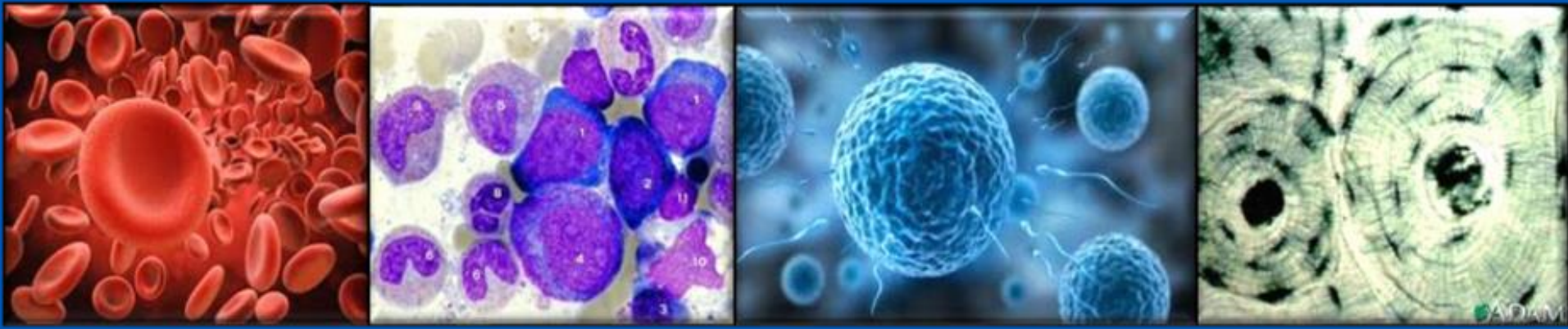


Proposal for a Regulation on standards of quality and safety for substances of human origin

EBA event: Blood establishments and the new SoHO Regulation
Protecting donors, delivering for patients

European Parliament, 25th of January 2023

DG SANTE/D2/SoHO



Problems to address

Mandate TFEU art 168.4a = safety&quality
Directive 2002/98/EC (blood)
Directive 2004/23/EC (tissues&cells)

-> Identified during the evaluation of BTC legislation (2019)



1. Patients are not fully protected from avoidable risks



2. Avoidable 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 BTC

CoVID confirmed problems

Objectives of this proposal



Key new and changed concepts

- **Fostering a donor basis - donor Protection and Voluntary Unpaid Donation**
- **Strengthening recipient protection**
- **Strengthening supply resilience**

Voluntary & Unpaid Donation

Principle maintained
Based on Recommendations of the
Council of Europe Committee on
Bioethics

SoHO entities shall not provide financial incentives or inducements to SoHO donors or their relatives or any persons granting authorisation on behalf of the prospective donors, in accordance with national legislation (Art. 54)

SoHO entities may compensate or reimburse SoHO donors as provided for by their competent authorities (...)

- **Compensation** or reimbursement for losses related to donation are permissible
- Based on fixed-rate allowances within **an upper limit set by Member State**
- Allowances must be **financially neutral** and consistent with standards for VUD

SoHO Donor Protection – significantly strengthened

SoHO entities shall ensure high levels of safety of SoHO living donors (...) before, during, and after the donation. (Art. 52)

Standards for Donor Protection (Art. 53)

- Including for donations by relatives
- Information & consent
- Data protection & safeguarding of anonymity
- **Donor health evaluation**
- Risk-proportionate approach to donor monitoring: registration of donors subject to
 - surgical procedures,
 - hormone treatment,
 - frequent or repeated donations.

+ Donor adverse occurrence reporting requirements
+ Possibility for self reporting (Art. 35 and 47)

Key new and changed concepts

- Fostering a donor basis - donor Protection and Voluntary Unpaid Donation
- Strengthening recipient protection
- Strengthening supply resilience

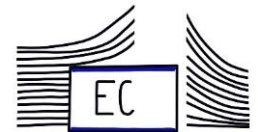
Up-to-date high level standards through technical guidelines

SoHO entities shall follow the highest available levels of standards (Art. 56 & 59):

Level 1

Commission Implementing Legislation

“where the Commission deems necessary”



If none:

Technical Guidance on the EU SoHO Platform

Published & updated by ECDC/EDQM

“Inspectors shall accept”

Level 2

OR:

