

Brussels, 24 April 2024

The European Blood Alliance (EBA) warmly welcomes the adoption of the SoHO regulation.

Peter O’Leary, EBA Executive Director, said “the text adopted today is a historic step forward for patients, donors, the blood sector, and all European citizens. Key developments include the strengthening of donor and patient protection and increasing the resilience of the SoHO supply system in Europe.”

The current blood directives came into force 20 years ago and were fundamental in setting a common minimum standard of quality and safety for blood products across the EU. In the last years, blood establishments have been calling on the EU to build on this foundation and evolve to an even safer and more agile legal framework, one that not only ensures the safety and quality of all blood products, but that also protects donors and better ensures a resilient and sustainable supply of all SoHO for Europe. The text adopted delivers on that aspiration.

EBA is particularly pleased that the SoHO Regulation:

- **strengthens the health protection of donors and patients.**

Donors are now more protected by the introduction of standards in the regulation, which do not exist in the current directives. Donors and patients’ health will be further protected by the setting up of a SoHO platform, donor registries, and minimum standards for data collection, which will help check that donors are not donating more frequently than is safe, and will allow more and better research on donor and patient health.

- **reaffirms the principle of voluntary non-remunerated donation and forbids financial gains.**

The clarification of the definition of compensation and the introduction of the principle of financial neutrality sets clear and transparent conditions for compensation. By forbidding donations from being a source of financial gain, the Regulation also protects donors and patients, while contributing to building more resilient SoHO supply systems.

- **contributes to increase the resilience and continuity in supply of SoHO**

In addition to reaffirming the principle of voluntary unpaid donation, the regulation promotes a diverse and broad donor-base to strengthen the resilience of SoHO supply systems. It also promotes a strong public and non-profit sector, while recognising that commercial interests may be a risk to the primacy of patients’ and the public’s interests. The Regulation also introduces robust requirements at national level to help ensure continuous and sufficient supply of critical SoHO. Nevertheless, these must still be complemented by an equally robust European strategy in the near future.

- **sets an agile and robust quality and safety standards system**

The Regulation introduces a stronger relationship with expert bodies of EDQM and ECDC, making safety and quality guidelines more directly applicable, with clear advantages for sharing SoHO and data across the EU. The future SoHO Coordination Board will play an important role in delivering the



full potential of the Regulation. EBA and its members will follow its work with great interest and invite the SCB to work with EBA as closely as possible.

EBA would like to thank all EBA members for their continuous focus on their donors and patients and to congratulate everyone who, over the last few years, worked to ensure that the SoHO Regulation meets the needs of European citizens. EBA is conscious that the work is only getting started and we call on all parties, at EU, national and regional level, to cooperate in the years ahead so that the Regulation can be successfully implemented in the agreed timeline.

About EBA:

The European Blood Alliance (EBA) is an association of 25 public and not-for-profit Blood Establishments across the EU, EFTA, and the UK. Together they share a goal 'to contribute to the safety and security of the blood supply for the citizens of Europe by developing and maintaining an efficient network of European blood services'. EBA members are working together in the interests of donors and patients to:

- contribute to the availability, quality, safety and cost-effectiveness of the blood and tissue supply for the citizens of Europe by developing and maintaining an efficient and strong collaboration amongst European blood and tissue services;
- increase public and professional awareness of voluntary and non-remunerated donation (VNRD) of blood and blood components, and of preparation of blood components as an indispensable therapeutic means to help patients;
- assist European blood establishments to continuously improve their performance, based on scientific and ethical principles for the benefit of patients.

For more detail visit <https://europeanbloodalliance.eu/>