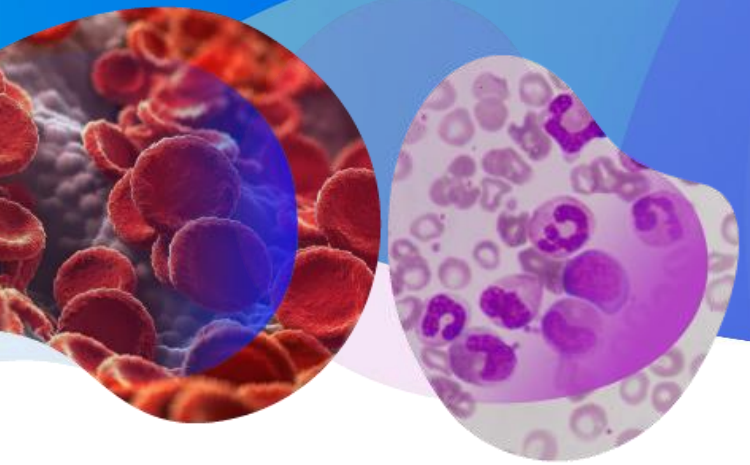
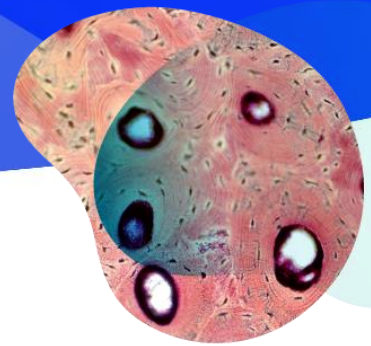
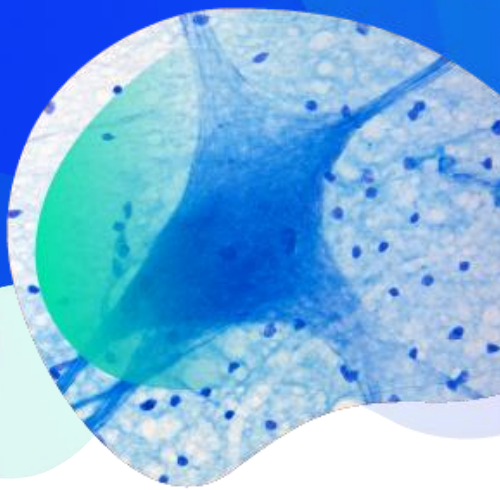
European Commission

EUROPEAN HEALTH UNION







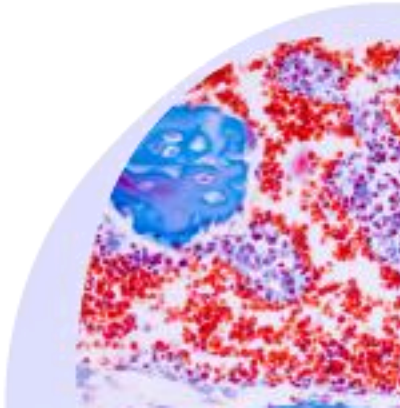
REGULATION ON
SUBSTANCES OF HUMAN ORIGIN

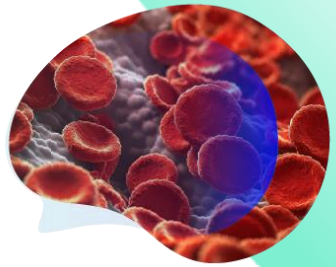
A comprehensive EU framework for safety and quality of SoHO

SoHO CONFERENCE

24 I 06 I 2024 - 10:00

Brussels



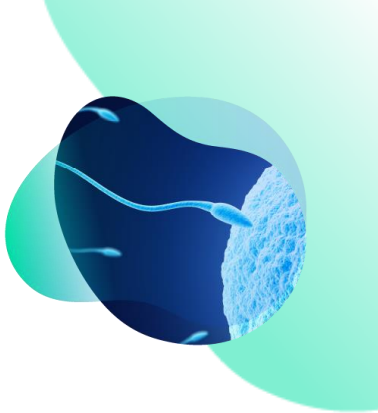


George Constantinou

Thalassemia International Federation

Impact statement

My concerns translated to ACTIONS
Does the SoHO Regulation address my concerns?



Speaking to you as a person who requires LIFELONG monthly (or even more often) red blood cells transfusions

Safety for me is CRUCIAL and means:

1. **Blood collected** through the **safest possible practices** i.e. voluntary non-remunerated blood donations.
2. **Well-screened** and **appropriately processed** RBCs – Every step quality assured and supervised by experts.
3. **Sufficient blood** to keep my haemoglobin level to those levels appropriate to support my bone marrow function and prevent medical complications associated with the pathology of thalassaemia.
4. **Existence of backup plans** for emergency crises that threaten adequacy and safety of blood and stability and resilience of healthcare systems.

A person with TDT, and other α-thal, β-thal & SCD cannot survive without lifelong, frequent red blood cell transfusions

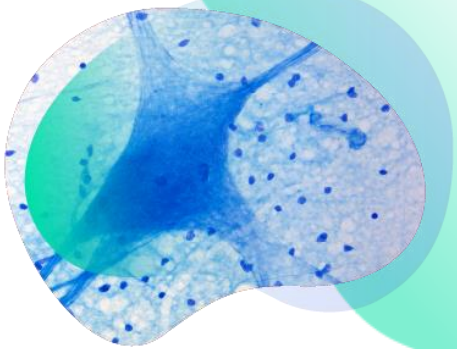
From the age of 6 months until now I have had to be transfused with **1126 units of blood which translates to two times a month**

I have to receive Piriton injections **due to the allergic reactions** I've experienced from the numerous blood transfusions I've undergone.

On occasions I had to **wait** for hours or days for **blood availability**.

I have been infected with HCV resulting in a Liver transplant operation.

SAFE & ADEQUATE BLOOD IS OUR LIFE COMPANION

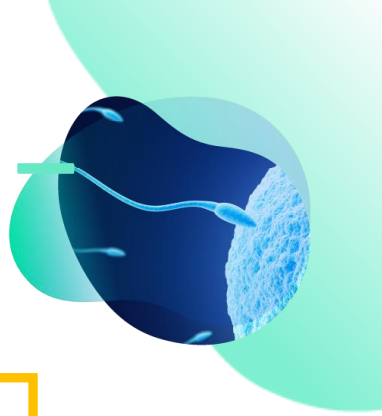


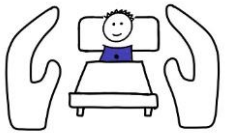
Deirdre Fehily

European Commission (Retired)

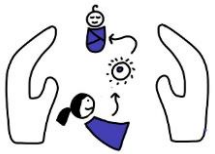
SoHO Team

Shortcomings from the 2019 evaluation –
Need for common, up-to-date technical rules





1. Patients are not fully protected from avoidable risks because some rules are out of date



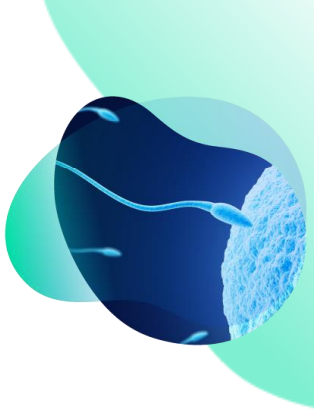
2. Legislation does not mitigate risks for BTC donors and for children born from donated eggs, sperm or embryos

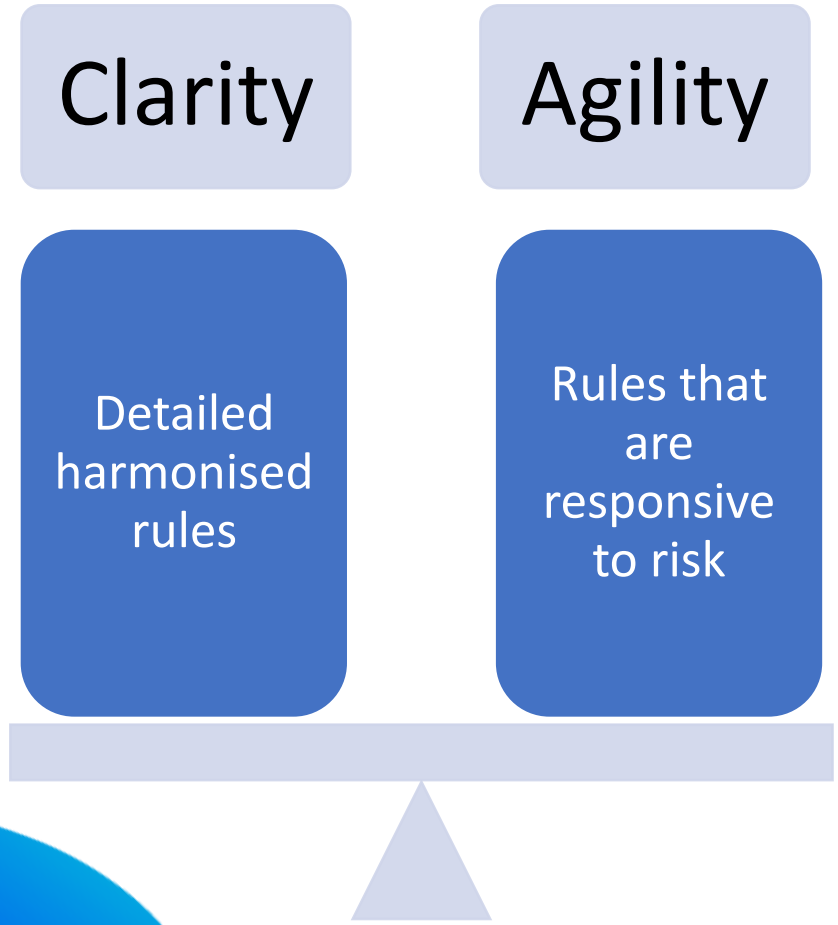
3. Member States have divergent approaches to oversight

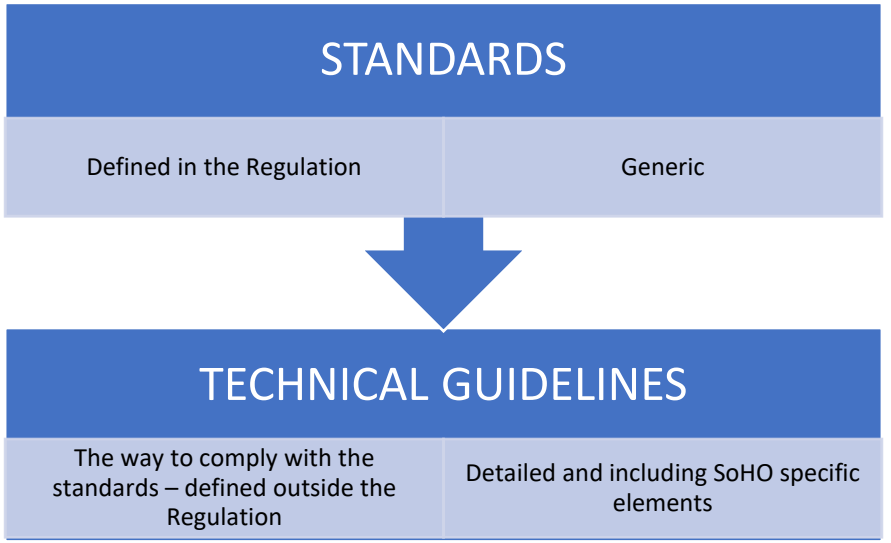
4. Full potential of innovative therapies is not reached for patients

5. Patients are vulnerable to interruptions in EU supply of some BTC

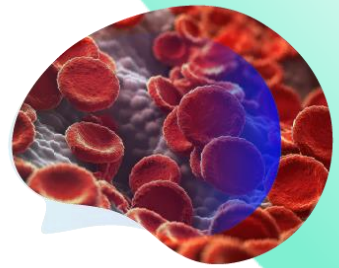
The challenge of setting technical rules

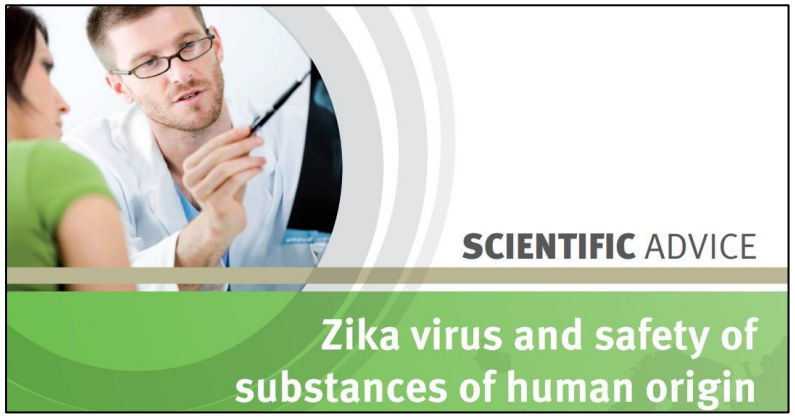


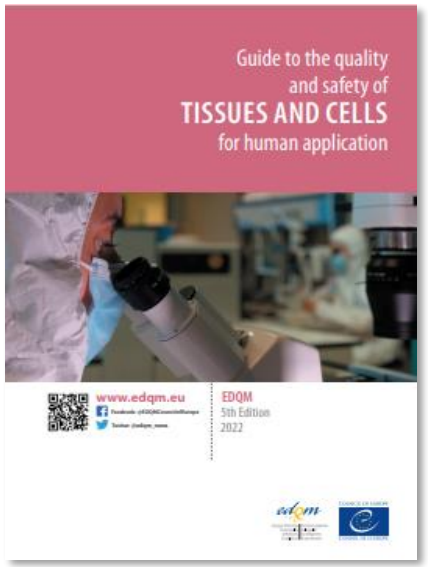


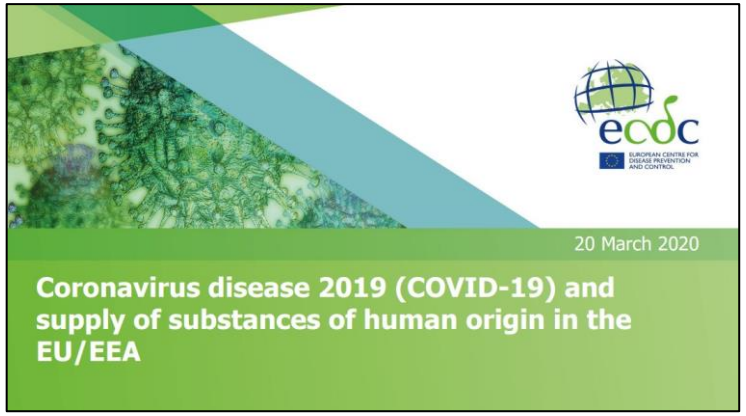


Respective scope of EDQM and ECDC guidance



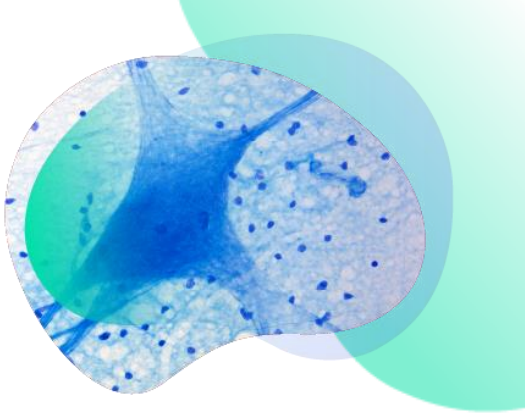




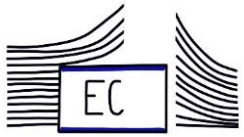


Implementation of generic standards through technical guidelines

Staying up-to-date with the science in an agile way



Commission Implementing Legislation → "where the Commission deems necessary"



If none:

Technical Guidance on the EU SoHO Platform → Published & updated by ECDC/EDQM

Inspectors shall deem the standards to be met

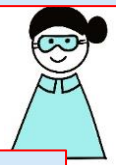
OR:

"Equivalent" Guidance → Demonstrated by MS to achieve the standards in the Regulation

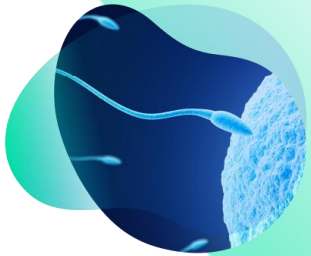
MS shall demonstrate compliance with standards – **may do so** by demonstrating equivalence to ECDC and EDQM

OR:

Other guidelines or methods based on international standards or scientific evidence



Entities shall demonstrate equivalence to inspectors – **may do so** by demonstrating equivalence to ECDC and EDQM



Marieke van der Werf

European Centre for Disease Prevention and Control (ECDC)

European Centre for Disease Prevention and Control

Prevention of communicable disease transmission through application of substances of human origin

Marieke J. van der Werf

24 June 2024, Brussels

EU regulations relevant for SoHO and ECDC

- Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a **European Centre for Disease Prevention and Control**
- Regulation (EU) 2022/2370 of the European Parliament and the Council of 23 November 2022 **amending Regulation** (EC) No 851/2004 establishing a **European Centre for Disease Prevention and Control**
- Regulation (EU) 2022/2371 of the European Parliament and the Council of 23 November 2022 amending Regulation (EC) of 23 November 2022 on **serious cross-border threats to health** and repealing Decision No 1082/2013/EU
- Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of **human organs** intended for transplantation
- Proposal for a Regulation on standards of quality and **safety for substances of human origin** intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

Framework for ECDC action on microbial safety of SoHO

Prevention of communicable disease transmission through application of substances of human origin

Coordinate SoHO network

Provide guidance on microbial safety

Threat detection, assessment, and response

SoHO regulation

Article 56 (4) and 59 (4)

For those standards concerning [SoHO donor protection or elements thereof]/[SoHO recipient and offspring protection] for which no implementing act has been adopted, SoHO entities shall take into account:

(a) the most recent technical guidelines, as indicated on the EU SoHO Platform, as follows:

(i) Published by the ECDC concerning the prevention of communicable disease transmission;

Source: Proposal for a Regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

Provide guidance on microbial safety

- Develop and update guidelines as referred to in the SoHO Regulation
  - Guideline development process according to ECDC procedures for developing guidelines
  - Collaboration with the European Directorate for the Quality of Medicines & HealthCare (EDQM) to ensure that technical guidelines published by EDQM and ECDC are aligned
- Develop guidance and recommendations on other topics relevant to the microbial safety of SoHO at the request of the SoHO network, the European Commission or on own initiative

