The Evaluation of the EU legislation on safety and quality of Blood, Tissues and Cells – **Plasma collection**

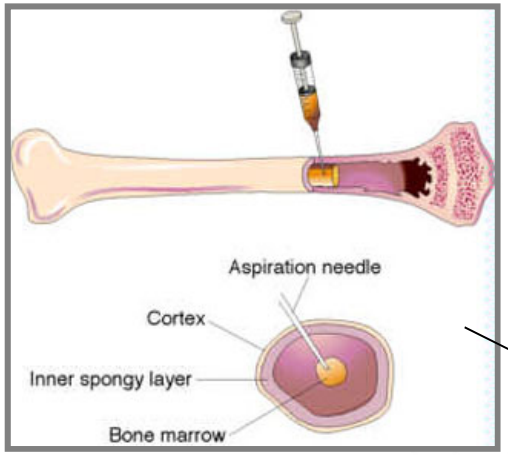
Stefaan Van der Spiegel, MD, MBA
Substances of Human Origin (SoHO)

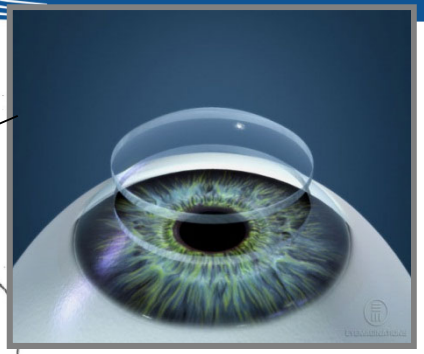
European Commission
DG Health and Food Safety (SANTE)
Unit B4 / Medical products:
quality, safety and innovation

IPFA-EBA workshop on plasma collection
14 January 2020, Amsterdam

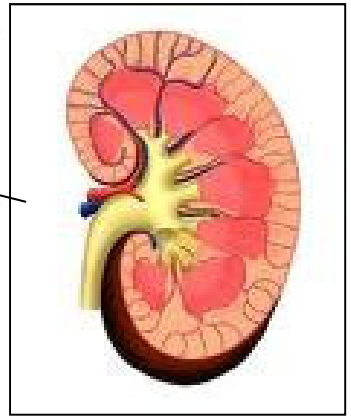
Substances of Human Origin

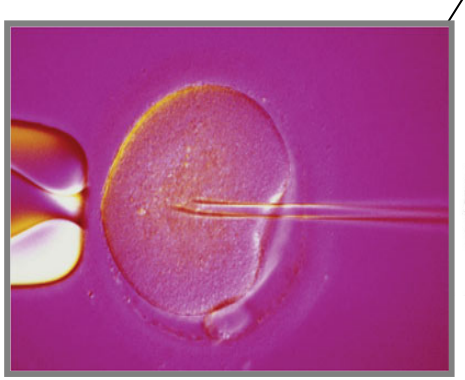
European Commission













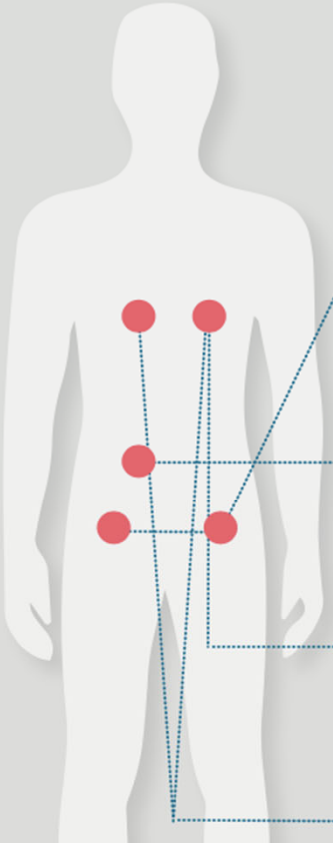
ORGANS, BLOOD, TISSUES & CELLS IN THE EU

