cutting themes emerging

5. Limited provisions to ensure sufficiency



EU needs to import >40%



- Reliance on US for plasma and some tissues
- Limited measures to protect supplies for patients
- Emergency preparedness

What's next

Revision of blood, tissues and cells legislation (CWP 2021)

- more flexible alignment to science/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.

Based on an Impact Assessment

- Inception Impact Assessment
- Open Public Consultation
- Data/digital study
- External study

https://ec.europa.eu/health/blood_tissues_organs/policy/revision_en

Planned adoption date: Q4/2021

Health

EDQM/EC Symposium plasma supply (2019) 1. Recommended Actions (1/2)

- European Commission
  - Donor protection and vigilance
  - Support collection (communication, awareness)
  - Support strategic independence (equitable access, access, free market)
  - Optimize legal framework (PMF, donation, GPG)
- EDQM (Council of Europe)
  - Data collection and reporting
  - Evidence based guidance
  - Networking and conferences (optimal use)
  - Awareness building, campaigns
- Member States/National Competent Authorities
  - National targets and support for collection
  - Monitoring and reporting on plasma and PDMP
  - Contingency plans and appropriate use
  - Donor vigilance

Health

EDQM / EC Symposium plasma supply (2019)

1. Recommended Actions (2 / 2)

- Manufacturers
  - Collaboration on optimal use
  - Data and knowledge sharing (SARE, best practice, decision support)
- Blood Establishments
  - Increase collection (awareness, collect more and better)
  - Donor safety and recognition
  - Collaborations (learnings, benchmark)
- Patient Associations
  - Collaboration on optimal use
  - Data and knowledge-sharing (contingency, databases)
- Donor Associations
  - Awareness building
  - Donor-recruitment best practices
- Professional Societies
  - Optimal use

Health

https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en

Health