ECDC guidelines – SoHO regulation

Pathogens

- Listed in blood and tissues and cells directives
  - ⟶ First batch: HIV, HBV, HCV, *Treponema pallidum*, West Nile Virus

- With current relevance (e.g., Dengue virus)
  - ⟶ Second batch: SoHO network consultation

SoHOs

As defined in the Regulation (i.e., not including organs)

Topics

- Testing strategies and laboratory testing methods
- Deferral strategies (including deferral periods)

ECDC guidelines development process

- Collection of **evidence** and development of **statements** regarding testing methods and strategies and deferral strategies
- Assessment of evidence and statements by **expert panel**
  - Structured meetings
  - Review of minutes
  - Aiming for consensus
- **ECDC to draft the guidelines** using evidence and advice of expert panel

Ad hoc scientific expert panel

- Panel established for each batch
- Call for interest to
  - ECDC networks: SoHO-Net and oth
  - National Competent Auth
  - Relevant professi
- Nominati
  - and experience (taking into account gender
  - of interest
  - approved by ECDC Advisory Forum
  - nomination by the ECDC Director

Assess evidence and advice ECDC

SoHO network

Network of Member State services supporting th… …bstances of human origin (SoHO-Net). Four sub-netw… …Focal Points and observers:

- Blood
- Tissues
- Organs
- Medically … …eproduction

Review

Stakeholders

- Stakeholders on list maintained by SANTE[1]
- European Directorate for the Qualit… …Care
- European Medicines Ag…
- World Healt…

[1] List of stakeholder organisations interested in participating in ad-hoc meetings with representatives of members of the Competent Authorities on Substances of Human Origin Expert Group

ECDC advisory forum

Advises the ECDC Director on the quality of the sci ork

Members:

- Senior repres stitutes and agencies
- Public healt an Commission
- Observers fr scientific associations and civil society groups
- WHO Europe

Review

ECDC guidelines development process – After review

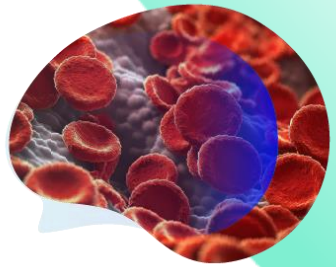
Revision of draft guidelines

ECDC internal review and clearance

Publication on ECDC website

Acknowledgements

- Flavia Cunha
- Francois-Xavier Lamy
- Jenny Mohseni Skoglund



Laurent Mallet

European Directorate for the Quality of Medicines and HealthCare (EDQM)

Ensuring the Quality and Safety of Substances of Human Origin Council of Europe/EDQM's role

Conference on the New Regulation on Substances of Human Origin

EUROPEAN COMMISSION

24 June 2024, Brussels

Laurent MALLET,
Head of Department
European Directorate for the Quality of Medicines and HealthCare (EDQM)

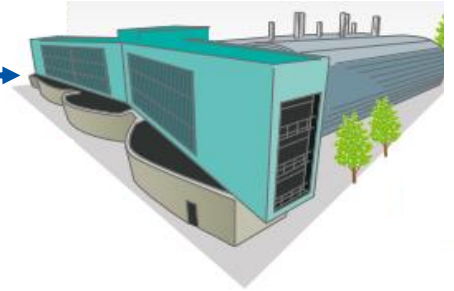
The EDQM, an entity within the Council of Europe

COUNCIL OF EUROPE

- Founded in **1949**
- **Intergovernmental** organisation, Strasbourg
- **46** Member States
- More than **700 Million** Citizens

COMMITTEE OF MINISTERS | PARLIAMENTARY ASSEMBLY | CONGRESS OF LOCAL AND REGIONAL AUTHORITIES | EUROPEAN COURT OF HUMAN RIGHTS | COMMISSIONER OF HUMAN RIGHTS | CONFERENCE OF INGOS

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



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

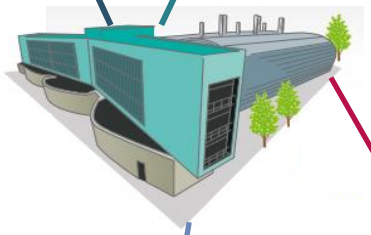
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

- Founded in 1964
- Work in the framework of a **Partial Agreement, 39 Members & the EU**
- Ensures the availability of and access to good and safe quality medicines, Substances of Human Origin (SoHO) and consumer health products

EDQM's areas of work

MEDICINAL PRODUCTS

- **Documentary standards** for manufacture and quality control of pharmaceuticals & **Reference Substances** (RS) ▶**European Pharmacopoeia**
- Granting **Certificates of Suitability** verifying compliance of pharmaceutical substances with European pharmacopoeia and GMP inspections of manufacturers of active substances ▶**Certification for Suitability**
- **Control of medicines:** pool expertise and effectively use limited resources *e.g. Market surveillance, proficiency testing, audits.* ▶**OMCL network**



CONSUMER HEALTH: Cosmetics & Food Contact Material

- Safety standards for cosmetics and food contact materials
- Control of cosmetics *e.g. Market surveillance, proficiency testing* ▶**OCCL network**

SUBSTANCES OF HUMAN ORIGIN

- Quality & safety standards ▶**Blood, Tissues & Cells and Organ guides**

▶ **B-PTS & B-QM programmes**

- Data collection ▶ **EU SARE, Newsletter Transplant, Blood report**
- Improving quality system & capacity building of Blood and Tissues & Cells Establishments *e.g. Proficiency testing, audits, trainings*

PHARMACEUTICAL CARE

- Policies & model approaches for the safe use of medicines
- Cooperation to combat falsification of medical products

EDQM and EU cooperation

COOPERATION MODALITIES

Regular **High level meetings** since 2018

High-level dialogue

Mutual representation

Representation in respective committees

~ 40 agreements signed since 1991

Technical cooperation (Joint programmes)

Regulatory/Legal cooperation

A number of EDQM standards and activities **referred into the EU legislation**

- **The EDQM, a regulatory and technical partner of the EU**
  - **60 years of collaboration in the field of medicinal products**
  - **15 years of collaboration in the field of SoHO**

Governance of SoHO activities

EDQM

Department of Biological Standardisation, OMCL Network & HealthCare
SoHO Division

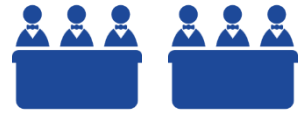
COMMITTEES

European Committee on Organ Transplantation (CD-P-TO)
European Committee on blood Transfusion (CD-P-TS)
39 Member States (MS) including the 27 EU MS, and observers

PRINCIPLES

Non-commercialisation of substances of human origin	Mutual assistance	Protection of donors & recipients

WORKING GROUPS



ACTIVITIES

1. Standard-setting: legal instruments, technical standards, policies

2. Monitoring data & practices Annual reports (blood and Transplant)

3. Capacity building supporting SoHO establishments in implementing CoE standards & EU legislation

Standard-setting on quality and safety

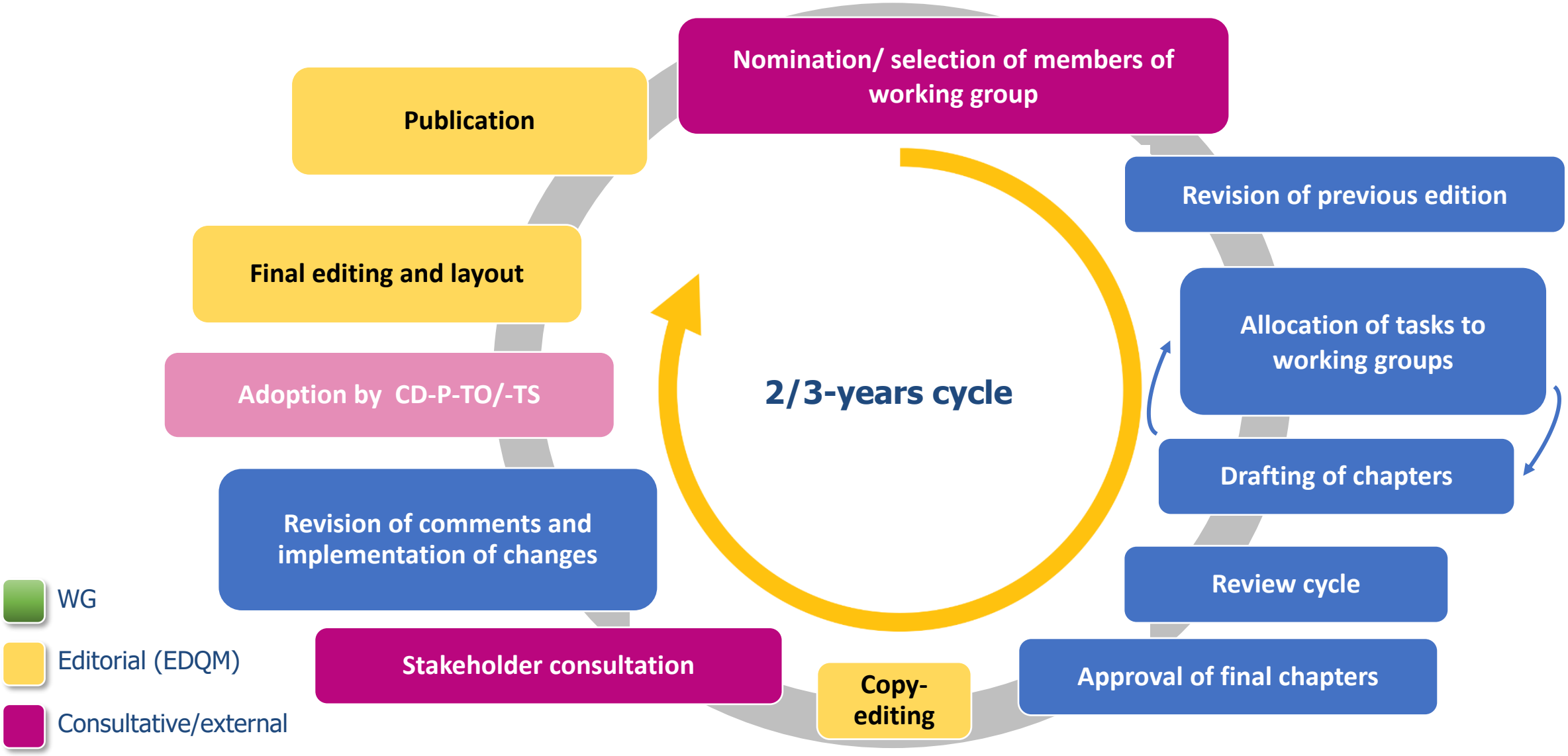
Funded by the European Union and the Council of Europe
EUROPEAN UNION
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE
Implemented by the Council of Europe

- Comprehensive guidelines **based on best available scientific evidence** to provide professionals with a useful overview of the most recent developments in the field.
- Ensure **high level of quality and safety.**
- Contribute to the **harmonisation of standards and practices** among European countries.
- **Continuous update** and maintenance.
- **Consensus documents** elaborated by working groups (under the aegis of the CD-P-TO, CD-P-TS) composed of experts nominated by Member States and observers (including professional associations).

▶ **INCREASED QUALITY AND SAFETY OF ORGANS, BLOOD, TISSUES & CELLS**

▶ **IMPROVED CLINICAL OUTCOMES**

Development/revision cycle process



Stakeholders' engagement throughout the cycle

Working group

- Working group composed of 40 experts nominated by member states and observers (including professional associations).
- Final composition of WG is decided by the Secretariat and the Chairs of the CD-P-TO or CD-P-TS and the chair of the previous edition of the Guide, taking into account:
  a) technical and scientific expertise in the required fields
  b) drafting needs
  c) active participation in the elaboration of previous editions of the Guide
  d) broad and balanced geographic representation
- Declaration of interest form (DoI) and confidentiality undertaking form.

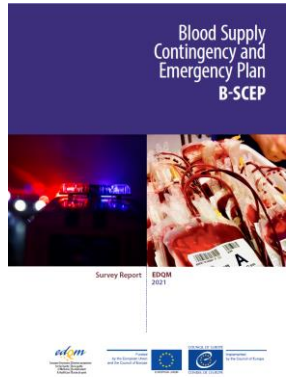
Stakeholder consultation

- Invitations sent to National Health Authorities (via CD-P-TO and CD-P-TS members, participants and observers, and the EC NCA mailing list); relevant scientific/professional associations; and others designated by any of the above.
- Consultation period: 6 weeks.
- Each comment is assessed and decisions on acceptance are justified.

Putting standards into practice

- **Monitoring data/practices**
  - Annual reports: Newsletter Transplant and Reports on the collection, testing, and use of blood and blood components in Europe;
  - Analysis of biovigilance data in the EU (Blood and Tissues & Cells) (SARE);
  - Harmonisation of data collection on T&C.

- **Capacity building activities**
  - Best practices:
    - Biovigilance best reporting practices (Blood and Tissues & Cells)
    - Optimal use of plasma and plasma-derived medicinal products (PDMP) and rare disease treatments
  - Quality management programmes



Funded by the European Union and the Council of Europe
EUROPEAN UNION
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE
Implemented by the Council of Europe

Putting standards into practice – Quality Management Programme

- **Trainings**

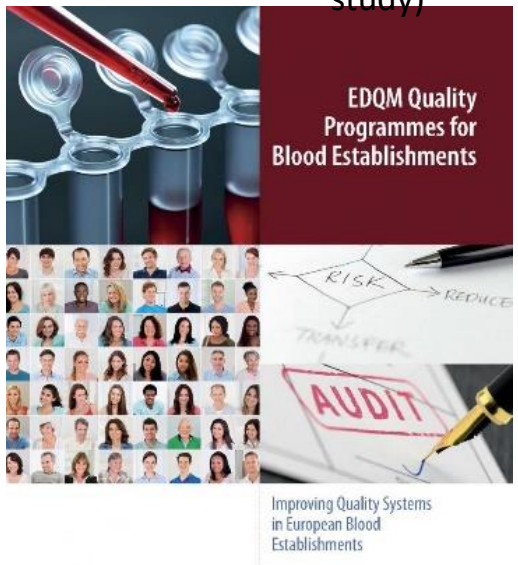
  Training courses and conferences on Quality Management

- **Audits**

- **Blood-Proficiency Testing Scheme (B-PTS)**

77 B-PTS studies conducted

71 Participating laboratories (on average, per study)



Nucleic Amplification Technique (NAT)

HBV, HCV, HIV

Serology

Anti-HCV
Anti-HIV/p24
Anti-*Treponema*
HBsAg/Anti-HBC

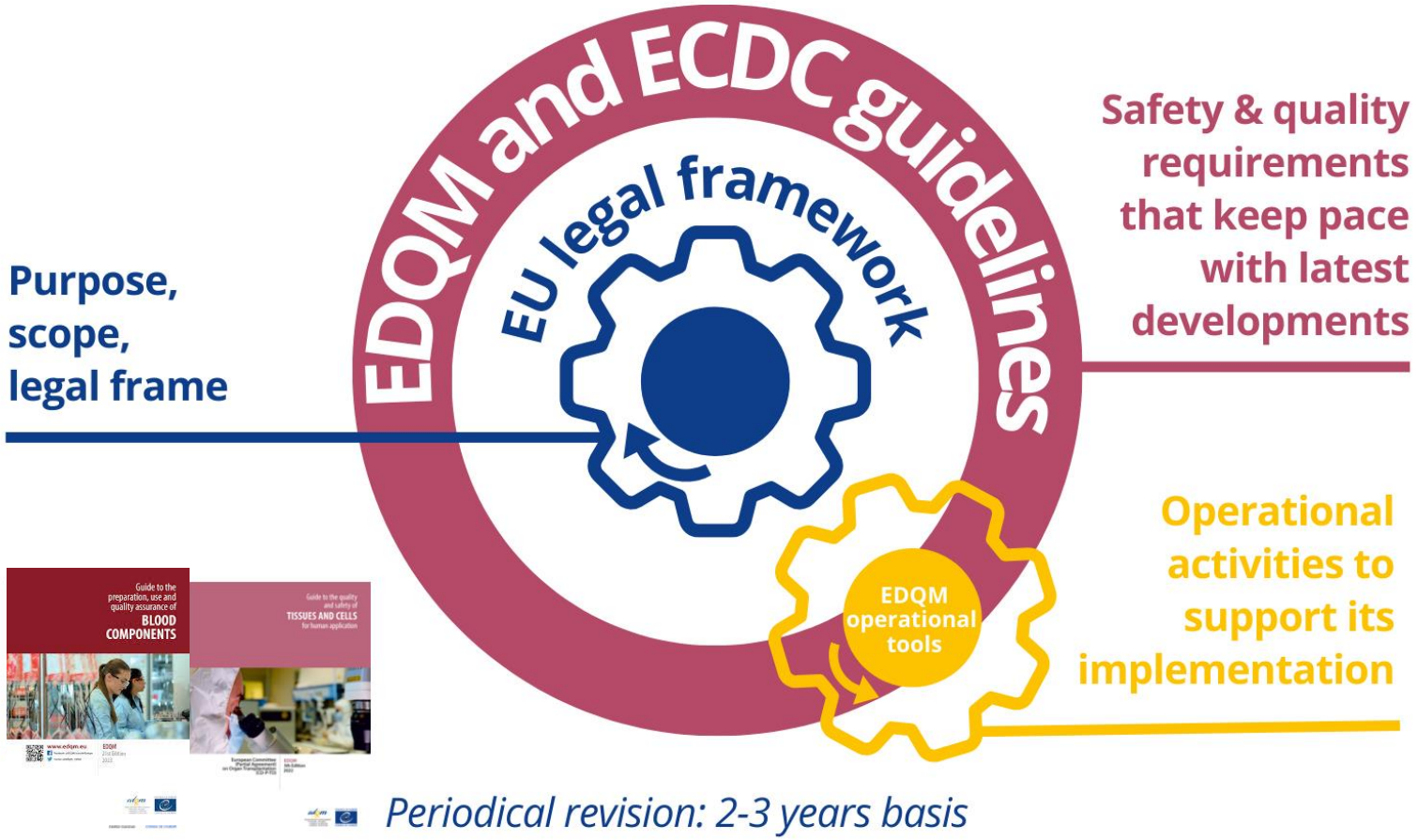
Immunohaematology

ABO, Rhesus, Kell, extended phenotyping and irregular antibodies

Bacterial testing

A regulatory framework that keeps pace with its environment

- Complementarity of EU legislation and CoE/EDQM standards
- Future-proof regulatory framework