BLOOD TRANSFUSION
26 MILLION UNITS / YEAR

BONE MARROW TRANSPLANTS
33 THOUSAND UNITS / YEAR

IN VITRO FERTILISATION
540 THOUSAND CYCLES / YEAR

OTHER TISSUES :
HEART VALVES | SKIN | BONE | CORNEA



ORGAN TRANSPLANTS

20 102 KIDNEY

7 694 LIVER

2 235 HEART

1 818 LUNG

OTHERS
- PANCREAS
- SMALL BOWEL
- HAND
- FACE

TOTAL
33 THOUSAND

MEDICAL CENTRES

1 400
BLOOD ESTABLISHMENTS

3 000
TISSUE ESTABLISHMENTS

800
ORGAN TRANSPLANT PROGRAMMES

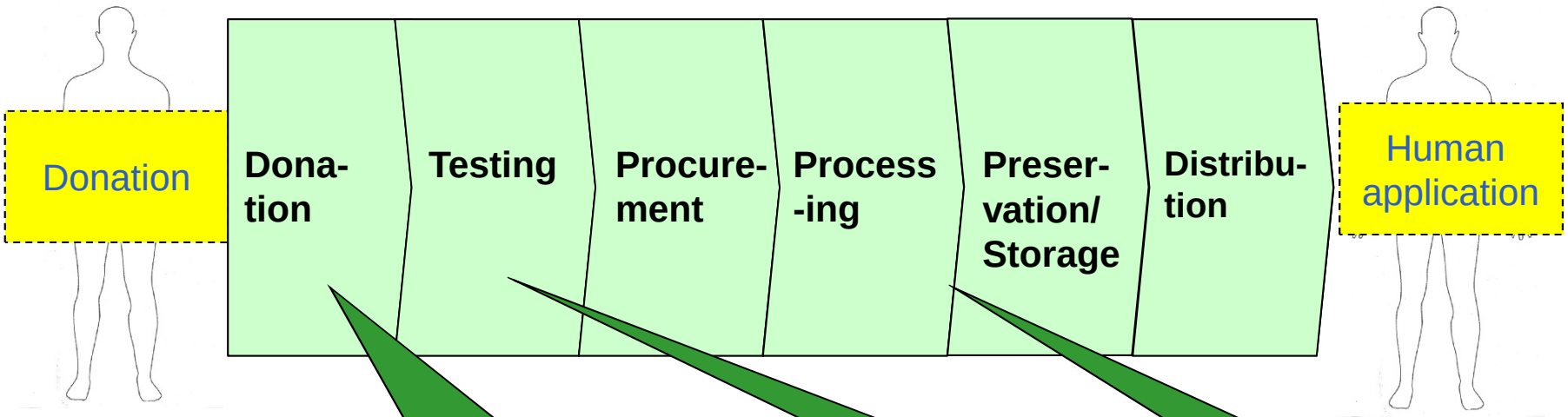
TYPE OF ACTORS

ACADEMIC SETTING

MAINLY PUBLIC ACTORS

SOME FOR-PROFIT AREAS (IVF, bone, ...)

EU legal frameworks



① **Professionals**

Selection/deferral, consent…

HIV, Hepatitis B, Hepatitis C..