“Equivalent” Guidance

Deemed by CAs to achieve equivalent standards

“Entities shall demonstrate equivalence to inspectors”



If none:

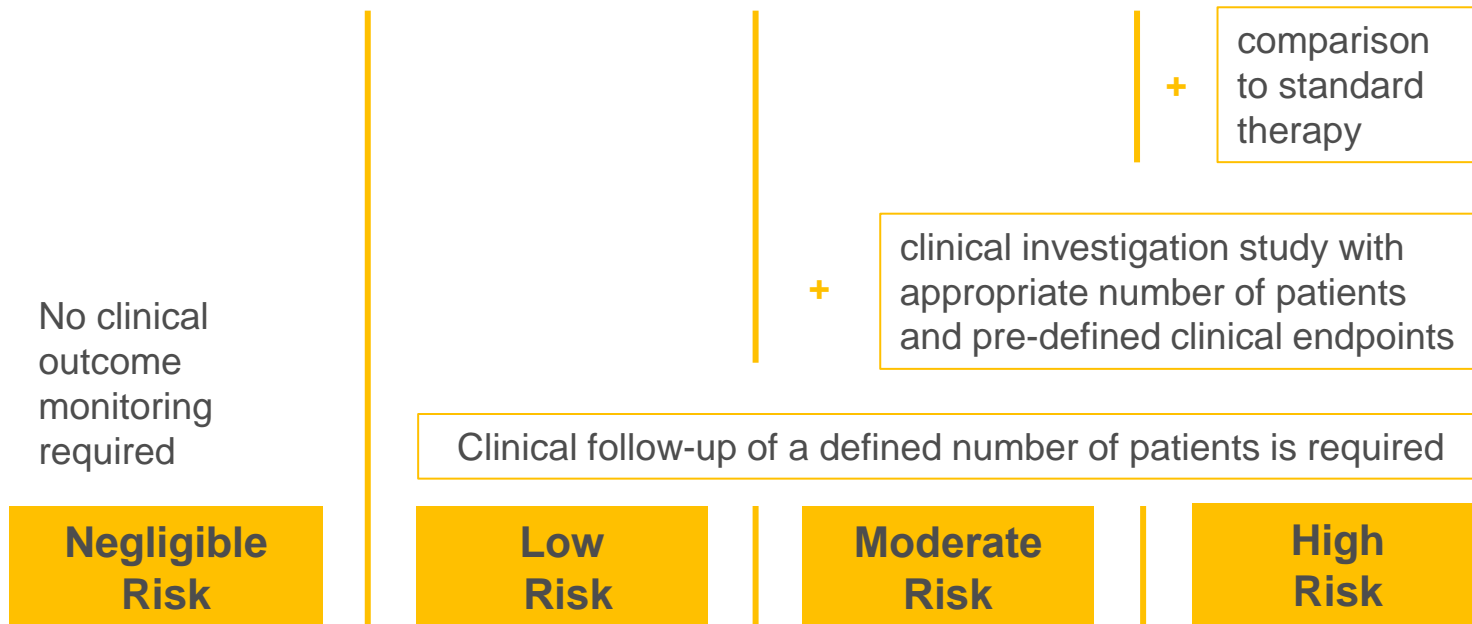
Level 3

Methods based on international standards or scientific evidence

“Entities shall demonstrate equivalence to inspectors”



Risk-based requirements to authorize innovation – balancing risk and access



Basis for preparation process authorization (art 20-22, 40-41)



Based on preparatory work done by GAPP Joint Action (incl. stakeholders from 17 countries: 15 CAs & professional associations)



Key new and changed concepts

- **Fostering a donor basis - donor Protection and Voluntary Unpaid Donation**
- **Strengthening recipient protection**
- **Strengthening supply resilience**

Resilience of Supply



Critical SoHO

‘**Critical SoHO**’ are SoHO that for which an insufficient supply will result in serious harm or risk of harm to patients (Art. 3)

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 patients (Art. 3)

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

- **Activity data collection** and reporting (Art.44)
- Supply **alerts** (Art. 63)
- National **SoHO emergency plans** & SoHO Entity emergency plans (Art. 62 & 66)
- **Derogations** and additional measures in emergency situations (Art. 64 & 65)

Need for actions crossing SoHO + pharma
Need for legal + non-legal (organisational) actions
(e.g., Structural Dialogue, EU4H SUPPLY project)

Thank you