A step further to have state-of-the-art standards and enhance dissemination

- Digitalisation of the guides and of the consultation process
- Re-inforcement of the scientific evidence-based approach

Achieve and maintain sustainable supplies of SoHOs

- Support the exchange and implementation of good practices
- Support the development of an action plan

Data collection and reporting by entities/ establishments

- Provide guidelines and data sets

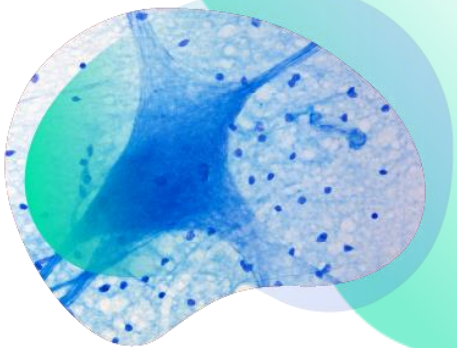
Quality Management programme extension

- Extension of audits to tissue establishments
- PTS studies for laboratories testing blood samples from living organ, tissue and cells donors
- Evaluate feasibility of conducting validation studies on post-mortem blood testing

Thank you for your attention

Stay connected with the EDQM

EDQM Newsletter: **https://go.edqm.eu/Newsletter**
LinkedIn: **https://www.linkedin.com/company/edqm/**
X: **@edqm_news**
Facebook: **@EDQMCouncilofEurope**

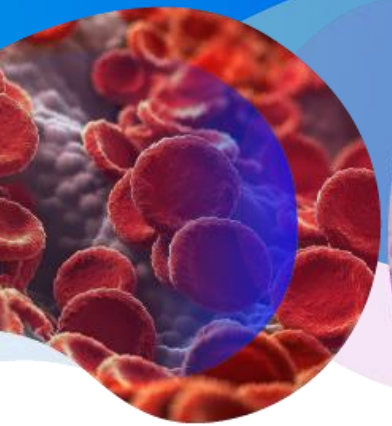
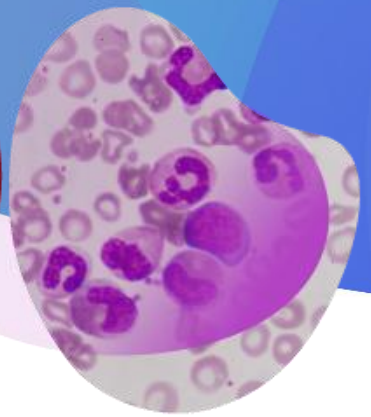
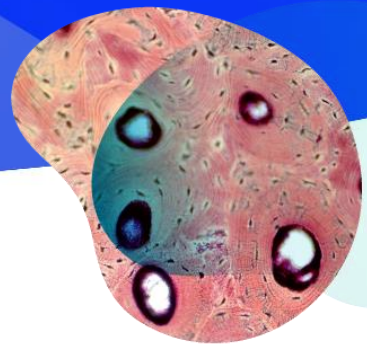
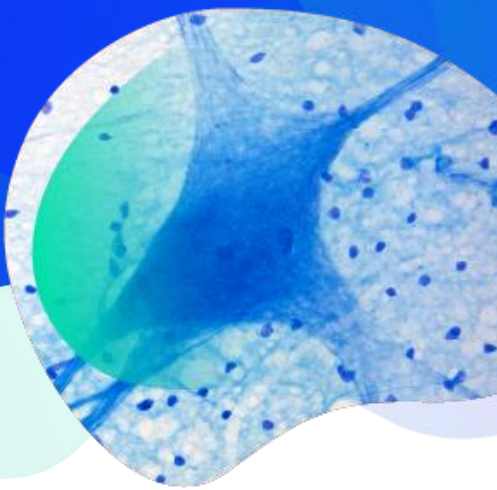


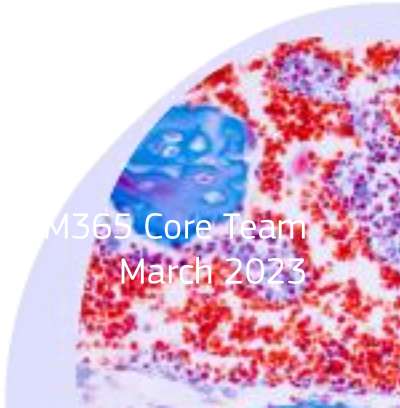
Nick van Gelder

Belgian Federal Agency for Medicines
and Health Products (FAMHP)

European Commission

EUROPEAN HEALTH UNION

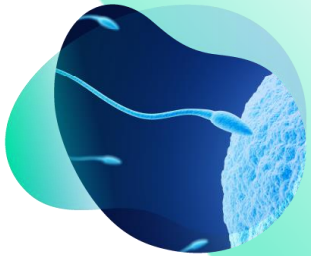







Ensuring compliance with the Safety and quality standards in SoHO entities – the role of the competent authorities

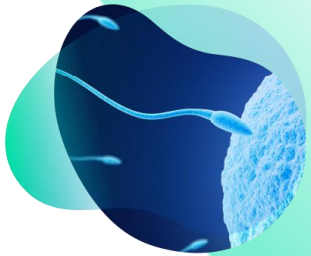
M365 Core Team
March 2023

Overview



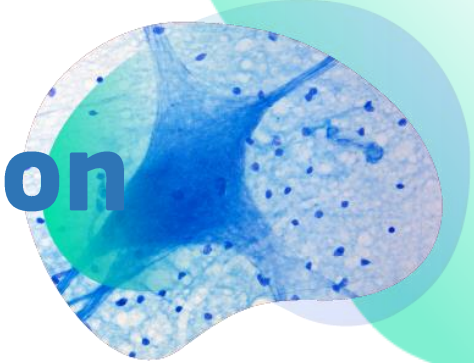
- SoHO Competent authority – role and national legislation
- Supervisory activities
  - Registration
  - Authorisation
  - Inspection
- Safety and Quality Standards
  - EDQM/ECDC
  - National Standards
  - Specific standards
- Cooperation

Soho National / Competent Authority



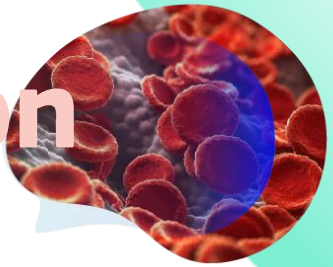
- Important role – national level
- Practical considerations – national legislation
  - Sufficiently empowered to perform supervisory activities
  - Have sufficient resources, (experienced) personel, etc.
  - Independence and impartiality
    - Political and stakeholders
    - DoI
- One or multiple Competent Authorities
  - One SoHO National Authority

Supervisory activities – Registration



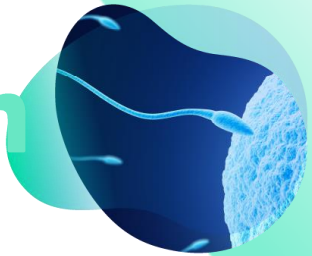
- (National registry)
- SoHO Platform
- Validation/check by SoHO CA
- Essential – allows Member States to identify entities
- If necessary – guide towards authorisation

Supervisory activities – Authorisation



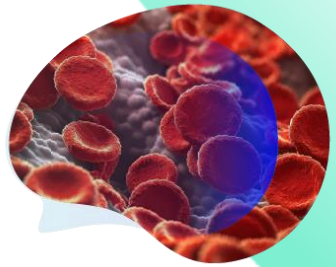
- SoHO Preparation
  - Quality, safety, efficacy
  - Based on available data
    - Risk or insufficient data? Clinical outcome monitoring plan.
  - Document based review
    - Inspection “on site” (or virtual) possible

Supervisory activities – authorisation



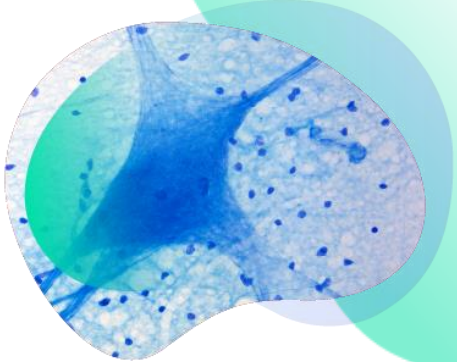
- SoHO Establishment
  - See def.
  - Standard: on site, exception: virtual or document based
    - 1 on-site inspection every four years
    - Only if all conditions are fulfilled (*see infra)*
- SoHO Establishment – Import
  - See supra
  - Possibility of inspection at third party providers

Supervisory activities – Inspections



- Triggers:
  - Announced routine
  - Announced or unannounced – possible non-compliance
  - Announced or unannounced – specific activity or topic
  - Follow-up inspections (corrective and preventive actions)
- On-site, exception: virtual or remote document review
  - No risk to quality and safety of SOHO;
  - Does not prejudice effectiveness of inspections;
  - Protection of donors/recipients/offspring is respected
  - Max interval between two on-site inspections = 4 years

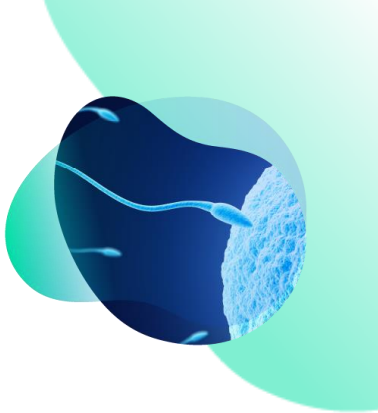
Quality and safety standards



Chapters **VI and VII**

- ECDC/EDQM
- National standards
  - Adopted at Member State level
  - Before the inspection
  - Equivalent to ECDC/EDQM
- Specific standards
  - Burden of proof = entity
  - Equivalent safety/quality to ECDC/EDQM

Panel members



Carlos Calhaz-Jorge European Society for Human Reproduction and Embryology (ESHRE)

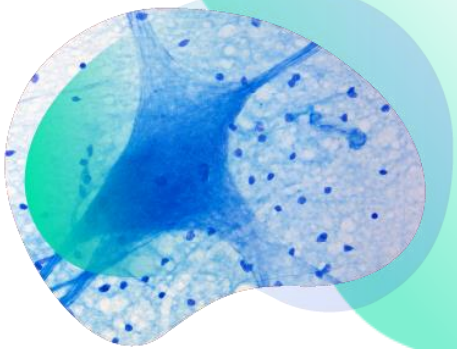
Françoise Rossi International Plasma and Fractionation Association (IPFA)

Marilena Vrana Plasma Protein Therapeutics Association (PPTA)

Sertac Arslanoglu European Milk Banks Association (EMBA)

Christian Lodberg Hvas EurFMT

Martin Börgel Common Representation of SoHO Associations (CoReSoHO)



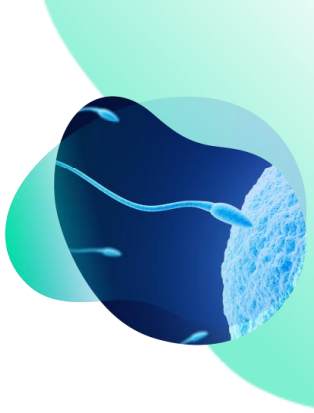
Klaudija Kordic

Fertility Europe

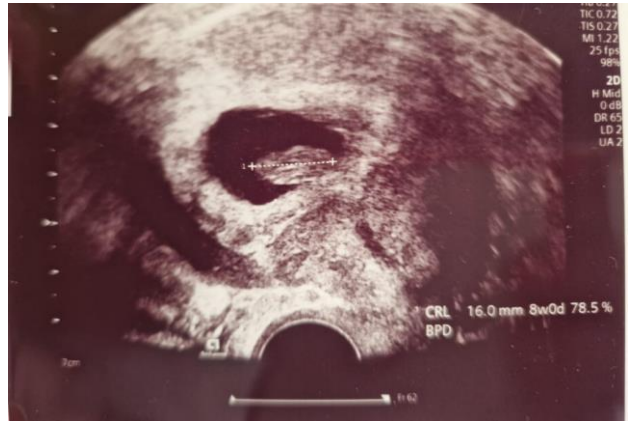
Impact statement

SoHO CONFERENCE • 24 I 06 I 2024 Brussels

The new SoHO regulation in the field of medically assisted reproduction

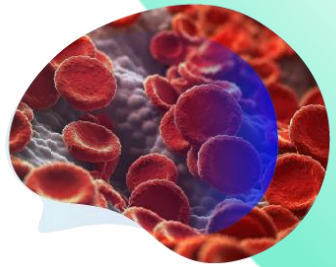


- Prioritizes transparency and **safety for donors, recipients**, and **offspring**
- Respects rights and principles of the Charter of Fundamental Rights of the EU (**rights of the child, integrity of the person, human dignity**...)
- Ensures consent for donation is **freely given** and **informed**.
- Bases donor eligibility criteria on scientific evidence.
- **Prohibits commercial promotion** and misleading information.
- **Guarantees equitable access** to SoHO based on medical needs.