Quality requirements

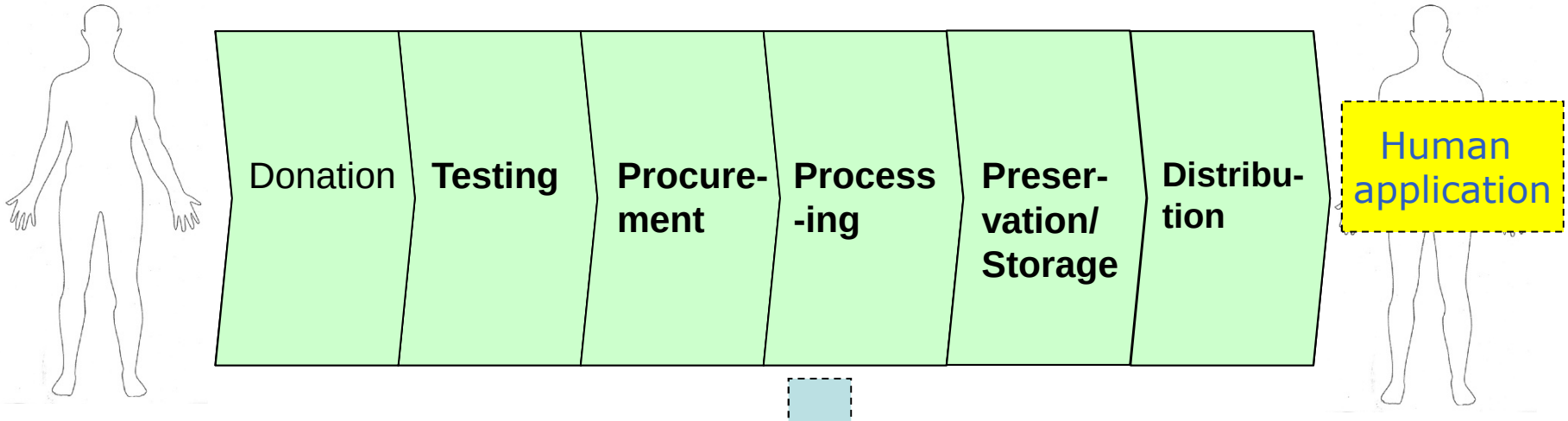
② **National Competent Authorities**

Oversight: autorisation, inspection, vigilance, traceability,…

③ **European Commission**

EU-level support: rapid alerts, coding system…

BTC become Medicinal Product



Evaluation EU law blood, tissues, cells

- Directive 2002/98/EC on safety and quality of **blood/components**, and implementing legislation
- Directive 2004/23/EC on safety and quality of **tissues and cells**, and implementing legislation

- Did the EU legislation help **improve safety and quality**? Is it still **fit for purpose**?

- Evidence based process: large stakeholder consultation (200+, including all key associations), literature, independent study, Commission reports, …

- Dissemination event on 28/10 in Brussels

- Basis for possible improvement (political decision)

Key outcome

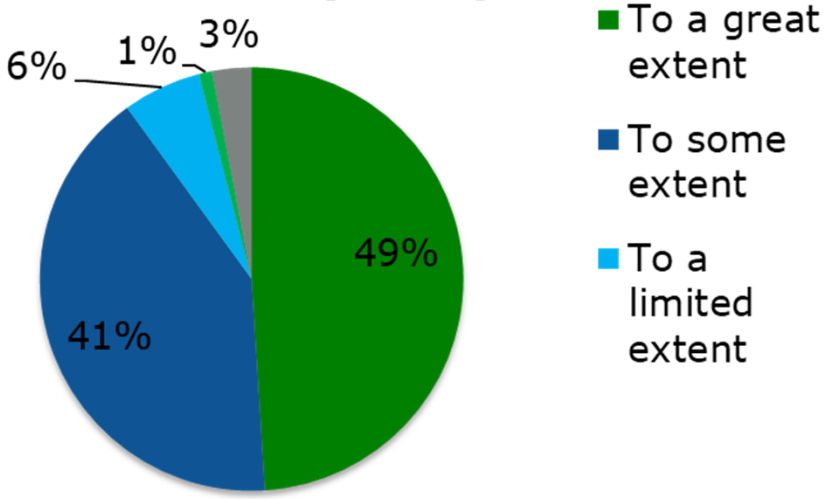
Overall increased safety and quality

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:

