

Joint PLUS Stakeholders' statement on the Commission proposal for a SoHO regulation

On 24th and 25th January 2023, PLUS¹ organised a Stakeholders Conference in which the following organisations were present: Alpha-1 Belgium, American Plasma Users Coalition (A-PLUS), European Blood Alliance (EBA), European Haemophilia Consortium (EHC), European Plasma Alliance, GBS-CIDP Foundation International, International Federation of Blood Donor Organisations, International Plasma and Fractionation Association (IPFA), International Patient Organisation for Primary Immunodeficiencies (IPOPI), Plasma Protein Therapeutics Association (PPTA).

The first session of the Conference focused on the revision of the SoHO legislation and it was agreed that this piece of legislation is key to enable the EU to collect more plasma for the supply of PDMPs. Increased plasma collection in the EU is a strategic imperative to allow optimal management of patients dependent on PDMPs.

The following key points were jointly identified:

Recital 13 - Plasma as implying a "significant risk"

This Recital was identified as a part of the Commission proposal text that should be optimised. As currently phrased this sentence could be subject to misinterpretation and could become counterproductive especially in a context needing to collect more plasma in the EU. Organisations in attendance have different proposals as to how this sentence should be improved but they all agreed that how it is currently worded is problematic.

Recital 18

"As a matter of principle, programmes promoting the donation of SoHOs should be founded on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient. Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health."

It was agreed by organisations in attendance that plasma for fractionation from remunerated and non-remunerated donors results in PDMPs of equivalent safety. This was stated by the European Medicines Agency (EMA) in the following document EMA/CPMP/BWP/1818/02/Final (available at: <https://www.ema.europa.eu/en/documents/scientific-guideline/cpmp-position->

¹ PLUS is a coalition of organisations which represent the views of over 110,000 patients in Europe who are regular users of plasma or plasma derived products. We represent the views of the European Haemophilia Consortium (EHC), the World Federation of Hemophilia (WFH), the International Patients Organisation for Primary Immune Deficiencies (IPOPI), Alpha Europe, the GBS-CIDP Foundation International, Hereditary Angio-Oedema International (HAEI) and the ITP Support Association.

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New Recital 33.a

“It is important that the Commission, the ECDC, the EDQM, when assessing scientific guidelines involve, when appropriate, existing professional, scientific, industry, donor and patient representative groups in the field of SoHOs”.

Justification: As a principle, stakeholders such as professional, scientific, industry, donor and patient representative groups should be included in the interest of transparency and expertise.

New Recital 37.a

Member States are encouraged to develop or strengthen plasmapheresis programmes to ensure capacity to collect more plasma and the Commission shall assist them in this task by providing guidance and facilitating the exchange of best practices.

Justification: it was agreed that by fostering more plasmapheresis, EU Member States will be in a position to increase their collection capacity. The Regulation should foresee the development of a European strategy with concrete timeframes to address the patients' needs and the current European dependency on third countries for the plasma required for the PDMPs.

New article 62 bis - **Implementation of a strategy for the promotion of European autonomy in the supply of SoHO**

The Commission shall, within two years of the adoption of this Regulation, publish a strategy for promoting greater European autonomy in the supply of SoHO. This strategy will set specific targets for SoHO, as defined by the Commission in coordination with national competent authorities, the European Parliament, and relevant professional, scientific, industry, donor and patient representative groups.

Justification: The Regulation should foresee the development of a European strategy with concrete timeframes to address the patients' needs and the current European dependency on third countries for the plasma required for the PDMPs.