European Fertility Week 2024 – 04-10 Nov 2024

GAMETE DONATION – towards best practice

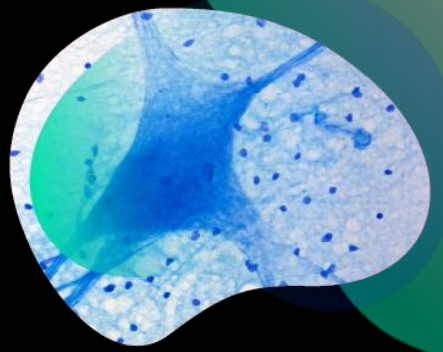


Christian Lodberg Hvas

EurFMT

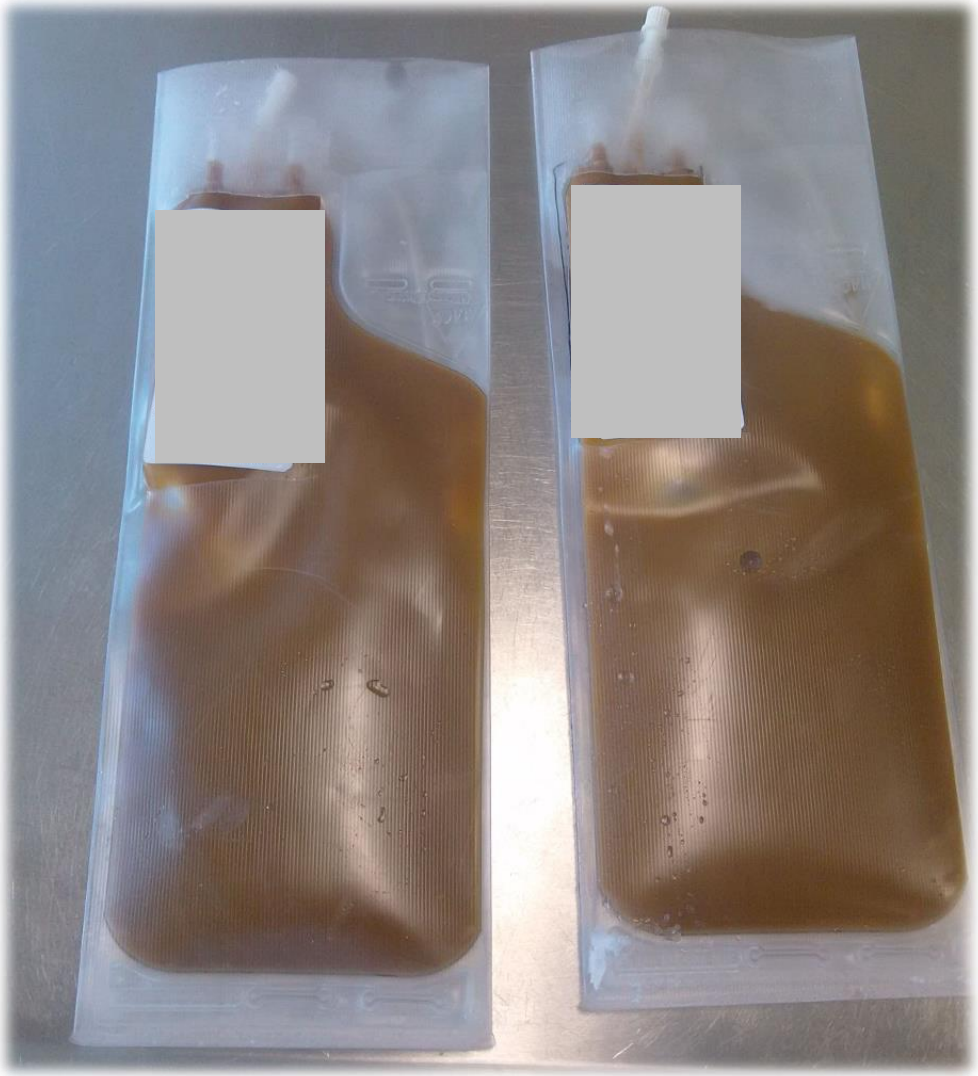
Impact statement

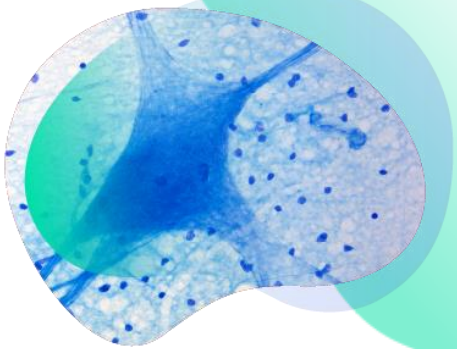
Intestinal microbiota

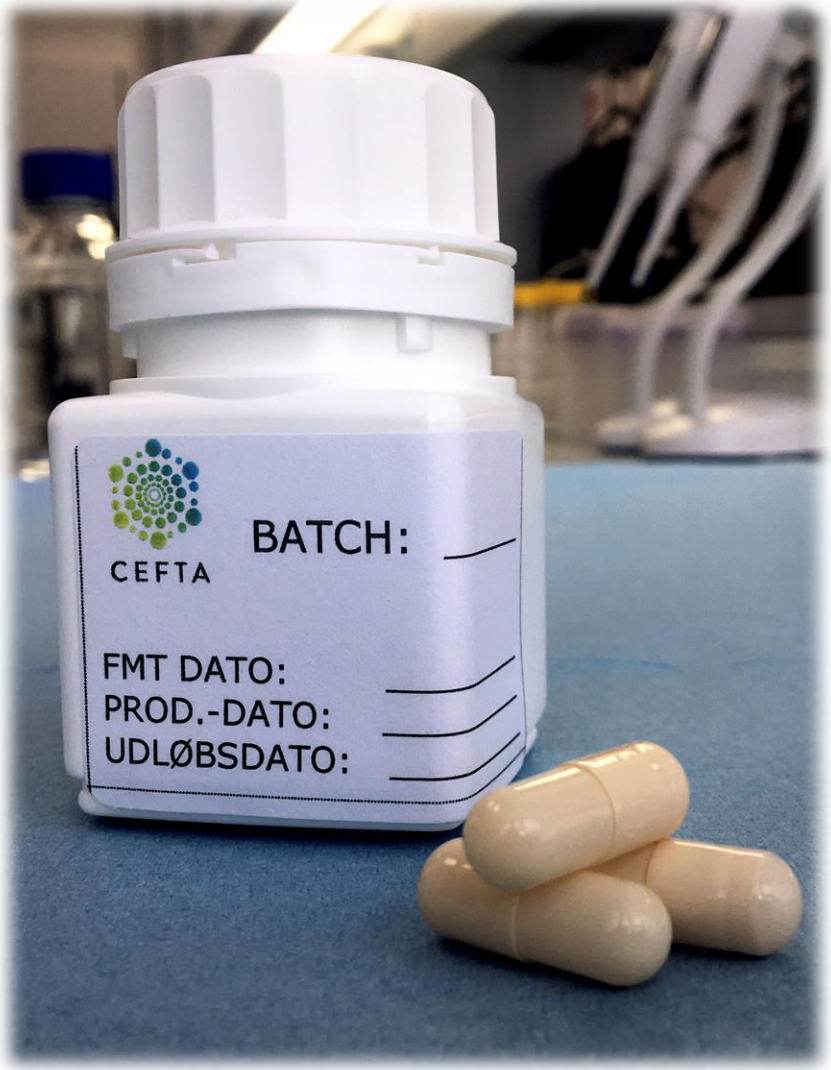


FMT

SoHO CONFERENCE • 24 I 06 I 2024 Brussels

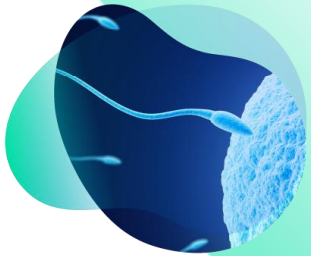






European Commission

SoHO CONFERENCE • 24 I 06 I 2024 Brussels



Esteve Trias

European Leitat Foundation

THE FUTURE OF SoHO INNOVATION
Opportunities & Challenges

June 24th, 2024

Dr. Esteve Trias
Executive Medical Director of LEITAT Technological Centre, Barcelona, Spain &
Technical Director of the Advanced Therapies Unit of Hospital Clinic Barcelona, Spain

What is innovation?

- *Transfer an idea (research) into a product (innovation).*

- *A systematic practice of developing breakthrough products and services for **adoption** by customers.*

- *The development of a **new** process, policy, product or program that **increase quality, impact and efficiency**.*

- *'New or improved' health policies, practices, systems, products and technologies, services, and delivery methods that **result in improved (value) healthcare**.*

IN THE ERA OF PERSONALISED MEDICINE…

Innovation: Multi-faceted Symbiosis

PEOPLE

Educate, Enable & Empower

- *Individuals*
- *Employers*
- *Comunities*

PROCESS

Introduce, measure, improve & Repeat

- *Innovation in org's production or service operations – to produce a product or to render a service*

PRODUCT

Invent and Disrupt at Scale

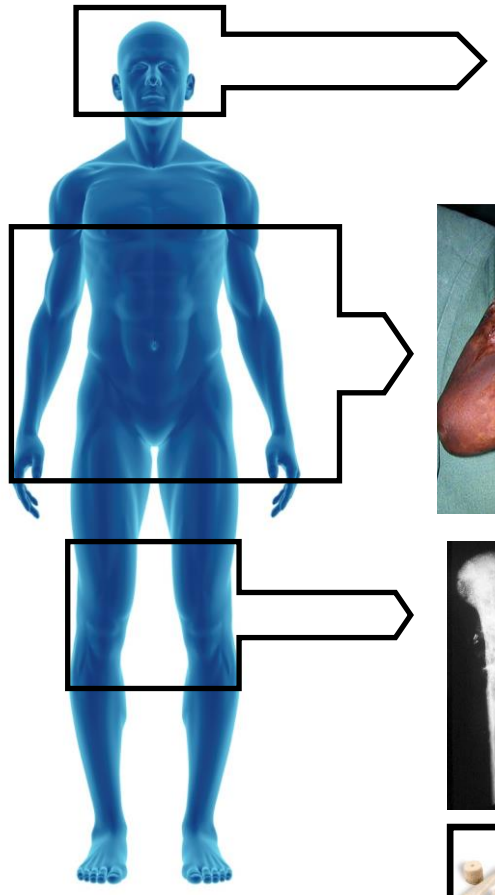
- *Goods, products or services offered to customers or clients – introduced to address user or market needs.*

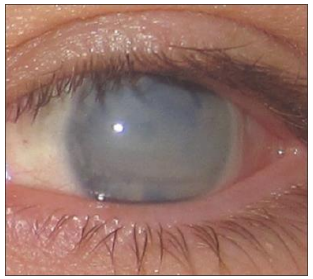
POLICY

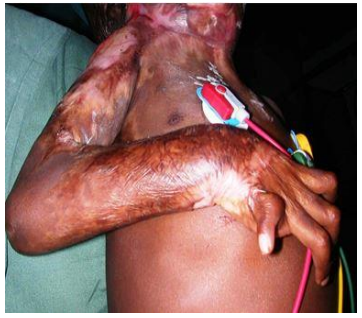
Law, Policy, Partnerships

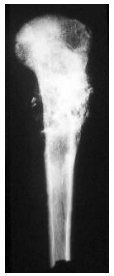
- *Regulatory Industry*
- *Public-Private Collaboration*
- *Costs of Policy & value of innovation*

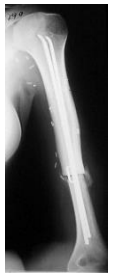
The Future of SoHO Innovation

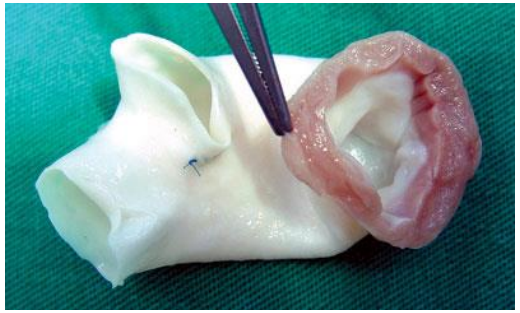


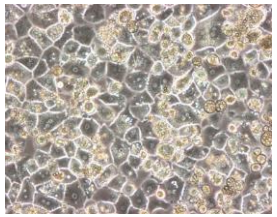












WHAT IS THE FUTURE OF SoHO INNOVATION?

Bridging the innovation-regulation gap:

A regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions following risk-based approach that facilitate the development and authorization of **innovative therapeutic solutions based on SoHO.**

- ***On one hand, developers need regulatory certainty on the path to follow to secure authorization.***

- ***On the other hand, Regulators need to calibrate what's right in terms of regulatory oversight of emerging, novel clinical products.***

The challenge of Innovation in SoHO

The Challenge of Innovation

Innovation in SoHO is a big challenge and it is clear there is a need to manage Quality, Safety and Efficacy demonstration as well as management of the associated risks.

BTC sector has all the **tools** to achieve and guarantee that (GTP I, EDQM Guides, GTP II, GAPP)

In essence, the academic-public sector is the main source of clinical needs identification as well as the initial place where the product is developed.

The Challenges….

- Affording Innovation in the public sector, generating value & protecting donation models
- Professionals and Regulators to jointly work for Quality, Safety guarantees and Efficacy demonstration under the basis of a Risk Based Approach
- HTA instruments to show the value & long-term impact on the EU Health Systems
- Network at EU level – Collaboration beyond states borders.
- Create and Open Exchange of Knowledge and Intellectual Property-IP – Knowledge Platforms.
- Solidarity and Altruism for patient benefit.
- Global patient access to Donate and to receive a consolidated or innovative therapy based on SoHO
- Matching the needs with society involvement and commitment: professional management, efficacy and evidence evaluation (HTA)

<u>Trust & Equity as a consequence</u>

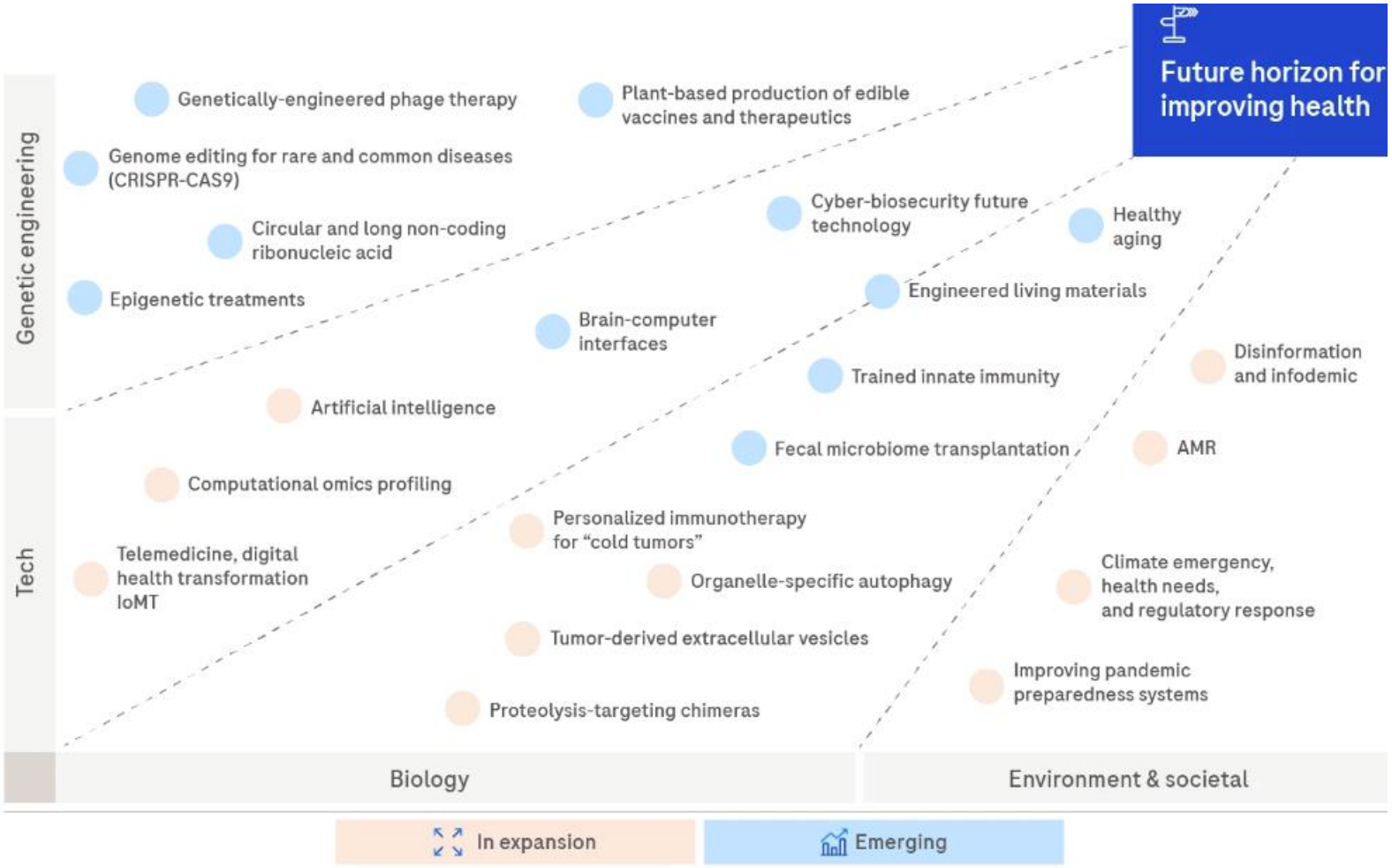
The Opportunities…..

- A new regulation to provide **strength to the high degree of innovation** in the SoHO field
- Involving European Experts and Professional Bodies in all valuable innovation pathway: identifying the needs and the opportunities for development
- EU Investment in Health Data Infrastructures eg Registries to support the professional and regulatory sectors
- Complementarity with private sector aligned with global and common objectives and principles:
  - (1) Investment on Non Profitable Regions – Global Access
  - (2) Non Profitable age groups – Paediatric Patients
  - (3) Non Profitable Diseases – Prevalence
- Constructive and Collaborative network with SoHO and other regulatory frameworks like ATMP and M Devices
- Reinforcing Donation Programmes - Access is not only cost, but also availability
- Focus on the Outcomes / Efficacy – Efficiency – Risk benefit
- Better tools to take decisions – Better training and professional opportunities

<u>Patient Centricity – Social Value</u>

WHAT IS THE FUTURE OF SoHO INNOVATION?

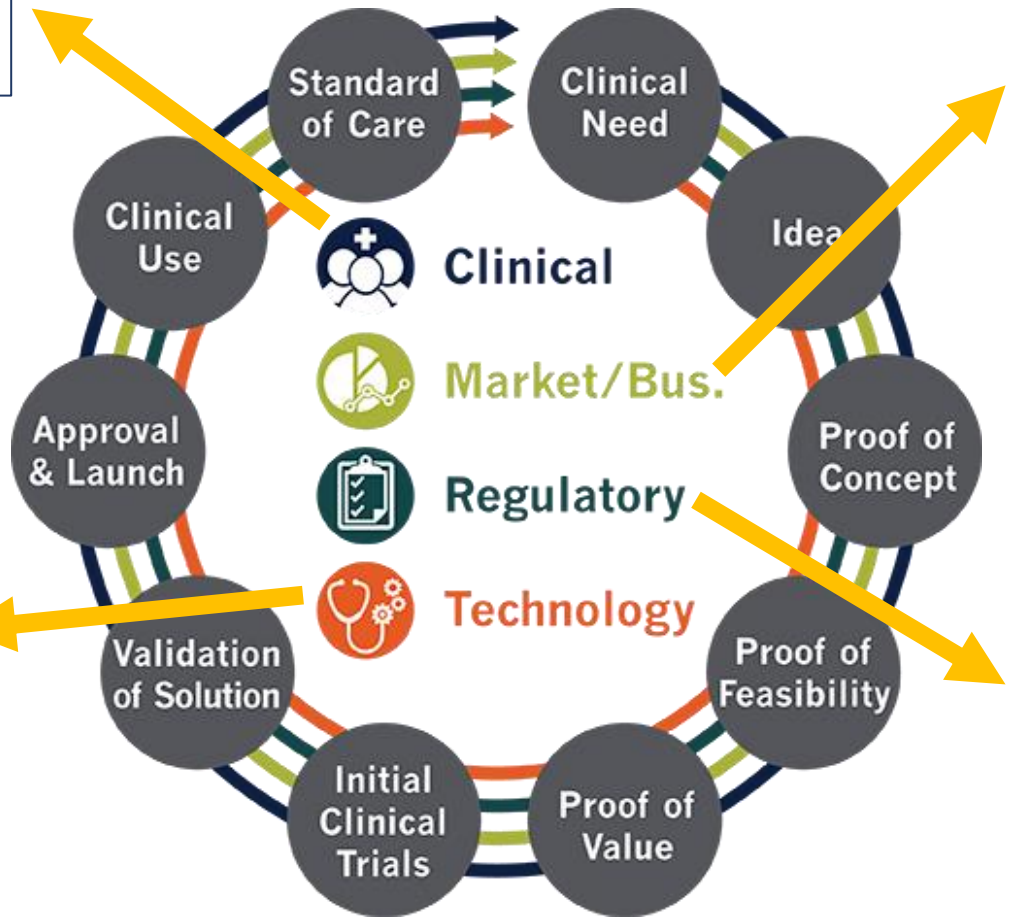
The most experimental therapeutic solutions, the principles of **quality, safety, and efficacy**, as well as of benefit- risk assessments, continue to guide **regulatory decisions.**



Health horizons: Frontiers in Medicine journal, December 2022.

Healthcare innovation cycle

✓ **Clinical and value based health oriented level:**
Data, patient and professionals.