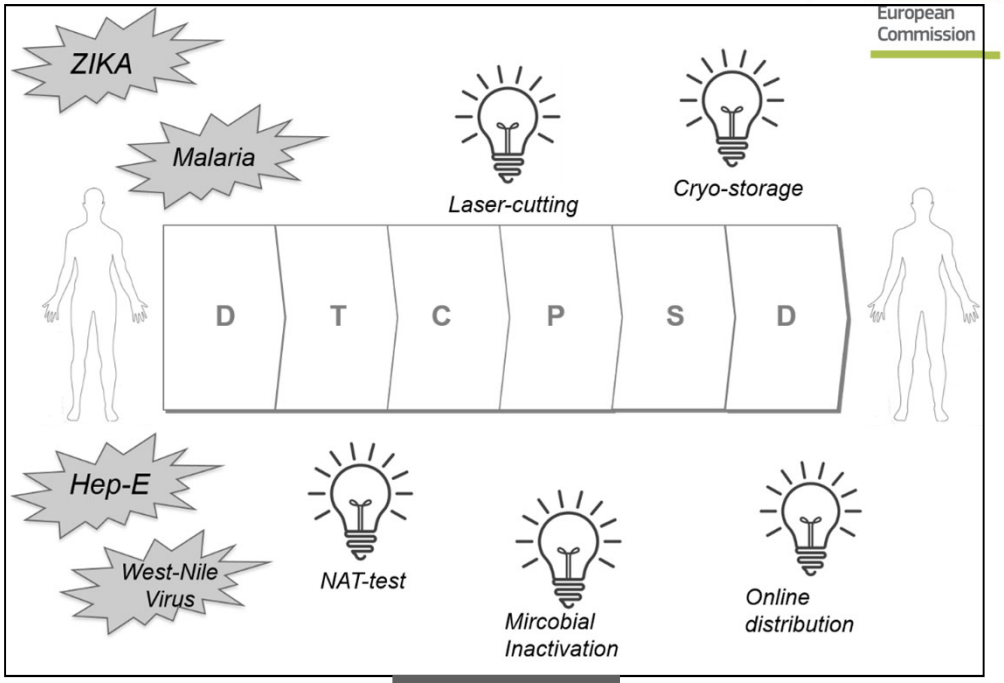
- this could not have been achieved at national level, or
- might have happened but EU legislation sped up the process

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



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

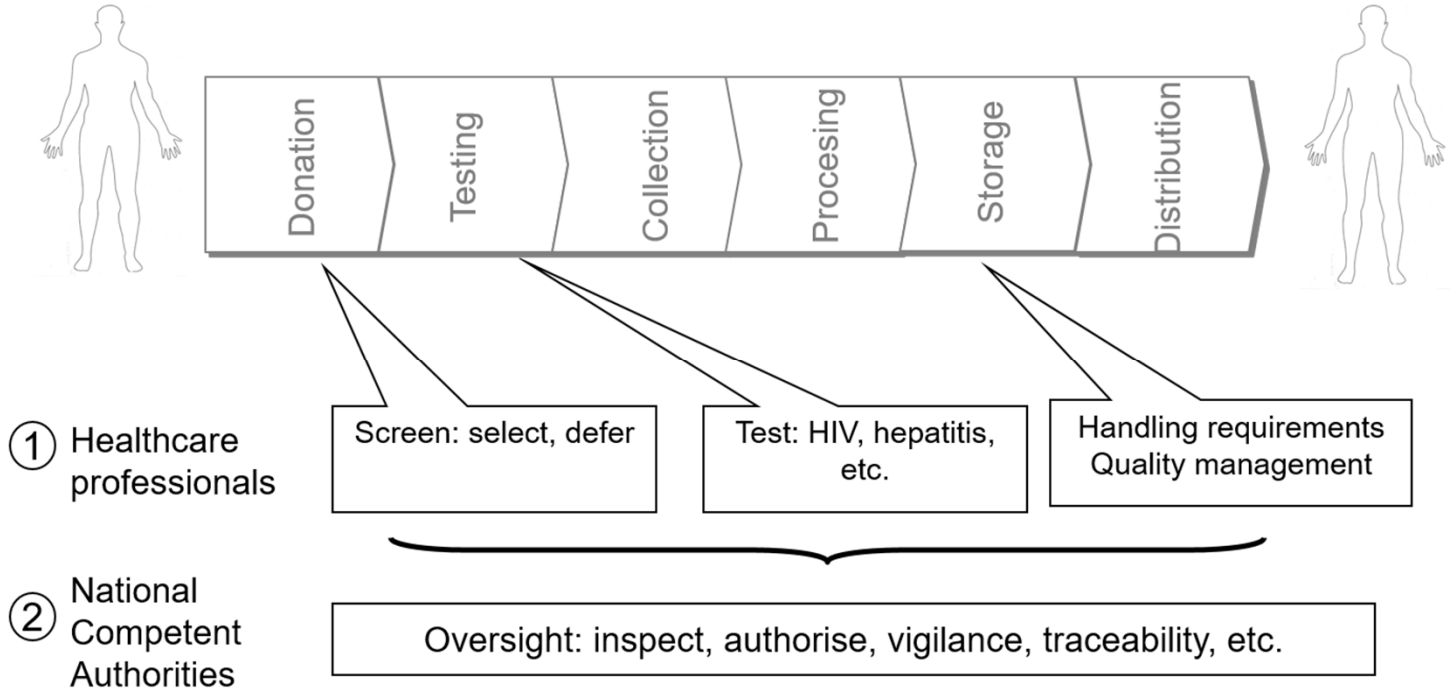
Risk of ZIKV transmission via substances of human origin (SoHO)

