



The EU SoHO Regulation implementation at midpoint:

A call for national action to strengthen plasma collection systems in the EU

As we reach the midpoint of the three-year transition period foreseen for the implementation of the Regulation on Substances of Human Origin (SoHO), the International Patient Organisation for Primary Immunodeficiencies (IPOPI) wishes to reaffirm the central importance of patient-centred policy making and to highlight the urgent need to strengthen plasma collection in the EU to safeguard patient safety and access to life-saving therapies.

The SoHO Regulation, published in July 2024 and applicable from August 2027 following a three-year transition period, represents a major step forward in harmonising and modernising quality and safety standards for substances of human origin across Europe. IPOPI welcomes the Regulation's strengthened patient protection, its expanded scope compared to the previous Directives, and its flexible, future-proof approach through an open definition of SoHOs supported by technical guidance.

Crucially for patients, the Regulation recognises the importance of guaranteeing the availability of substances of human origin to ensure optimal access. For people living with primary immunodeficiencies (PIDs) and associated conditions, this recognition must now translate into concrete national action. A majority of patients with PIDs depend on lifelong immunoglobulin replacement therapies to prevent severe and recurrent infections. These therapies are plasma-derived medicinal products, manufactured from human plasma and regulated as pharmaceuticals under the pharma legislation. For many patients there is no therapeutic alternative to these lifesaving and life-enhancing therapies.

From a patient perspective, while immunoglobulin products in the European Union are highly regulated to ensure safety and quality, the main concern is the continuity of supply. Historical, persistent shortages continue to undermine treatment stability and place patients at risk. In June 2024, the European Medicines Agency reported immunoglobulin shortages affecting 14 European countries, with disruptions expected to continue throughout the year. This shortage information notification has been recurrently updated since and considers that the current shortages are expected to last at least until June 2026¹, although this timeline has already been postponed since the issuing of the first information notification in 2024. One of the main underlying causes is the limited availability of human plasma as the essential starting material.

IPOPI therefore strongly welcomes the SoHO Regulation's acknowledgement of the unique nature of plasma for fractionation, which differs significantly from blood, as well as the explicit

¹ European Medicines Agency. Shortage information on human normal immunoglobulins. <https://www.ema.europa.eu/en/medicines/human/shortages/human-normal-immunoglobulins> (last access January 16th, 2026).



recognition of the need to increase plasma collection to meet patient needs. While respecting Member States' competencies in organising blood and plasma collection systems, IPOPI urges national authorities to use the implementation phase to strengthen and optimize their plasma collection strategies.

In particular, IPOPI believes that plasmapheresis must be prioritised at national level to enable the collection of sufficient volumes of plasma in a safe and sustainable manner. In addition, pragmatic and well-regulated public-private collaboration should be embraced where appropriate, as a means to increase capacity, resilience, and donor engagement, while fully upholding safety, ethical standards, and public trust. The co-existence of both public and private plasma collection sectors in four Member States (Germany, Austria, Czechia and Hungary) has shown to deliver significantly higher levels of plasma collection than in other member states where only the public sector is involved. IPOPI believes this model should be seen as best practice and implemented in additional Member States where feasible, as the involvement of both public and private sectors is crucially needed to meet patient needs.

IPOPI also calls on national policymakers to ensure coherence between the SoHO framework and pharmaceutical legislation. Plasma for fractionation, regulated under SoHO, must be fully recognised as a critical raw material for finished medicinal products such as immunoglobulins. National implementation choices should support, rather than hinder, patient access to these life-saving therapies.

At this halfway point, IPOPI urges national decision-makers to seize the opportunity offered by the SoHO Regulation to build robust, patient-centred plasma policies and considering how their plasma collection model could be optimized. Ensuring sufficient, stable, and predictable access to immunoglobulin therapies is not only a regulatory objective, but a fundamental responsibility towards patients whose lives depend on them. IPOPI calls on national authorities to work with IPOPI's national member patient organisations and relevant stakeholders to support implementation that truly delivers for patients.