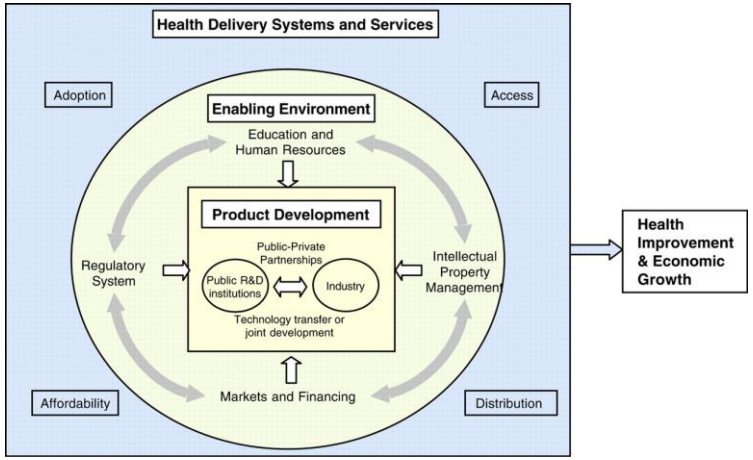


✓ **Economic level:**
Advanced HTA, reinvestment…

✓ **Technical level:**
New **platforms** to accelerate services or cycle.
Examples: Decellularization, Cryopreservation….
mRNA, CAR-T, …

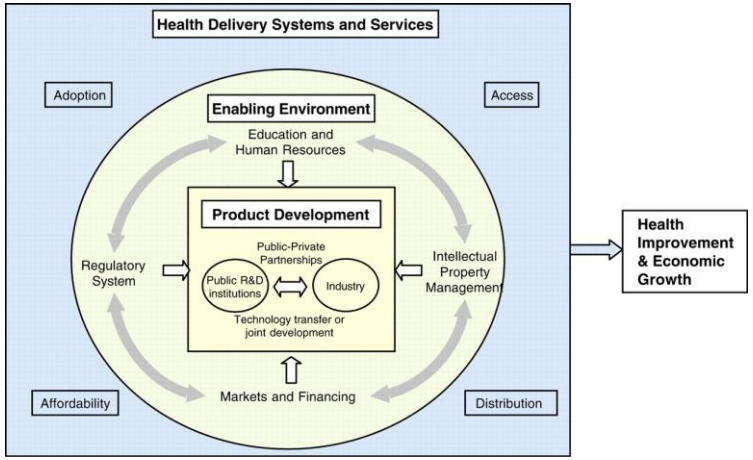
✓ **Regulation level:**
Risk based approach, efficacy demostration – Existing tools - GAP

CONCLUSIONS I



- **High degree of Innovation in the SoHO field** and the need of a framework for overseeing that innovation, from safety to efficacy & clinical evidence
- Innovation with SoHO can change the regulatory status, becoming an ATMP or a MDs and there is a need for **clarification on the regulatory borderlines**
- **SoHO Coordination Board** plus the ***Joint Committee*** with other regulatory frameworks - **cross sector discussion & collaboration**

CONCLUSIONS II



- We should change some **pre-existing Paradigms** to place Translation Research on the patient bed side - **Innovation**
- R&D+i **Open Platforms** to accelerate developments and regulatory approvals
- Access to technology and **know-how** is one of the greatest challenges of health organizations – **IP**
- Collaboration between SoHO players to build an effective **Network** for Thinking Innovative
- **Transparency** on costs, including the concepts of funds origin as well as "reasonable profit"
- Fostering collaboration, including **public-private cooperation**
- **HTA**, cost/value analysis as a systematic approach for planification and management in the way for **Adoption**
- **Data** access as a global key element
- **Patient Access** must always be the **priority**

NEW SCENARIO, NEW OPPORTUNITIES

Dr. Esteve Trias

etrias@leitat.org

etrias@clinic.cat

LEITAT
managing technologies

LEITAT
Acondicionamiento Tarrasense
Tel. +34 93 788 23 00
www.leitat.org
info@leitat.org

@Leitat | @AgendaLeitat

@leitat-technological-center | @Projects Blog Leitat

Terrassa
C/ de la Innovació, 2
08225 Terrassa (Barcelona)

Vilanova del Camí
Centre d'Innovació Anoia
C/ dels Impressors, 12
08788 Vilanova del Camí (Barcelona)

Valencia
Biopolo La Fe
Hospital La Fe, Torre A, Planta Baja
Avda. Fernando Abril Martorell, 106
46026 Valencia

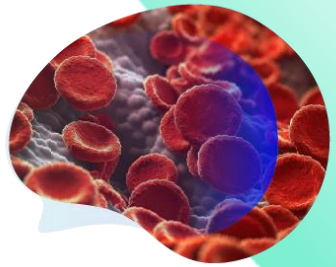
Barcelona
22@
C/ de Pallars, 179 – 185
08005 Barcelona

R6
C/ Rivadeneyra, 6
08002 Barcelona

DFactory
C/ 27, 10-16
Sector BZ Zona Franca
08040 Barcelona

Parc Científic
C/ de Baldiri Reixach, 15
08028 Barcelona

Vall d'Hebron Institut de Recerca
Edificio Mediterránea. Hospital Vall d'Hebron
Passeig de la Vall d'Hebron, 119 – 129
08035 Barcelona

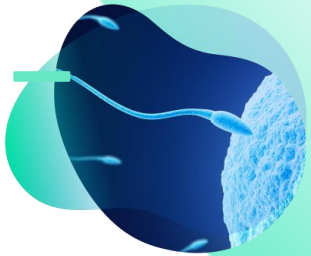


Stefaan van der Spiegel

European Commission

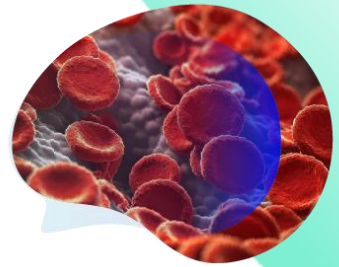
SoHO Team

Shortcomings from the 2019 evaluation –
Need for legal clarity and an innovation pathway



	1. Patients are not fully protected from avoidable risks because some rules are out of date
	2. Legislation does not mitigate risks for BTC donors and for children born from donated eggs, sperm or embryos
	3. Member States have divergent approaches to oversight
	4. Full potential of innovative therapies is not reached for patients
	5. Patients are vulnerable to interruptions in EU supply of some BTC

Scope of the SoHO Regulation



DONATION / COLLECTION

PROCESSING / APPLICATION

SoHO – transfusion, transplantation, assisted reproduction

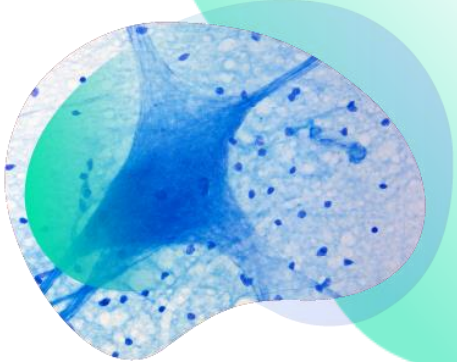
+ Breast milk and FMT

Medical devices

Medicinal products

Borderline criteria are not set in this Regulation, but in other frameworks – FUTURE PROOFING

SoHO Coordination Board will provide legal clarity



Documentation of
- **best practices** for supervision, compensation, …
- **Indicative criteria** for critical SoHO (entities)

Support for **joint oversight activities** (inspections, assessments)

Support **coordination during emergencies**

Support COMM to develop the **SoHO Platform**

SCB

Members:
2 per Member State

Observers:
Union bodies/institutions/agencies & other invitees

Co-chairs: Commission and MS

Secretariat: Commission

Advice on **whether the SoHO Regulation applies**

- **Consult** Advisory bodies in other legislative frameworks

Compendium on regulatory status, with record of:
- SCB advice (EU)
- National decisions

Own initiative list of substances/ products where an opinion is needed

Exchanges on good practices with Expert bodies – ECDC, EDQM, EMA

Building coherent views across SoHO and pharma frameworks (COM proposal)

3. If needed, COM decisions

d. Request/give COM decision

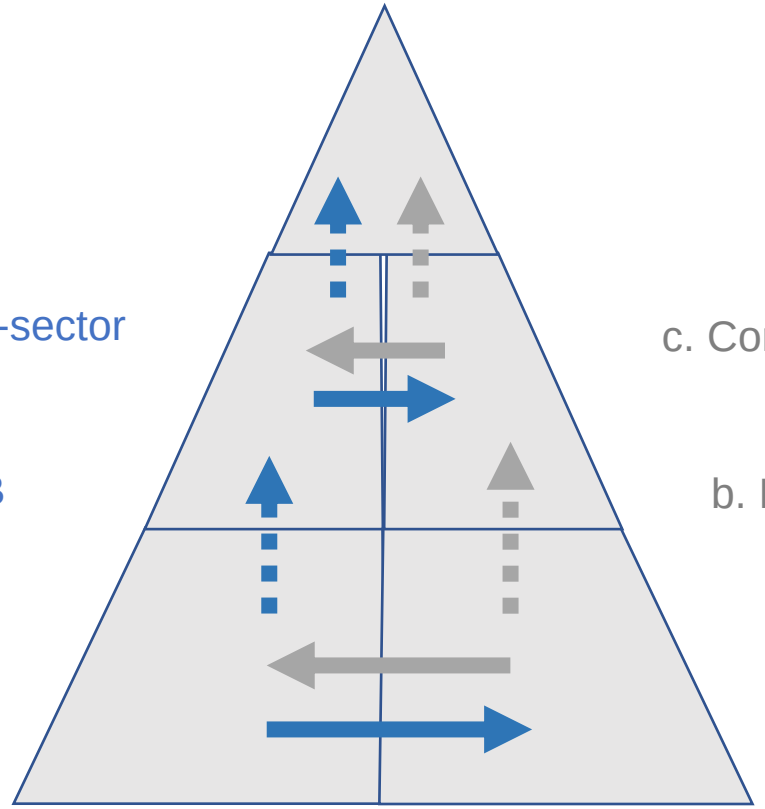
2. If needed, EU-level advice

c. Consult other-sector advisory bodies

b. Request **SCB** opinion

1. National decisions

a. Consult other-sector NCA



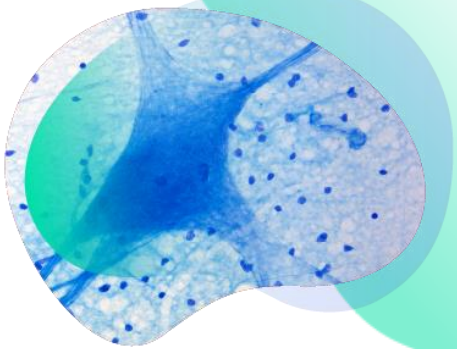
d. Request/give COM decision

c. Consult other-sector advisory bodies

b. Request EU-level scientific advice

a. consult other-sector NCA

SoHO **Pharma**

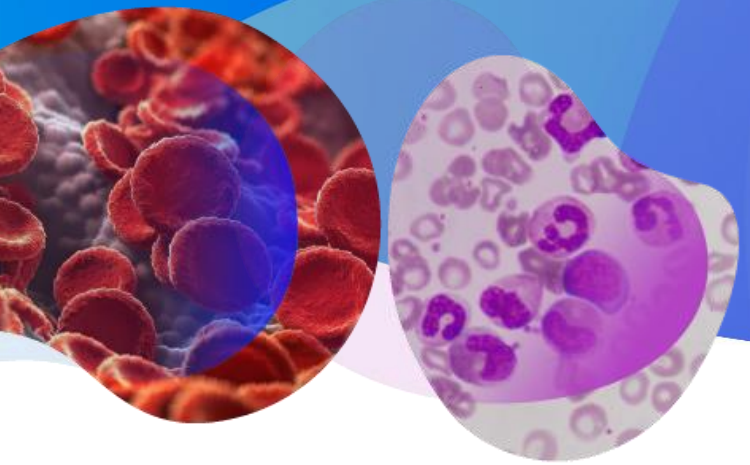


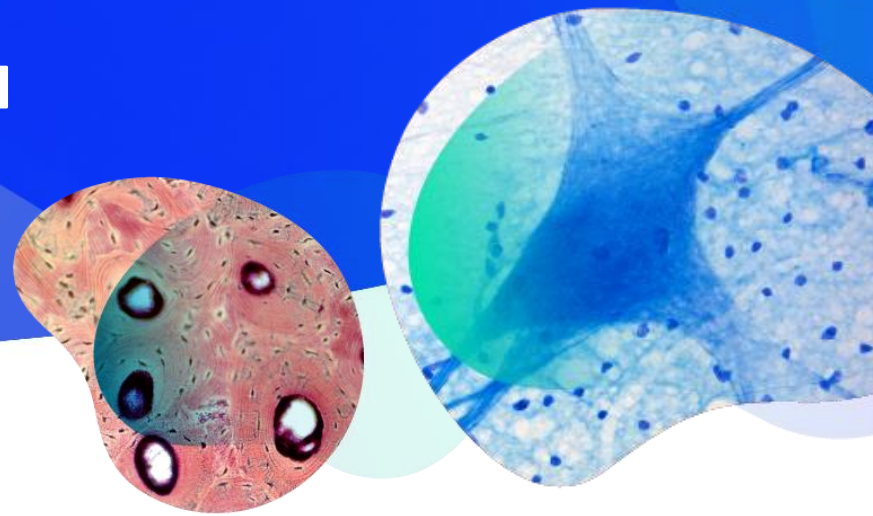
Giuseppe Feltrin

National Transplant Centre (Italy)

European Commission

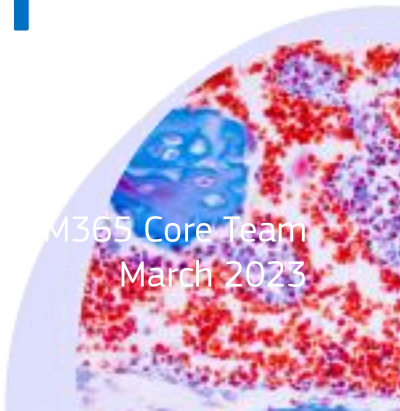
EUROPEAN HEALTH UNION





Giuseppe Feltrin (CNT), Vincenzo De Angelis (CNS)

Authorisation of SoHO preparation processes
– based on clinical evidence



M365 Core Team
March 2023

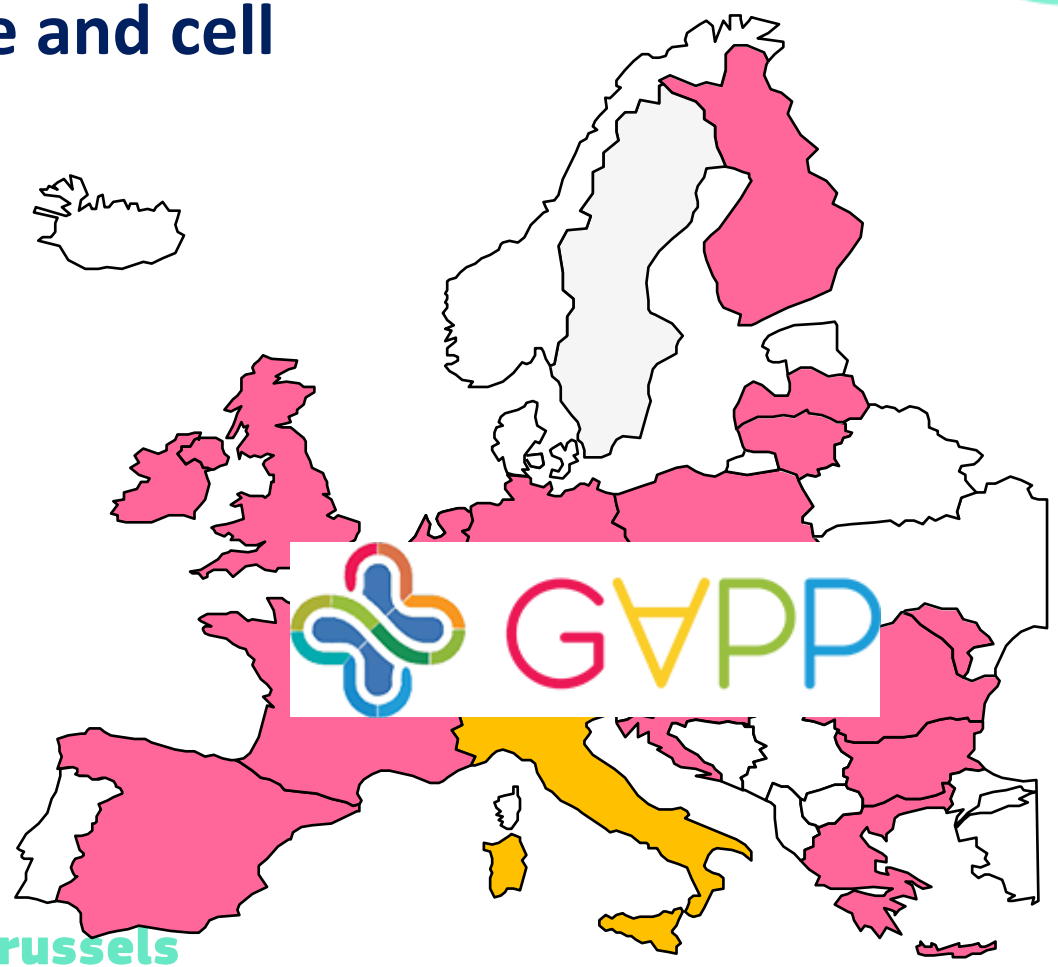
GAPP Joint Action 2018-2021

Co-funded by the Health Programme of the European Union

A large consortium of BTC Competent Authorities to define the **authorization pathways for blood, tissue and cell preparation processes**

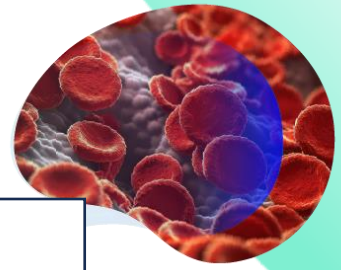
- **17 European Countries**
  - 16 EU MS
  - 1 non-EU MS
- **24 partners**
  - **1 coordinator**
  - **23** beneficiaries (+ 2 affiliated entities)
- **15 collaborating stakeholders**

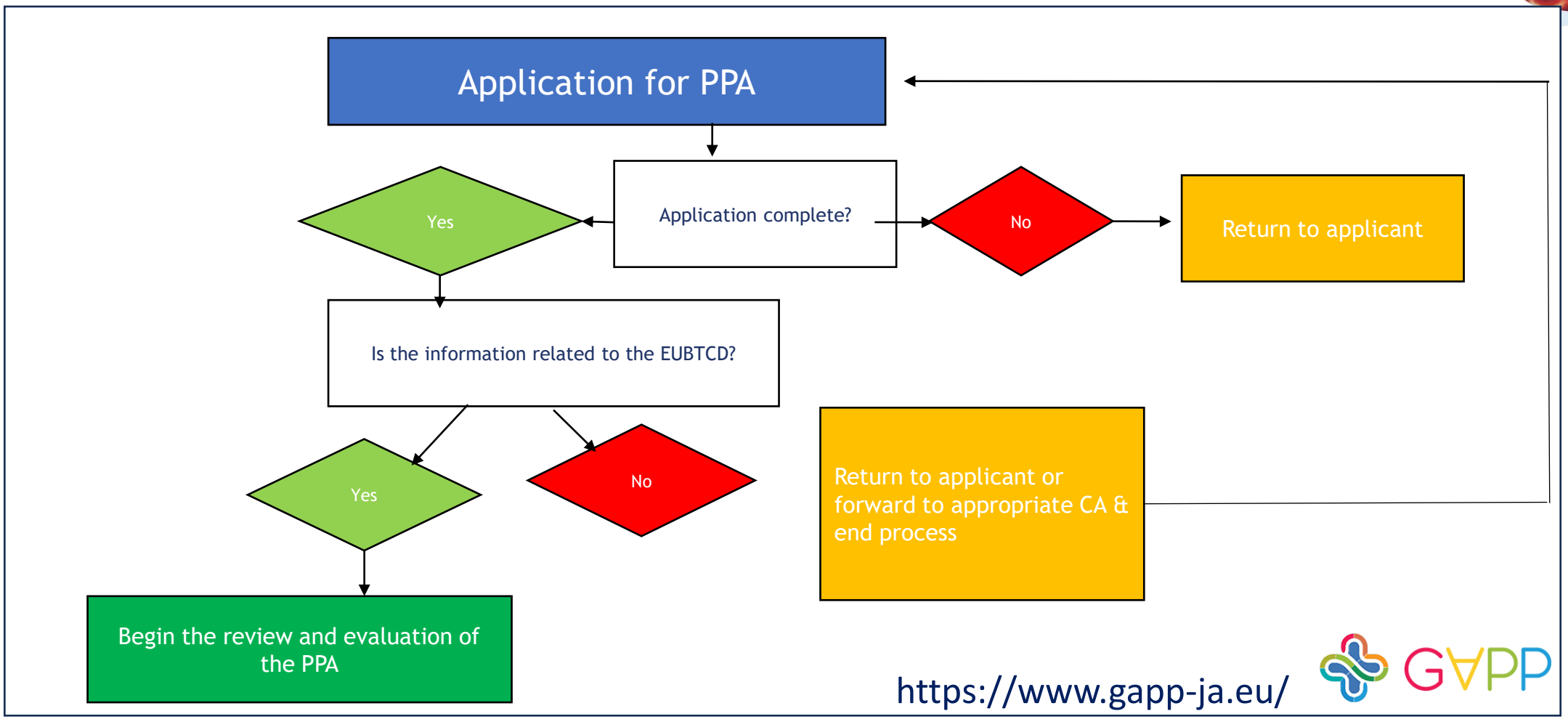
(NHSBT, SALAR, JPAC, Fundatia Renale, ESHRE, EBMT, ECDC, SOHO Consortium, ANSM, EFS, Hellenic National Blood Transfusion Centre, Croatian Institute for Transplantation and Biomedicine, Latvian State Agency of Medicine, EDQM, EHA)