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 RNA positive blood donations [57-59], and the reports of probable transfusion-transmitted (TT) cases [60,61] indicate that Zika-positive blood, donated by an asymptomatic infectious donor, may enter the blood supply and could be

Cross-cutting themes emerging

European Commission

2. Suboptimal oversight provisions

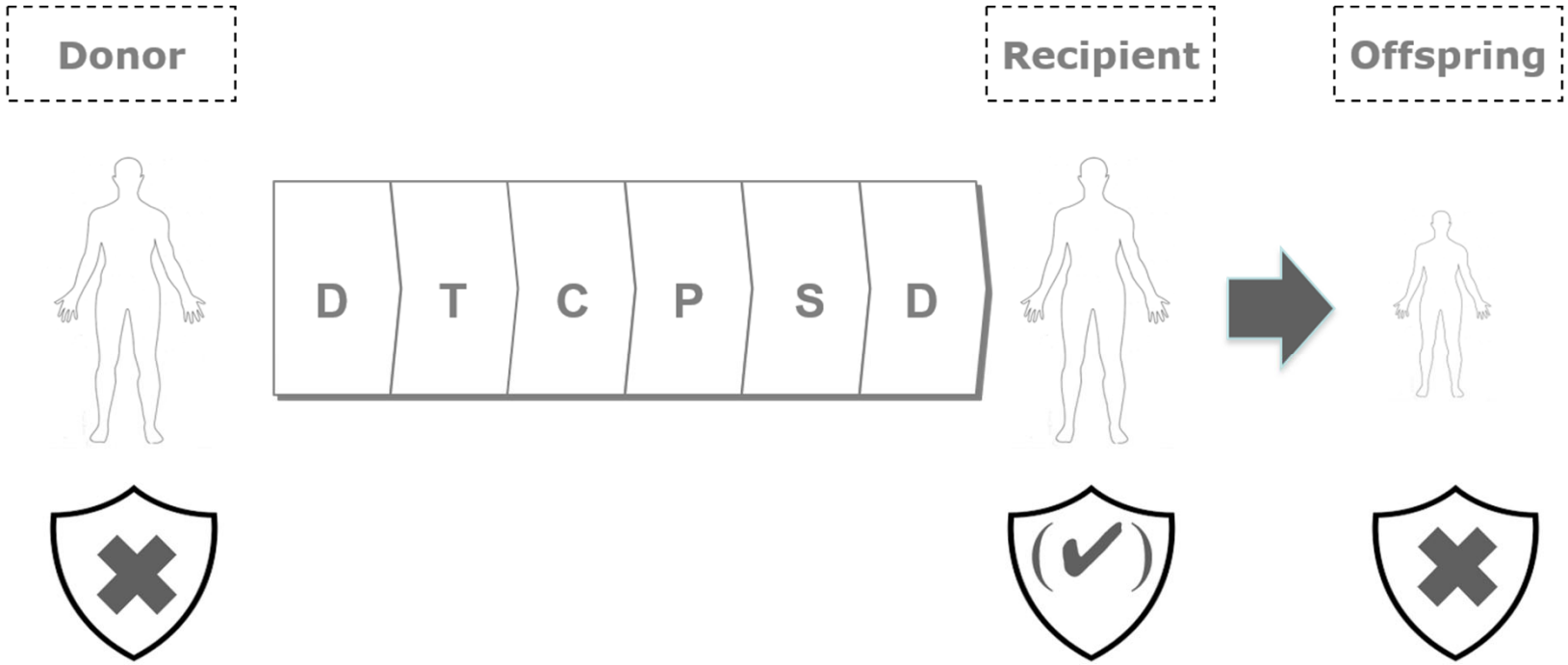


- Independence and effectiveness of inspections and vigilance – harmonisation - trust
- Capacity and skills of NCAs, particularly for novel therapy regulation

