



Press release

IPOPI welcomes the Commission's proposal for a Regulation on Substances of Human Origin

The International Patient Organisation for Primary Immunodeficiencies (IPOPI) welcomes the European Commission proposal for a Regulation on standards of quality and safety for substances of human origin (SoHO) intended for human application published in July 2022. IPOPI considers that this proposal as a good basis to help tackling some of the shortcomings of the current system and will work with the EU institutions to ensure that the final legislative text is patient centred while ensuring the protection of donors.

Over the last years the demand for immunoglobulin replacement (Ig) therapies has been growing at a rate of about 8% per annum and Europe has increasingly been relying on US plasma to meet patient needs. This has prompted IPOPI and other relevant patient organisations to call for increased plasma collection in Europe and more regionally balanced plasma collection worldwide to attain global sufficiency in Plasma Derived Medicinal Products.

This much awaited proposal is therefore key to ensure that EU patients with primary immunodeficiencies (PIDs) and many other patients relying on plasma-derived medicinal products, can ultimately and sustainably access an appropriate supply of high quality and safe medicines. Ig therapy is a life-saving treatment for the majority of people with PIDs as it offers protection against life-threatening infections and reduces autoimmune symptoms. There is no alternative treatment for these patients.

IPOPI is pleased that this proposal effectively recognises patients and aims to ensure that they are protected and receive high quality and safe medicines. Additionally, we consider a positive step to recognise the importance of ensuring the availability of SoHOs to ensure optimal patient access and sufficiency of supply. At IPOPI we recognise and are grateful to both blood and plasma donors, for their gift of life. We consider it a good step forward that this proposal recognises donor compensation as compatible with the standards concerning voluntary and unpaid nature of SoHO donations.

In short, IPOPI considers the Commission proposal as an encouraging starting point to ensure that patients, such as patients with PIDs, can have access to their life-saving therapies in a safe and continued manner. IPOPI is committed to engage with policymakers in the next months to identify areas in the proposal which could be further improved and provide an optimal framework for the collection of life-saving plasma in Europe.

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About IPOPI: *The International Patient Organisation for Primary Immunodeficiencies is dedicated to improving awareness, access to early diagnosis and optimal treatments for primary immunodeficiency (PID) patients worldwide. More information: www.ipopi.org*