European Commission

An application whenever a new SoHO or a change indicating novelty

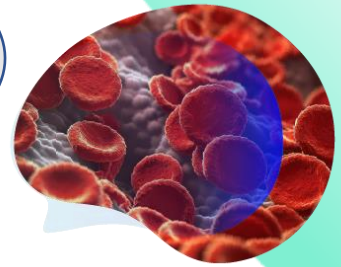




https://www.gapp-ja.eu/

The authorisation pathway for SoHO preparations

Consider relevant EDQM monographs



a) Systematic **Benefit/Risk Assessment** by the SoHO establishment, in order to determine the available evidence on safety, quality and effectiveness, possibly through EURO GTP tool

b) Submission of an **application**, including **laboratory validation** and other safety, quality and effectiveness data and, where relevant, a **clinical outcome monitoring plan** proportionate to risk

c) **Assessment** of the application by the competent authority

Grant authorisation for the SoHO preparation

OR

Grant an **approval of the Clinical Outcome Monitoring plan** or request an amended plan

OR

Refuse authorisation

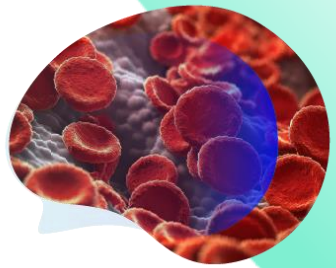
d) **Assessment** by the competent authority of evidence of safety, quality and effectiveness data gathered in clinical outcome monitoring

Grant authorisation

OR

Refuse authorisation

Standard Risk assessment tool: EUROGTP II



The **Euro GTP II** Methodologies [(1)] and Interactive Assessment Tool (IAT) [(2)] developed to assist professionals to:

- Determine if a BTC or preparation process has any **novelty** (Step 1)
- Assess the **risks associated** with the BTC or preparation process (Step 2)
- Determine the extent of any **studies and/or follow up required** to assure the safety and efficacy of BTC (Step 3)

EURO GTP II
Good Tissue & cell Practices

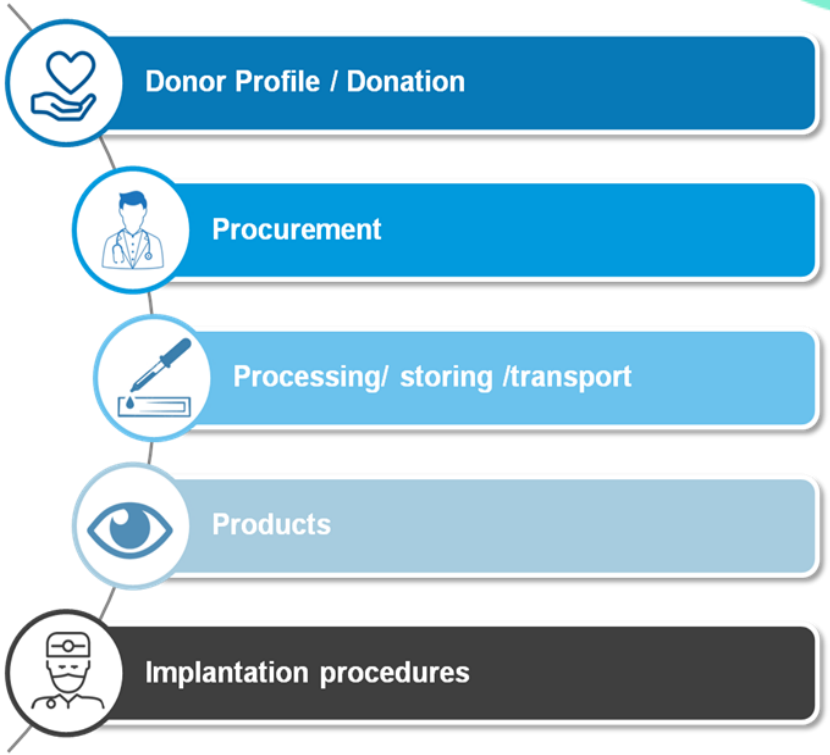
Unexpected immunogenicity

Implant failure/Engraftment failure/ Pregnancy loss

Disease transmission

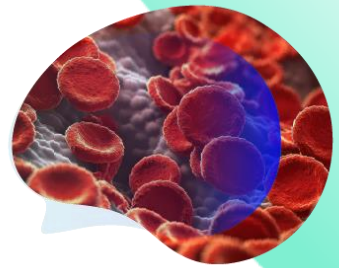
Toxicity / Carcinogenicity

Other potential risks (can be associated with specific TCP/therapy)



(1) Details available on the website: https://tool.goodtissuepractices.site/
(2) Adopted by EDQM for implementation guidelines: https://soho-guides.edqm.eu/home

Risk/benefit balance



BTC defined by quality, safety and efficacy

Degree of novelty and risk defined by available data on quality, safety and efficacy

	Complete set of data	Limited set of data				Insufficient data	
	Benefit risk ratio quantified and acceptable	Benefit risk ratio estimated. Expected benefit justifies expected risk				Benefit risk ratio not assessable / Expected benefit does not justify risk / Quality and safety concerns	
	Sufficient evidence to ensure quality, safety and efficacy	**Conditional Authorisation**				**Refusal of Authorisation**	
	Full authorisation	Further data sets required for final decision making					
Risk	Negligible (N)	Low (L)		Moderate (M)	High (H)	Negligible Low	Moderate High
BTC	√ Quality √ Safety √ Efficacy	X Quality √ Safety √ Efficacy	√ Quality X Safety √ Efficacy	√ Quality √ Safety X Efficacy	X Quality X Safety √ Efficacy	X Quality √ Safety X Efficacy	√ Quality X Safety X Efficacy	X Quality X Safety X Efficacy
Follow up	SARE Reporting (N)	SARE Reporting (LMH) CFupP (LMH) CIP (MH) Comparison Therapy (H)					

Clinical outcome monitoring in function of level of risks

Possible use clinical trials/studies/low-intervention

Possible use Real World Data

	Negligible Risk	Low Risk	Moderate Risk	High Risk
				Compare standard therapy
			Clinical Invest. Plan	Clinical Invest. Plan
		Clinical Follow-Up Plan	Clinical Follow-Up Plan	Clinical Follow-Up Plan
	SARE reporting+ Prep-Proc Dossier.	SARE reporting + Prep-Proc Dossier.	SARE reporting + Prep-Proc Dossier.	SARE reporting + Prep-Proc Dossier.

Level of risk ➔

Standard ⟷ *Rare (<5%)*

GAPP-PRO will pilot and roll-out approach by 2027

14 Main beneficiaries

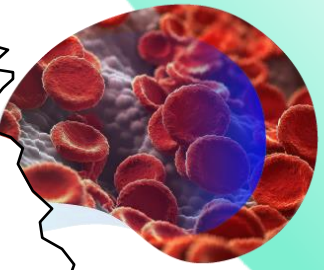
7 Affiliated entities

from 13 EU countries and 1 non-EU country

Project start date: 15/02/2024

Project duration: 40 months (14/06/2027)

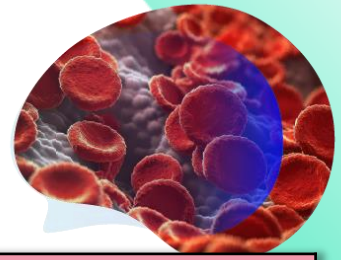
Co-funded by
the Health Programme
of the European Union



- Map current status of authorised SoHO preparations and inherent risks
- Pilot GAPP methodology: test, assess and improve
- Test cross-entity/country applications and assessments
- Test cross-sector collaboration for SoHO preparations entailing medical devices
- Refine and update the methodology

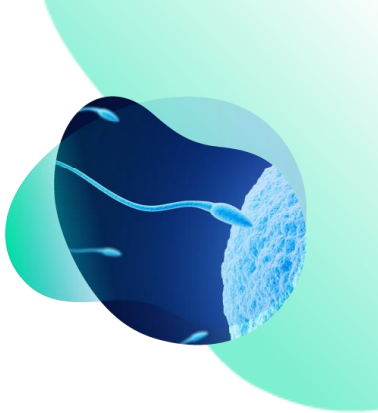
GAPP PRO

From theory to practice



Snapshot of SOHO preparation processes in Europe grouped by different risk level, including bed-side preparations	The main goal of this WP is to gain clear insight into the current European authorization of SoHO preparation processes, including bed-side preparations, grouped by different risk level. In particular it will: • investigate the presence of ongoing evaluation of new SoHO preparation processes; • investigate the presence of **already authorised SoHO preparation processes in relation to identified risk level**
Pilot-test of GAPP methodology on SoHO	To perform the test to **assess the GAPP methodology applicability** on selected SoHO (including at least 2 autologous bedside preparations), from application to final assessment in order to: • Test the evaluation of different levels of risk (negligible, low, medium, high); • Detect strengths and weaknesses of GAPP methodology through the performance of a SWOT analysis.
Pilot-test of GAPP methodology for cross country and joint country assessments	To organise and perform **cross-country applications and joint-country assessments** involving a group of Member States and experts (inspectors and assessors) in order to test and prove its feasibility and added value.
Analysis of pilot tests results	This WP will perform a thorough **analysis of pilot outcomes**, including interactions in the assessments and authorisation process with those of other regulatory frameworks, for example, where a new SOHO preparation process relies on the use of a new medical device.
Refine of GAPP Guideline	The aim of this WP is to **refine/update the GAPP Guidelines** on the basis of the pilot-tests results. Moreover, within this WP, the existing EUROGTP II platform will be extended to other SoHO (i.e. breast milk and faecal microbiota) so to provide European professionals with the opportunity to perform risk assessment also for other products.

Panel members



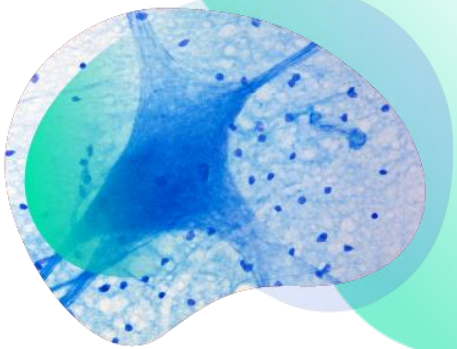
Pia Ekbom Danish Patient Safety Authority

Christian Chabannon Institut Paoli-Calmettes Comprehensive Cancer Centre

Celine Druart Pharmabiotic Research Institute

Nigel Talboys Blood Transfusion Association of Medical Device Manufacturers

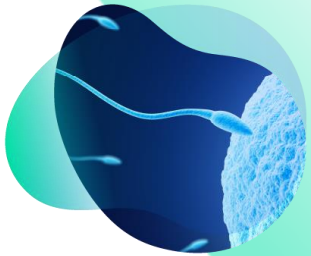
Steffen Thirstrup European Medicine Agency



Anne Birgit Hovde

MS patient

Impact statement

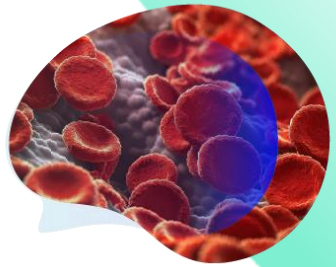


Jacques Allegra

International federation of Blood Donors

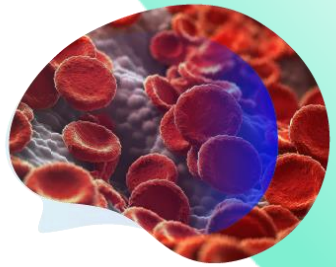
Impact statement

Volunteer donors involved in SoHO donation

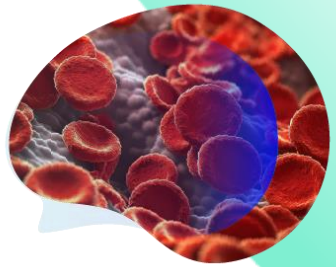


- The SoHO regulation will make it possible to have **common rules** for SOHO donation in all the countries of the European Union.
- Europe is a benchmark for human rights, and the application of the SoHO Regulation must ensure respect for the **health and dignity of donors**.
- Ethics based on volunteering, anonymity, voluntariness and unpaid donation through the **financial neutrality of donations** must be at the heart of all strategies for promoting and appealing for donations.
- Patients, Donors, we are linked by a common objective: to provide **access** for everyone with the BTC product they need.

IFBDO and Donors of Health Europe commitment



SoHO CONFERENCE • 24 I 06 I 2024 Brussels

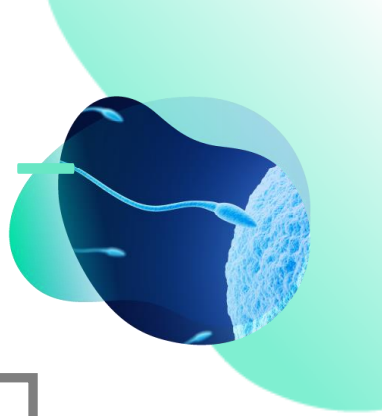


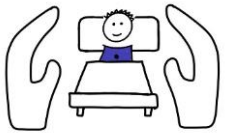
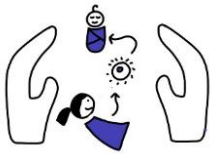
Beatrice Marquez-Garrido

European Commission

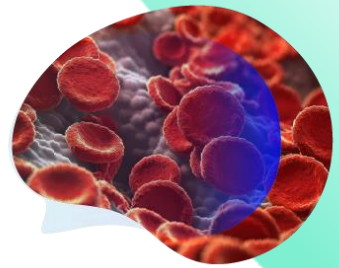
SoHO Team

Shortcomings from the 2019 evaluation –
Need to manage supply concerns



	1. Patients are not fully protected from avoidable risks because some rules are out of date
	2. Legislation does not mitigate risks for BTC donors and for children born from donated eggs, sperm or embryos
	3. Member States have divergent approaches to oversight
	4. Full potential of innovative therapies is not reached for patients
	5. Patients are vulnerable to interruptions in EU supply of some BTC

Measures to ensure supply of critical SoHO



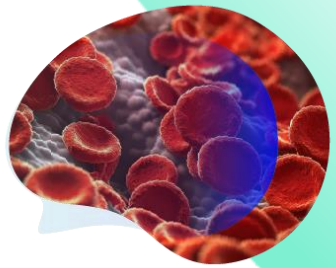
'Critical SoHO' are SoHO that for which an insufficient supply will result in serious harm or risk of harm to patients or a serious interruption in manufacture of critical products regulated by other legislation.

A '**critical SoHO entity**' is a SoHO entity that carries out activities contributing to the supply of critical SoHOs and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for recipients.

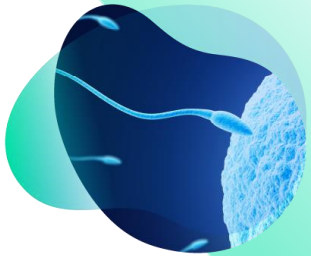
Supply of **critical SoHO** is protected by:

- **Obligations on Member States** to ensure a sufficient, adequate and resilient supply
  - Facilitate donation
  - Communication and education
  - Optimal use
- **Activity data collection** and monitoring
- Supply **alerts**
- National **SoHO emergency plans**
- SoHO Entity **emergency plans**
- **Derogations** and additional measures in emergency situations

Further measures facilitating supply of SoHO to EU patients



- **Donor protection** measures, including Voluntary Unpaid Donation, reassure general population and support willingness to donate (Chapter VI)
- **Harmonization of technical requirements** (guidelines by EDQM/ECDC expert bodies) allow use of SoHO in healthcare settings across the EU
- Strenghtened, aligned and **joint oversight practices** (inspections, assessments) take away barriers at borders
- Stronger **cross-sector coordination**, for SoHO that become starting materials for medicinal products (like plasma and PDMP)



Peter O’Leary

European Blood Alliance

How to achieve EU sufficiency for plasma – the SUPPLY project

Peter O'Leary,
SUPPLY Project Co-ordinator and Executive Director, European Blood Alliance

As the project outputs are those of the SUPPLY consortium, they cannot be considered to necessarily reflect the views of any individual organisation which forms part of the consortium.

Co-funded by the European Union

This report is part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

Why are patients struggling to access life-saving immune globulin?

Immune deficient patients across the world are having issues getting access to the only drug that can keep them alive: immune globulin. Allie Nawrat investigates what is behind this ongoing shortage, whether medicine stockpiling is adding fuel to the fire, and what can be done to prevent a repeat of this situation in the future.