Cross-cutting themes emerging

European Commission

3. Incomplete protection citizens

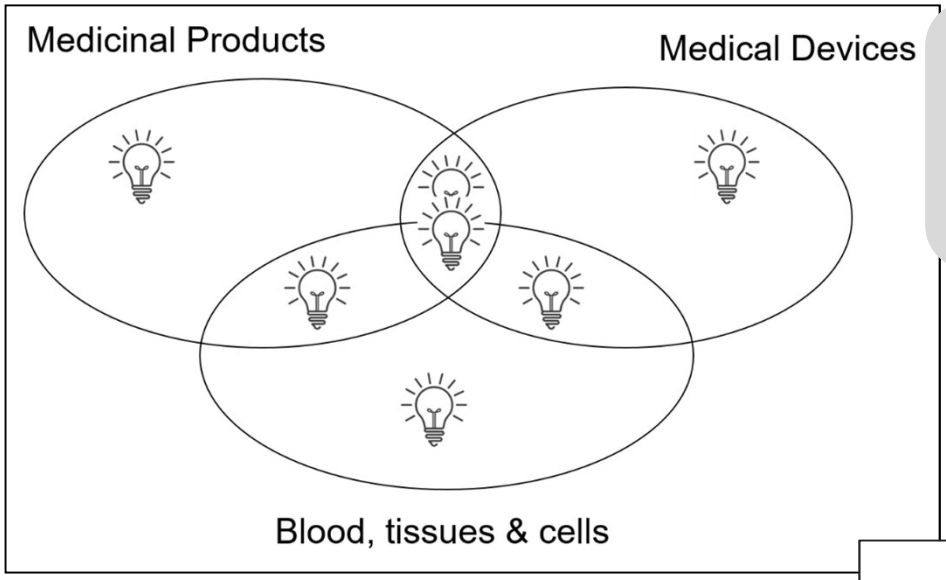


Many provisions to keep BTC and recipient safe, but

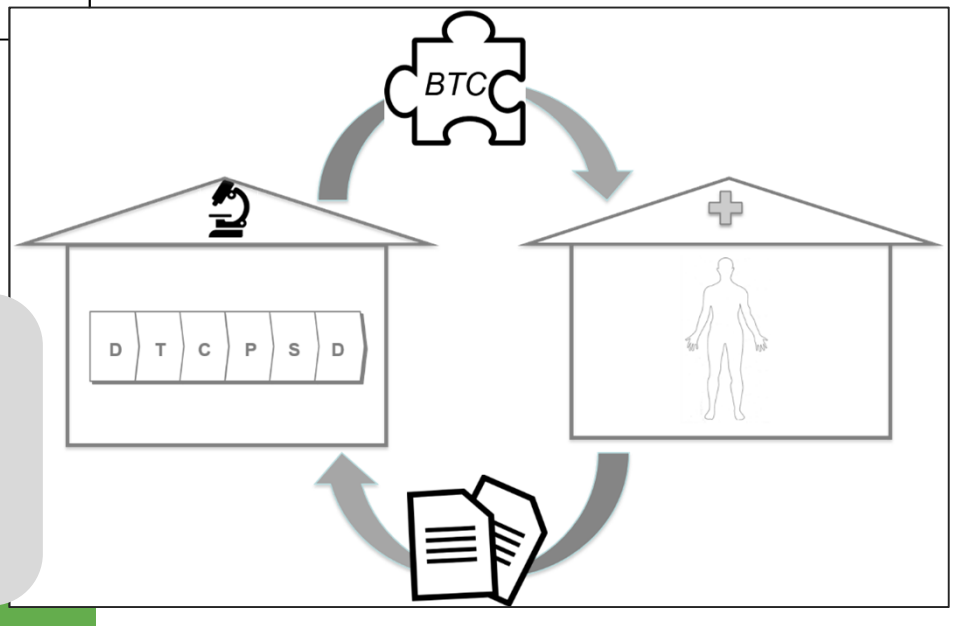
- Donors – increased demand, commercial interest, limited provisions for protection or follow up
