

PROTECTING DONORS, DELIVERING FOR PATIENTS

European Blood Alliance position on the European Commission's proposal for a SoHO Regulation

EBA is pleased with the general direction of the proposal and its level of ambition. In particular:

Strengthening of the health protection for donors and patients

- + the references to the European Charter of Human Rights (ECHR) and specifically to “integrity of the person”
- + SoHO platform and cross-entity registry exchanges can greatly enhance donor and patient health

What can be strengthened:

- need to clarify language (such as frequent or repeated donations) to ensure increased donor protection and wellbeing
- longstanding principle of “absence of profit on the part of the establishments involved in blood transfusion services” must be reinstated

Reaffirming of the principle of voluntary non-remunerated donation

- + References to the work of the Council of Europe

What can be strengthened:

- clearer definition of “compensation” needed. The Nuffield Council on Bioethics’ intervention ladder can help frame ethical boundaries
- unclear how member states can ensure financial neutrality if fixed rate allowances are introduced



Scope of the regulation

- + new scope helps address borderline cases and make regulation future-proof

What can be strengthened:

- address excessive legal uncertainty with regards to other legislation, including future one. SoHO regulation scope must be better ringfenced

Ensuring resilience and continuity in supply of SoHOs

- + Promoting a strong public and non-profit sector

What can be strengthened:

- EU needs European and national strategies on how to increase sufficiency of SoHO, and of plasma in particular
- promote diverse and broad donor-base to strengthen resilience

Other key elements:

- + New relationship with expert bodies of EDQM and ECDC is positive and blood establishments need formal role there
- + New risk-based frequency for inspection of SOHO facilities welcomed
- + Member States must be encouraged to establish transfusion medicine as an independent medical subject with structured training



Scan for the complete EBA response to the SoHO Regulation proposal



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