Allie Nawrat | February 24, 2020

EUROPEAN BLOOD ALLIANCE

WORKING GROUPS EUROPEAN AFFAIRS EVENTS RESOURCES

October 12, 2021

PLASMA SHORTAGE IN EUROPE: PROPER INVESTMENT IN PUBLIC BLOOD ESTABLISHMENTS IS THE ANSWER, NOT UNDERMINING ETHICAL PRINCIPLES

EUROPE

POLITICO

Home EU election War in Ukraine Israel-Hamas war Newsletters Podcasts Poll of Polls Policy news Events

Attention, EU. We've got a plasma donation problem.

FDA extends immunodeficiency drug's shelf life as pandemic exacerbates shortages

By **Fraiser Kansteiner** · Jan 6, 2021 6:20pm

Safety warnings | Medicines | 28/06/2021

The supply of immunoglobulins[1)] in Austria is limited due to reduced plasma donations.

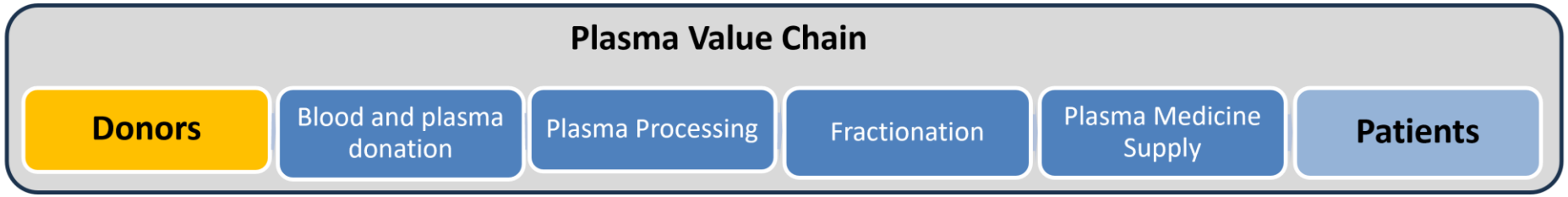
The Brussels Times

BUSINESS ART & CULTURE EU AFFAIRS WORLD BELG

EU looks to reduce dependency on the US for human plasma needs

There is currently an estimated shortfall of over 5 million litres of plasma in the EU.

Tuesday, 7 March 2023



Strengthening voluntary non-remunerated plasma collection capacity in Europe

Goals

- **Increase the volume and resilience of unpaid plasma collection in Europe by the public health sector**

and

- **Ensure safe and adequate access for EU patients to essential Plasma medicines**

SUPPLY | Co-funded by the European Union

This report is part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

What is *Sufficient* Plasma ?

“The main safety concern for patients with Primary Immunodeficiency Diseases in the EU is SUPPLY. [We need] **continued and stable access** to Immunoglobulins as prescribed by the treating physician.”

International Patient Organisation for Primary Immunodeficiencies (IPOPI) 22nd EU PID Forum

True Strategic Independence of plasma and plasma medicines in the EU will have been reached when:

- an equal or larger volume of plasma is collected in the EU than is required to meet the maximum estimated plasma-related requirements of EU Citizens
- meeting these requirements is legislatively guaranteed to EU Citizens
- *and* the EU has the capacity to act without being dependent on other regions or markets

SUPPLY | Co-funded by the European Union

This report is part of the project “101056988/SUPPLY” which has received funding from the European Union’s EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

a large prospective study in plasma donors to examine the **health consequences of plasma donation** at varying frequencies is needed

Focus on **retaining donors** while building a sustainable donor base

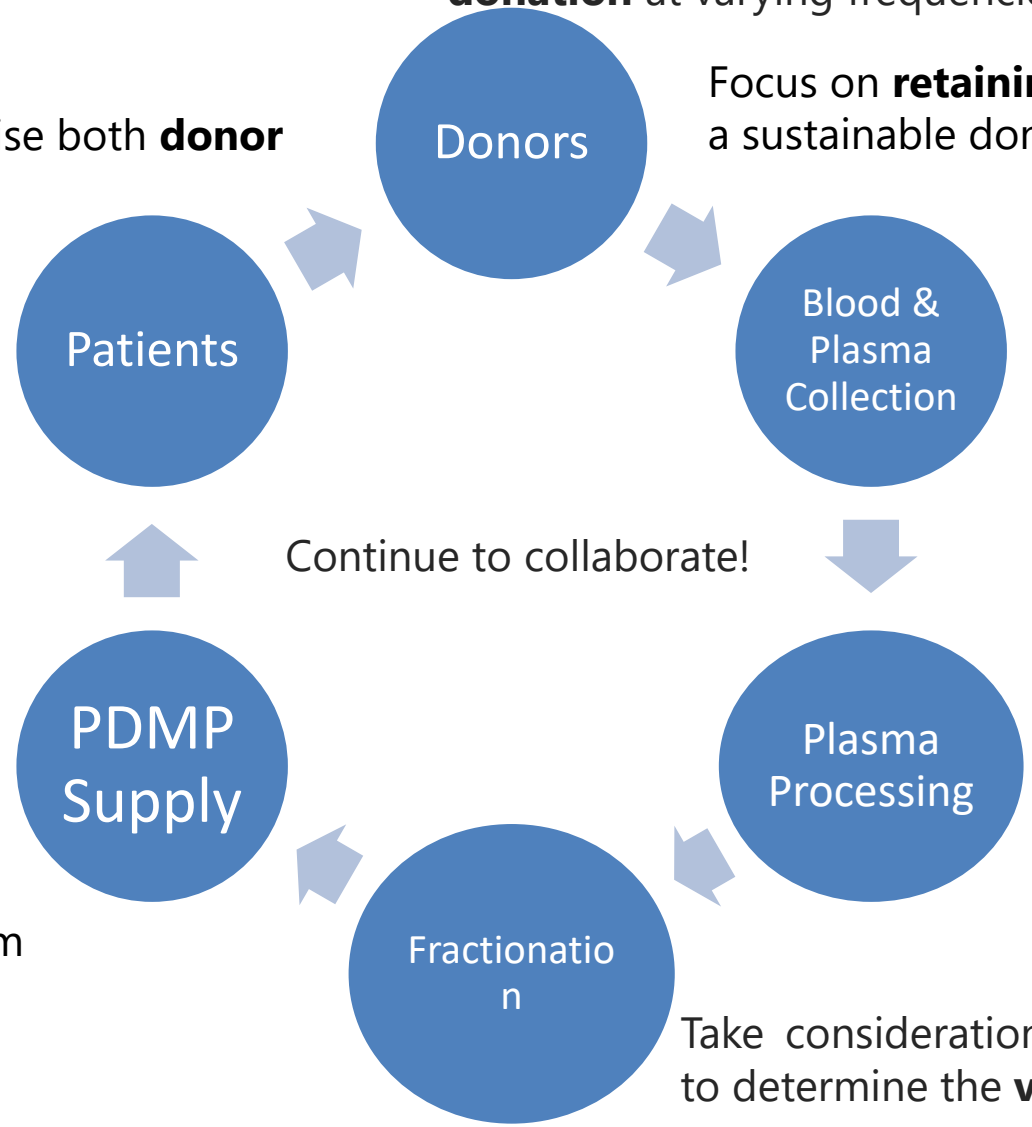
- **Invest** to increase and improve **plasma collection**
- Comprehensive **plasma-PDMP-patient strategies** are required
- EU Member States create **action plans**!

Take consideration of the **IgG level** to determine the **value of plasma**

Introduce legal provisions at national level which ***link*** **collected plasma to the usage of products manufactured** from this plasma

Create **national databases** on Plasma Medicine (Ig) **usage** at patient level

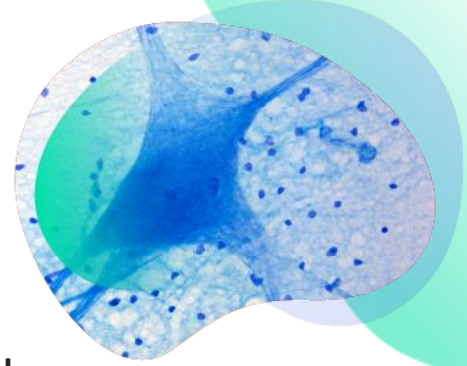
Important to prioritise both **donor *and* patient health**



SUPPLY | Co-funded by the European Union

This report is part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

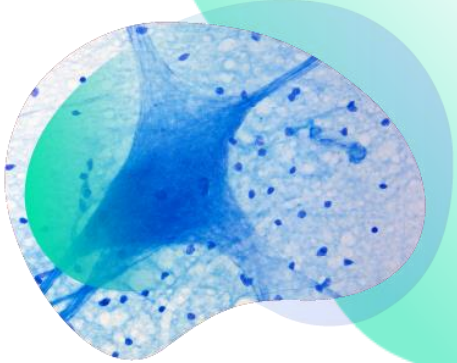
How to achieve EU sufficiency for plasma?



SoHO Regulation: Recital 65 (see also Article 62)

To increase European self-sufficiency in terms of SoHO, Member States should be urged to increase their collection capacity and donor base for critical SoHO, in particular plasma, by developing non-profit and public plasmapheresis programmes.

How to achieve EU sufficiency for plasma?



SoHO Regulation: Recital 65 (see also Article 62)
To increase European self-sufficiency in terms of SoHO, Member States should be urged to increase their collection capacity and donor base for critical SoHO, in particular plasma, by developing non-profit and public plasmapheresis programmes.

SUPPLY Key Messages:

- Successful Plasma Collection Models have a *high degree of participation of the stakeholders* combined with an underlying *political interest and commitment*.
- Commitment and Control

  It is of critical importance that national *commitments to collect* sufficient volumes of plasma are accompanied by *sufficient control* and monitoring over the plasma-medicine-patient chain to ensure that the patient population needs are met.

SUPPLY

https://supply-project.eu/resources/

SUPPLY Home About News Our Partners Resources Work Packages

SUPPLY Resources

The SUPPLY Project consortium is an excellent example of solidarity: many stakeholders from different Member States working together to improve the lives of EU citizens. As the project outputs are those of the SUPPLY consortium, they cannot be considered to necessarily reflect the views of the European Blood Alliance or any individual organisation which forms part of the consortium. More details on the SUPPLY consortium can be found in the our partners section.

The SUPPLY project had many outputs including reports, tools, and position papers. Once the project has completed, all of these will be accessible and downloadable on this page.

Deliverable	Report
D1.1	Crisis Situations – The impact on the plasma-medicine-patient chain: Analysis and Recommendations (Scenario Evaluation Plan)
D2.1	Plasma Donor recruitment and retention – Current Practice (Analysis Report)
D2.2	Plasma Donor recruitment and retention strategies – Efficiency evaluation (Recommendations Report and Transfer Plan)
D3.1	Setting up a Plasma Centre: Practical tools (Plasma Collection Recommendations and Support Tool)
D3.2	The plasma journey from collection to transport to fractionator – Recommendations for Improvement
D3.3	Opportunities to increase Plasma volumes: Recovered and via plasmapheresis: Analysis and Recommendations
D3.4	Real-world experience: Implementation of the recommendations to increase Plasma volumes
D3.6	Focus on quality: An assessment of plasma donor characteristics, Immunoglobulin, and Total Protein in donated plasma

SUPPLY Home About News Our Partners Resources Work Packages

Deliverable	Report
D4.4	Member State steps on the European path to Strategic Independence for Plasma Medicines: A Position Paper
D4.6	Building Strategic Independence for Plasma Medicines: Policy Recommendations for the EU and EU Member States
D5.1	Protecting Plasma donor health: Current Practice (Analysis Report)
D5.2	Protecting Plasma donor health: a Support Tool for standardised Plasma Donor Vigilance data
D5.3	Protecting Plasma donor health: Recommendations
D6.1	Protecting Patients: 'A comparative analysis on the current use of immunoglobulins in individual countries: A clinical program'
D6.2	Protecting Patients: 'Final recommendations to achieve appropriate and prioritised use of immunoglobulins in Europe'

SUPPLY | Co-funded by the European Union

This report is part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

https://supply-project.eu/resources/

SUPPLY

Home About News Our Partners Resources Work Packages

SUPPLY Resources

The SUPPLY Project consortium is an excellent example of solidarity: many stakeholders from different Member States working together to improve the lives of EU citizens. As the project outputs are those of the SUPPLY consortium, they cannot be considered to necessarily reflect the views of the European Blood Alliance or any individual organisation which forms part of the consortium. More details on the SUPPLY consortium can be found in the our partners section.

The SUPPLY project had many outputs including reports, tools, and position papers. Once the project has completed, all of these will be accessible and downloadable on this page.

Deliverable	Report
D1.1	Crisis Situations – The impact on the plasma-medicine-patient chain: Analysis and Recommendations (Scenario Evaluation Plan)
D2.1	Plasma Donor recruitment and retention – Current Practice (Analysis Report)
D2.2	Plasma Donor recruitment and retention strategies – Efficiency evaluation (Recommendations Report and Transfer Plan)
D3.1	Setting up a Plasma Centre: Practical tools (Plasma Collection Recommendations and Support Tool)
D3.2	The plasma journey from collection to transport to fractionator – Recommendations for Improvement
D3.3	Opportunities to increase Plasma volumes: Recovered and via plasmapheresis: Analysis and Recommendations
D3.4	Real-world experience: Implementation of the recommendations to increase Plasma volumes
D3.6	Focus on quality: An assessment of plasma donor characteristics, Immunoglobulin, and Total Protein in donated plasma

SUPPLY

Home About News Our Partners Resources Work Packages

Deliverable	Report
D4.4	Member State steps on the European path to Strategic Independence for Plasma Medicines: A Position Paper
D4.6	Building Strategic Independence for Plasma Medicines: Policy Recommendations for the EU and EU Member States
D5.1	Protecting Plasma donor health: Current Practice (Analysis Report)
D5.2	Protecting Plasma donor health: a Support Tool for standardised Plasma Donor Vigilance data
D5.3	Protecting Plasma donor health: Recommendations
D6.1	Protecting Patients: 'A comparative analysis on the current use of immunoglobulins in individual countries: A clinical program'
D6.2	Protecting Patients: 'Final recommendations to achieve appropriate and prioritised use of immunoglobulins in Europe'

SUPPLY | Co-funded by the European Union

This report is part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

https://supply-project.eu/resources/

SUPPLY

Home About News Our Partners Resources Work Packages

SUPPLY Resources

The SUPPLY Project consortium is an excellent example of solidarity: many stakeholders from different Member States working together to improve the lives of EU citizens. As the project outputs are those of the SUPPLY consortium, they cannot be considered to necessarily reflect the views of the European Blood Alliance or any individual organisation which forms part of the consortium. More details on the SUPPLY consortium can be found in the our partners section.

The SUPPLY project had many outputs including reports, tools, and position papers. Once the project has completed, all of these will be accessible and downloadable on this page.

Deliverable	Report
D1.1	Crisis Situations – The impact on the plasma-medicine-patient chain: Analysis and Recommendations (Scenario Evaluation Plan)
D2.1	Plasma Donor recruitment and retention – Current Practice (Analysis Report)
D2.2	Plasma Donor recruitment and retention strategies – Efficiency evaluation (Recommendations Report and Transfer Plan)
D3.1	Setting up a Plasma Centre: Practical tools (Plasma Collection Recommendations and Support Tool)
D3.2	The plasma journey from collection to transport to fractionator – Recommendations for Improvement
D3.3	Opportunities to increase Plasma volumes: Recovered and via plasmapheresis: Analysis and Recommendations
D3.4	Real-world experience: Implementation of the recommendations to increase Plasma volumes
D3.6	Focus on quality: An assessment of plasma donor characteristics, Immunoglobulin, and Total Protein in donated plasma

SUPPLY

Home About News Our Partners Resources Work Packages

Deliverable	Report
D4.4	Member State steps on the European path to Strategic Independence for Plasma Medicines: A Position Paper
D4.6	Building Strategic Independence for Plasma Medicines: Policy Recommendations for the EU and EU Member States
D5.1	Protecting Plasma donor health: Current Practice (Analysis Report)
D5.2	Protecting Plasma donor health: a Support Tool for standardised Plasma Donor Vigilance data
D5.3	Protecting Plasma donor health: Recommendations
D6.1	Protecting Patients: 'A comparative analysis on the current use of immunoglobulins in individual countries: A clinical program'
D6.2	Protecting Patients: 'Final recommendations to achieve appropriate and prioritised use of immunoglobulins in Europe'

SUPPLY | Co-funded by the European Union

This report is part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

https://supply-project.eu/resources/

SUPPLY

Home About News Our Partners Resources Work Packages

SUPPLY Resources

The SUPPLY Project consortium is an excellent example of solidarity: many stakeholders from different Member States working together to improve the lives of EU citizens. As the project outputs are those of the SUPPLY consortium, they cannot be considered to necessarily reflect the views of the European Blood Alliance or any individual organisation which forms part of the consortium. More details on the SUPPLY consortium can be found in the our partners section.

The SUPPLY project had many outputs including reports, tools, and position papers. Once the project has completed, all of these will be accessible and downloadable on this page.

Deliverable	Report
D1.1	Crisis Situations – The impact on the plasma-medicine-patient chain: Analysis and Recommendations (Scenario Evaluation Plan)
D2.1	Plasma Donor recruitment and retention – Current Practice (Analysis Report)
D2.2	Plasma Donor recruitment and retention strategies – Efficiency evaluation (Recommendations Report and Transfer Plan)
D3.1	Setting up a Plasma Centre: Practical tools (Plasma Collection Recommendations and Support Tool)
D3.2	The plasma journey from collection to transport to fractionator – Recommendations for Improvement
D3.3	Opportunities to increase Plasma volumes: Recovered and via plasmapheresis: Analysis and Recommendations
D3.4	Real-world experience: Implementation of the recommendations to increase Plasma volumes
D3.6	Focus on quality: An assessment of plasma donor characteristics, Immunoglobulin, and Total Protein in donated plasma

SUPPLY

Home About News Our Partners Resources Work Packages

Deliverable	Report
D4.4	Member State steps on the European path to Strategic Independence for Plasma Medicines: A Position Paper
D4.6	Building Strategic Independence for Plasma Medicines: Policy Recommendations for the EU and EU Member States
D5.1	Protecting Plasma donor health: Current Practice (Analysis Report)
D5.2	Protecting Plasma donor health: a Support Tool for standardised Plasma Donor Vigilance data
D5.3	Protecting Plasma donor health: Recommendations
D6.1	Protecting Patients: 'A comparative analysis on the current use of immunoglobulins in individual countries: A clinical program'
D6.2	Protecting Patients: 'Final recommendations to achieve appropriate and prioritised use of immunoglobulins in Europe'

SUPPLY | Co-funded by the European Union

This report is part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

https://supply-project.eu/resources/

SUPPLY Home About News Our Partners Resources Work Packages

SUPPLY Resources

The SUPPLY Project consortium is an excellent example of solidarity: many stakeholders from different Member States working together to improve the lives of EU citizens. As the project outputs are those of the SUPPLY consortium, they cannot be considered to necessarily reflect the views of the European Blood Alliance or any individual organisation which forms part of the consortium. More details on the SUPPLY consortium can be found in the our partners section.