- Children born from IVF – vigilance and outcome.

Cross-cutting themes emerging

4. Sub-optimal for innovation



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

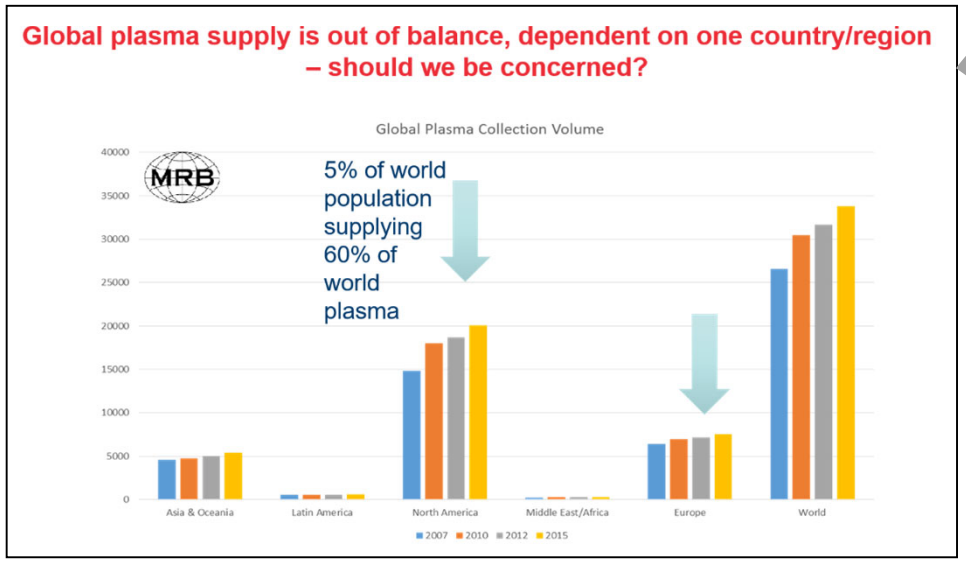


Innovations bring benefit (and risks) for patients ➔ requiring more clinical information (as part of autorisation)

