

EU should adopt research-based approach to ensure quality, safety of substances of human origin, argues study

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Substances of human origin (SoHOs) such as blood, plasma, skin, corneas, and embryos play an increasing role in life-saving medical procedures. Governments around the world are reevaluating their health care policies to ensure of a supply of SoHOs for their population, while also considering the best-interests of both donors and patients.

A [paper published](#) in *BMJ Global Health* examines the issues surrounding the regulation of SoHOs for governments, after the Council of the European Union (EU) and the European Parliament agreed in December 2023 on a new "Regulation on standards of quality and safety for substances of human origin intended for human application."

The paper, coauthored by Professor Nicola Lacetera of the University of Toronto, urges that it is imperative for the EU to adopt a balanced, empirically sound, and research-backed approach which promotes policies to safeguard the interests of donors and patients, while ensuring a safe supply of SoHOs.

"Recent studies and reviews of the evidence over the last 40 years have concluded that the statistically sound, field-based evidence from large, representative samples shows that properly devised rewards increase supply without compromising the quality and safety of blood and blood components," says Prof. Lacetera.

"At least where plasma for fractionation is concerned, the unpaid-[donor](#) system has failed to meet demand. In Europe, countries allowing [monetary compensation](#) for donors are the only ones achieving self-sufficiency in plasma collection for the production of immunoglobulin."

The paper concludes that the final objective of any new regulation should not merely be self-sufficiency in providing SoHOs for treatment, but ensuring the availability of safe, sufficient, and accessible SoHOs for all in need.

One of the more controversial aspects in the discussion has been the compensation of donors, with the new EU regulation stating that the "donation of SoHO should be voluntary and unpaid." Current scientific evidence shows that compensation increases supply without affecting the quality of the products. Without stronger individual incentives for donors and other strategies to reduce barriers to donate such as building additional collective centers, it is unlikely that the EU can achieve [self-sufficiency](#).

The paper has implications for other jurisdictions that are currently reviewing their policies on the donation and use of substances of human origin, including Canada, where the debate as to whether allow compensation to plasma donors is longstanding.

Lacetera is a professor of strategic management at the University of Toronto Mississauga with a cross-appointment to the Rotman School of Management. His co-authors of the paper are Prof. Julio Elias of Universidad del CEMA, Prof. Mario Macis of Johns Hopkins University, Prof. Axel Ockenfeis of the University of Cologne and Max Plank Institute for Research on Collective Goods and Prof. Alvin Roth of Stanford University.

More information: Julio J Elias et al, Quality and safety for substances of human origins: scientific evidence and the new EU regulations, *BMJ Global Health* (2024). [DOI: 10.1136/bmjgh-2024-015122](https://doi.org/10.1136/bmjgh-2024-015122)

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