The SUPPLY project had many outputs including reports, tools, and position papers. Once the project has completed, all of these will be accessible and downloadable on this page.

Deliverable	Report
D1.1	Crisis Situations – The impact on the plasma-medicine-patient chain: Analysis and Recommendations (Scenario Evaluation Plan)
D2.1	Plasma Donor recruitment and retention – Current Practice (Analysis Report)
D2.2	Plasma Donor recruitment and retention strategies – Efficiency evaluation (Recommendations Report and Transfer Plan)
D3.1	Setting up a Plasma Centre: Practical tools (Plasma Collection Recommendations and Support Tool)
D3.2	The plasma journey from collection to transport to fractionator – Recommendations for Improvement
D3.3	Opportunities to increase Plasma volumes: Recovered and via plasmapheresis: Analysis and Recommendations
D3.4	Real-world experience: Implementation of the recommendations to increase Plasma volumes
D3.6	Focus on quality: An assessment of plasma donor characteristics, Immunoglobulin, and Total Protein in donated plasma

SUPPLY Home About News Our Partners Resources Work Packages

Deliverable	Report
D4.4	Member State steps on the European path to Strategic Independence for Plasma Medicines: A Position Paper
D4.6	Building Strategic Independence for Plasma Medicines: Policy Recommendations for the EU and EU Member States
D5.1	Protecting Plasma donor health: Current Practice (Analysis Report)
D5.2	Protecting Plasma donor health: a Support Tool for standardised Plasma Donor Vigilance data
D5.3	Protecting Plasma donor health: Recommendations
D6.1	Protecting Patients: 'A comparative analysis on the current use of immunoglobulins in individual countries: A clinical program'
D6.2	Protecting Patients: 'Final recommendations to achieve appropriate and prioritised use of immunoglobulins in Europe'

SUPPLY | Co-funded by the European Union

This report is part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

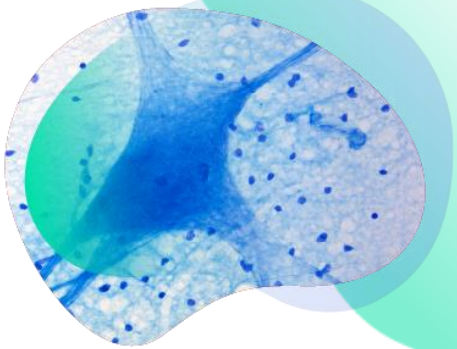
Thank You

Questions / Comments/ More Information :

- Website: www.supply-project.eu
- E-mail: info@supply-project.eu
  info@europeanbloodalliance.eu

SUPPLY | Co-funded by the European Union

This report is part of the project "101056988/SUPPLY" which has received funding from the European Union's EU4Health Programme (2021-2027). The content of this report represents the views of the author only and is his/her sole responsibility; it can not be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union.
The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.



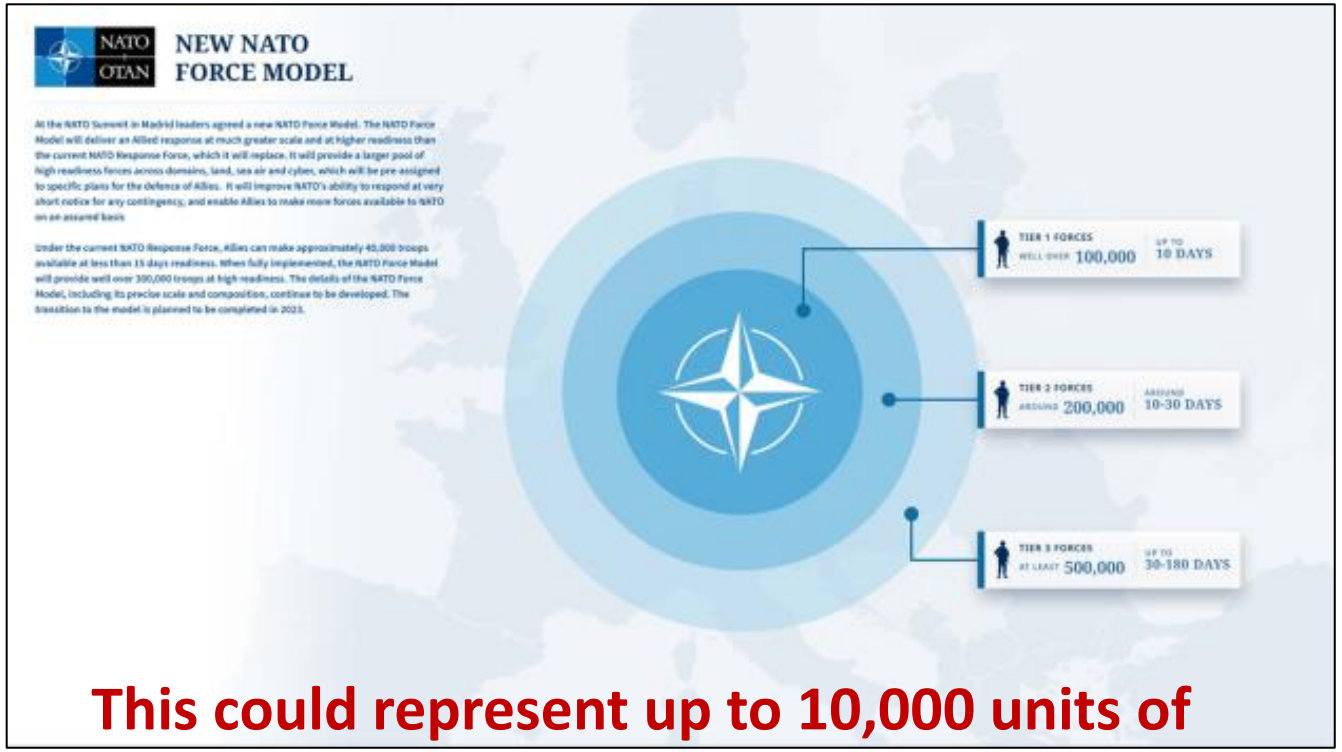
Major General **Tim Hodgetts**

Chair of **NATO Committee of the Chiefs of Military Medical Services**

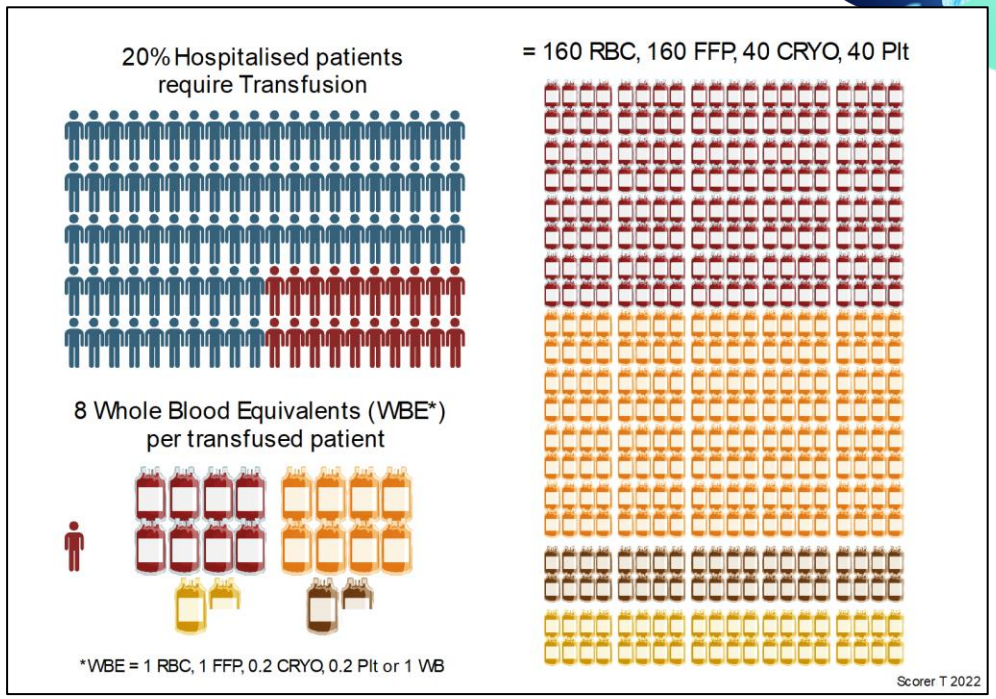
SoHO CONFERENCE • 24 I 06 I 2024 Brussels

Managing SoHO in emergency situations

Major General Tim Hodgetts, Chair COMEDS



This could represent up to 10,000 units of Whole Blood Equivalent (WBE) in the first week

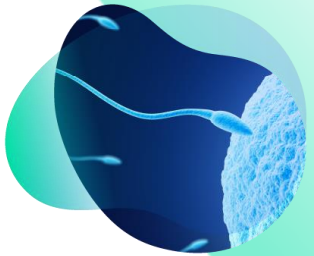


Planning for contingency options prior to full combat operations

- Dried plasma
- Emergency donor panel (EDP)
- Walking Blood Bank (WBB)

Managing SoHO in emergency situations

How new SoHO Regulations will assist NATO in emergency



- Obligation for national **emergency** plans (Article 62)
  - *Including a procedure for SoHO entities to request derogations from standards for donor and recipient protection (chapters VI and VII)*
  - *Taking into account guidance from ECDC and EDQM*
    Blood Supply Contingency and Emergency Plan (B-SCEP) - European Directorate for the Quality of Medicines & HealthCare (edqm.eu)
- Derogation from obligation to authorise SoHO preparations in **emergency** situations (Article 64)
- Additional **emergency** measures by MS (Article 65)
- Critical SoHO entity **emergency** plans (Article 66)
- Supply **alerts** (Article 63)
- Exceptional release – individual patient (Article 61)

Note: a number of non-legislative initiatives supporting increasing the EU supply of plasma for PDMP

European Commission

Limitations:

EU regulations not applicable to all NATO members & allies. Nations are responsible for the interpretation and application of the regulations.

Benefits:

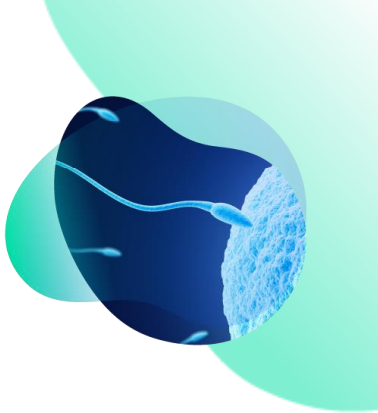
EU regulations can act as a baseline for standardization given that the majority of NATO members are EU members and required to comply with the regulations.

Summary of recommendations:

- There are no recommended changes to the EU regulations as written.
- Several considerations are made below for NATO assessments, involvement, and support for members to advance the Blood Far Forward (BFF) objectives.

BLOOD PANEL NATO OTAN COMEDS

Panel members



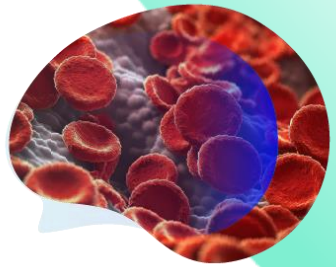
Mirjam Fechter World Marrow Donor Association

Gilbert Verbeken Brussels Military Hospital

Rita Piteira Banc de Sang i Teixits

Jeroen van Baare Dutch Health and Youth Care Inspectorate

Linda Larsson Swedish National Board of Health and Welfare



Bernd Dobbert

Impact statement

Alpha-1 Europe Alliance

Alpha1 Deutschland e.V.

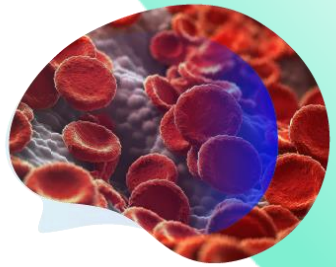
SoHO CONFERENCE • 24 I 06 I 2024 Brussels

Alpha-1 Patient Perspective on the SoHO Regulation

- Suffered from shortness of breath for 7 years before correct diagnosis
- Diagnosed with Alpha-1 antitrypsin deficiency (AATD) in 2012
- Happy to be on augmentation therapy with AAT produced from human plasma since 2014
- Augmentation therapy is leading to
  - Slower decline in lung function
  - Longer life expectancy
  - Improved quality of life

Alpha-1 Patient Perspective on the SoHO Regulation

- Existing high mental burden on patients using plasma products increased significantly during the pandemic
  - **Safety** of plasma-derived medicine (free from virus contamination)
  - **Security of supply** (collapse of imports from USA)
- SoHO Regulation focuses on the first issue, but also influences the second
  - Harmonised EU-wide standards regulating the safety of medicine, donors and recipients strongly welcomed
  - Self-sufficiency in plasma supplies is only guaranteed in countries with financial compensation for donors. The continued ability to pay this is therefore a good thing. However, an even more generous solution would have been preferred, so as to increase the amount of plasma collected in the EU



Silke Mader

European Federation for the Care of Newborn Infants

Impact statement

EFCNI european foundation for the care of newborn infants

SoHO CONFERENCE • 24 I 06 I 2024 Brussels

A baby born too soon, too small and too sick
is a nutritional emergency!

Why SoHo regulation on human milk is important for babies born **too** soon, **too** small or **too** sick in Europe

One of the most vulnerable patient groups with special nutritional needs: preterm, sick, and low birthweigth infants.

Only 30% of mothers of extremely preterm infants are able to supply 100% of their milk to meet their infants‘ needs.

Preterm birth, low birthweight, infections, abnormalities, and birth trauma are the main causes of neonatal death. In Europe, ~8,7% of all infants are born preterm.

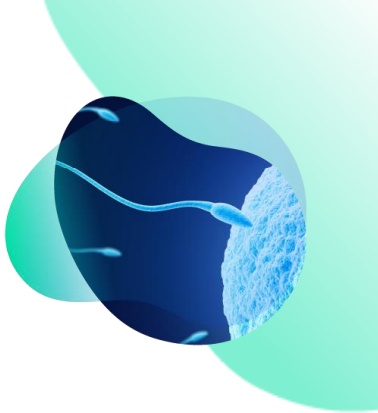
Safe (Donor) human milk supports survival and reduces the risk for diseases and morbidities (vision and lung disease, metabolic problems, brain damage, NEC, etc.).

(1) World Health Organization. Causes of newborn mortality and morbidity in the European Region.
(2) Chawanpaiboon S, et al. Lancet Glob Health. 2019. doi:10.1016/S2214-109X(18)30451-0.

Babies born preterm do not only have a tough time during the first days or months of life. Preterm birth may affect us and our families for a lifetime.

Developing and implementing a guideline which ensures safe access to human milk and avoid any further complications for our most vulnerable and tiniest patients!!!

Panel members



Petra Doerr Director EDQM

Marieke van der Werf for the Director of ECDC

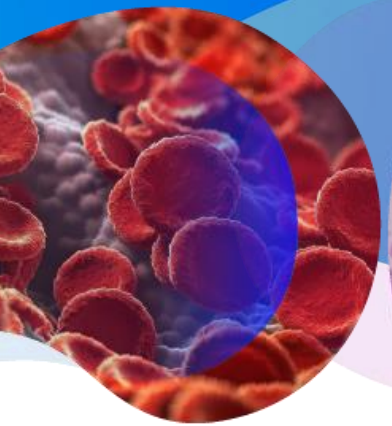
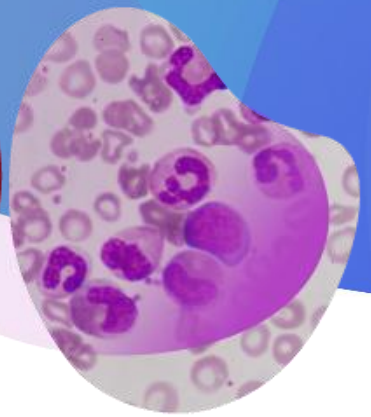
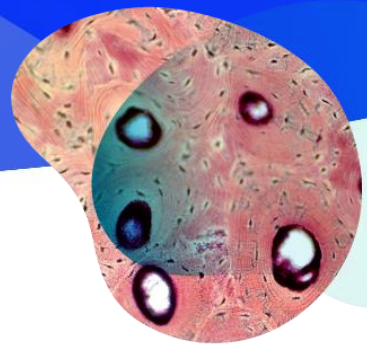
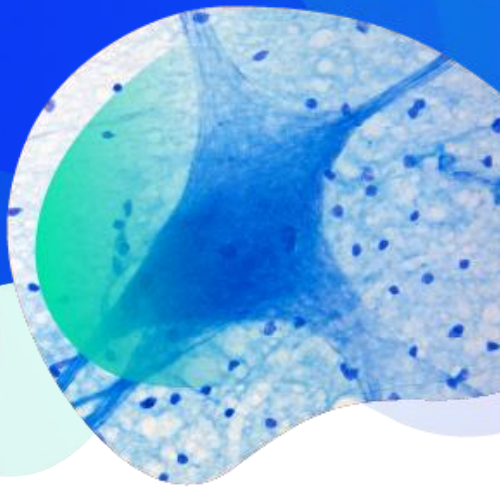
Beatriz Dominguez-Gil Director Spanish Transplant Agency (ONT)

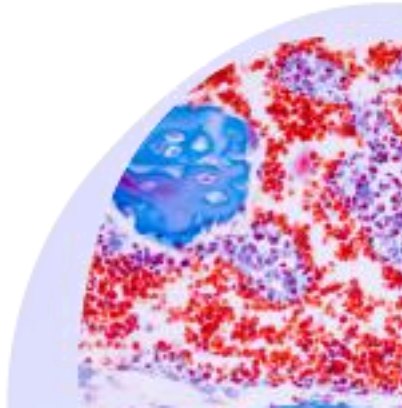
Hugues Malonne Director Belgian SoHO and pharma authority (FAGG)

Sandra Gallina Director-General DG SANTE, European Commission

European Commission

EUROPEAN HEALTH UNION



Thank you for joining!

SoHO CONFERENCE

24 I 06 I 2024

Brussels