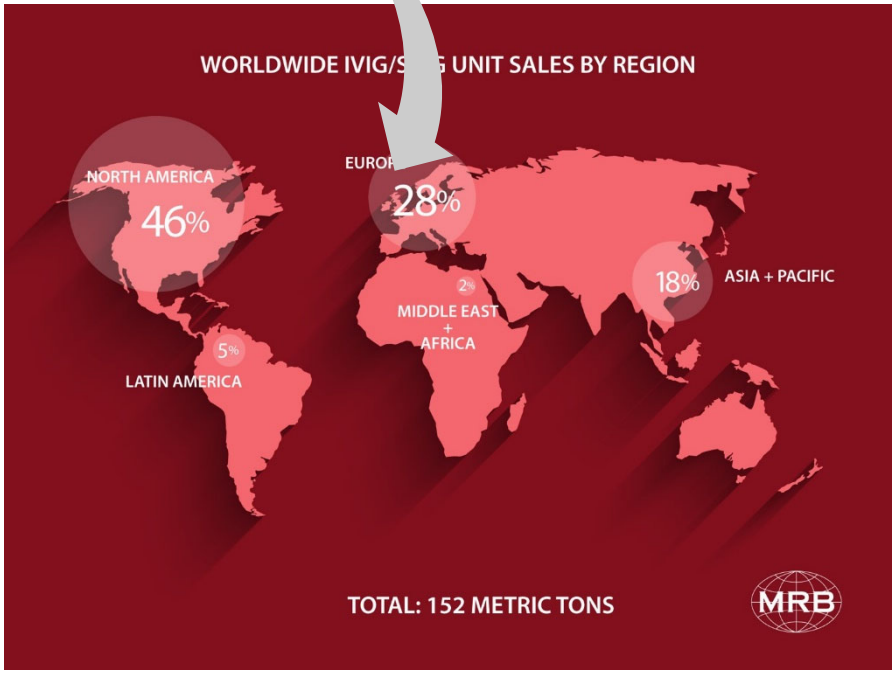
Cross-cutting themes emerging

European Commission

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
- No (good) requirements for activity reporting
- No measures for emergency preparedness

What's next …

- What are the best **tools** to address identified problems ?
  - Changing legislation
    Directive 2002/98/EC and 2004/23/EC
    Implementing Directives
  - Developing Guidance (soft law)
  - Policy Actions
  - Projects
  - (Or a combination of the above)

- **Impact Assessment:** which tools can most effectively address which problems ?
  - Drafting Inception Impact Assessment - Consultation

- Possible **Legal Proposal**

Considerations on plasma supply

European Commission

- **Holistic approach** needed:
  - European Commission, Council of Europe, Member States, National Competent Authorities, Blood (and plasma) establishments, Plasma Fractionators, Donors, Patients, Doctors/professionals

- **Elements** to consider ?
  - Monitoring/data on collection and use
  - Level of self-sufficiency: % and at national, EU or global level
  - Optimizing supply and demand
  - Awareness for all actors
  - Voluntary unpaid donation / compensation
  - Donor protection and follow-up
  - Need for technical or legal or policy actions
  - Guidance vs legislation

Donor Protection is a pre-requisite

TRANSPOSE aims at a structured, alternative approach to construct **risk-based Guidelines** and a **standard DHQ** for the procedures used to collect SoHO, including the selection and protection of donors.

The objective of this action is:

- To collect and compare EU and national donor selection and protection criteria;
- To identify the information needed from donors or their families to allow the application of appropriate donor deferral or exclusion criteria for the protection of recipients; and
- To propose approaches to control and minimise these risks.

WP Number	WP Title	Lead Beneficiary
WP1	Coordination of TRANSPOSE	Sanquin Blood Supply
WP2	Dissemination of the results of TRANSPOSE	Centro Nazionale Sangue
WP3	Evaluation of TRANSPOSE	Établissement Français du Sang
WP4	Inventory of Donor Selection & Protection Practices	University of Cambridge
WP5	Development of Donor Selection & Protection Guidelines	Region Hovedstaden Denmark
WP6	Development of a Standard Donor Health Questionnaire	University of Hamburg
WP7	Training Course/Workshop on the Use of the Guiding Principles	Sanquin & Centro Nazionale Sangue

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Collaboration Council of Europe – European Commission

- Technical guidance – complementing legislation
- Principles of voluntary unpaid donation, self-sufficiency
- Plasma symposium, Recommendations (holistic), Kreuth
- Coordination role
- …



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

Health