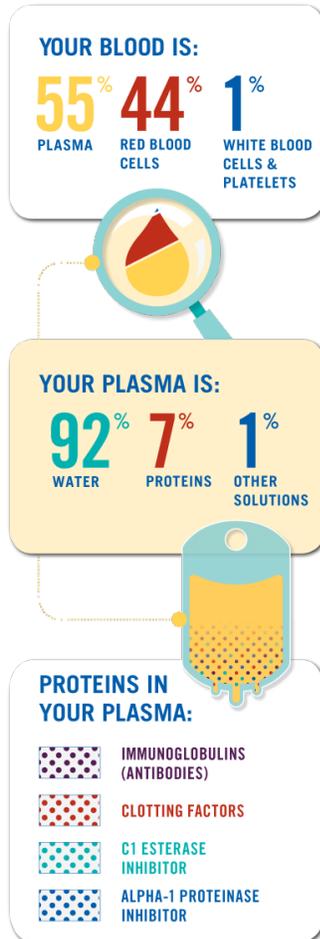


## Europe Needs to Collect More Plasma Position Paper

### Europe's need to collect more plasma



Plasma-derived medicinal products (PDMPs), derived from human plasma from healthy donors, are essential for around 300,000 European patients who rely on these therapies to treat a variety of rare, chronic, and potentially life-threatening conditions, which are often genetic in origin.<sup>1</sup> Without these treatments, many patients might not survive or would have a substantially diminished quality of life.

Plasma can be obtained from whole blood donations (resulting in recovered plasma) or collected directly through a process called plasmapheresis (resulting in source plasma). Plasma donation requires commitment from the donor, as it generally takes about one hour to donate plasma and can be donated more often than whole blood. The foundation of safe PDMPs is a regular healthy plasma donor population. Donating plasma is a very safe process with minimal or no side effects, just like a blood donation.

In Europe, 38% of plasma need is collected by public and NGO blood collection services, mainly via recovered plasma from whole blood donation. The private sector collects another 24%, but only from four countries (Austria, Czech Republic, Germany, and Hungary), mainly through plasmapheresis. For the remaining need of 38%, Europe is reliant on U.S. plasma imports.<sup>i</sup>

PPTA is calling policymakers at the national and EU level and concerned stakeholders to initiate an inclusive dialogue to increase plasma collection through plasmapheresis in Europe to decrease the reliance from third countries. As highlighted by the EU Commission, plasmapheresis is a more efficient method compared to the collection of recovered plasma.<sup>ii</sup>

### Stimulating plasma donations

Currently, in four European countries (Austria, Czech Republic, Germany, and Hungary) where public and private collectors coexist and work together, about 55% of source plasma is collected for the manufacturing of PDMPs in Europe. In these four countries four times more plasma per resident is collected compared to other countries.<sup>iii</sup> These countries allow plasma collection centres to compensate plasma donors for their expenses and inconveniences related to the donation. Compensating donors can be considered as a voluntary unpaid donation (VUD), which is conceptually recognized as such by analogy in the EU Tissue and Cells Directive,<sup>iv</sup> and also in the

<sup>1</sup> More patients across the EU are diagnosed every year with life-threatening plasma protein related disorders, such as immune deficiencies, immune-mediated peripheral neuropathies, Hereditary Angioedema, Alpha 1-Antitrypsin Deficiencies, Hemophilia and other bleeding disorders. In many cases, PDMPs are the only treatment option for these rare diseases. New indications, improved diagnostic techniques, greater use in emerging markets, an increased use in cancer treatment-induced secondary immunodeficiency are further contributing to the growing clinical need for PDMPs.

German Transfusion Law.<sup>v</sup> It is likewise reflected in the EU Commission Report on implementation of VUD Principle,<sup>vi</sup> and it is recognized by the Council of Europe DH Bioethics Committee.<sup>vii</sup> In addition, different types of incentives and compensation (e.g., tax benefits) are used by the public sector as well for the collection of whole blood.<sup>viii</sup>

### The role of the private sector

Over the past 10 years, the growth in plasma collection, to meet the growing clinical need for PDMPs, has mainly come from the private sector.<sup>ix</sup> For many years, the perception has been that coexistence between public and private collectors and the introduction of compensating donors could lead to a decline in whole blood donations (so called crowding-out). Nothing is less correct. Data<sup>x</sup> and publications from independent research institutes<sup>xi</sup> has shown that blood donations did not decrease because of the presence of private plasma centres, because whole blood and plasma donors are not part of the same donor population. The private sector has the expertise to share on operating efficient plasmapheresis programs.

### COVID-19's impact on plasma collection

Reports vary, but plasma collectors experienced significant declines in collections due, in part, to the impacts of social distancing measures and other mobility restrictions caused by the COVID-19 pandemic.<sup>xii,xiii</sup> Considering the complex manufacturing of plasma-derived therapies can take 7-12 months, any decline in plasma donations could impact patients' ability to access their lifesaving therapies.<sup>xiv,xv</sup> This sharp decline in plasma collections currently being experienced could cause more significant challenges in the months to come.

The COVID-19 pandemic thus introduced additional pressure on the fragile PDMP ecosystem and shed light on certain barriers which existed prior to the pandemic, with the potential to impact patients' access to PDMPs. The COVID-19 pandemic also highlighted the need to better prepare for future pandemics, during which plasma collection must be maintained and the therapeutic potential of convalescent plasma should be explored.<sup>xvi</sup>

### PPTA's position and asks

In order to collect more plasma in Europe and to ensure the availability of plasma, e.g. during a pandemic, European policies and planned changes to EU and national legal frameworks should:

- Recognize the unique nature of plasma and PDMPs and their ecosystem.
- Address Europe's reliance on U.S. plasma imports and remove current restrictive policies to establish a stronger plasma collection infrastructure by:
  - Establishing dedicated plasma collection (plasmapheresis) programs and coordinated outreach campaigns towards plasma donors in ALL EU Member States (MS).
  - Stimulating plasma donations by also allowing compensation of donors for expenses and inconvenience related to donation, similar to EU Tissues & Cells Directive 2004/23/EC, art. 12.1.
  - Allowing the co-existence of public sector and private sector plasma collection centres.
  - Differentiating between whole blood for transfusion and plasma collection for manufacturing of PDMPs, currently lacking in many policy frameworks, e.g., by defining what is plasma and donor compensation.



## About PPTA and its mission

The Plasma Protein Therapeutics Association (PPTA) is the global industry trade association with a strong European presence representing the private sector manufacturers of PDMPs, and privately-owned plasma donation centres, which includes more than 150 centres in Europe. PPTA is steadfast in its mission to promote the availability of, and access to, safe and effective plasma protein therapies for patients around the world.

## References

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- <sup>v</sup> German Transfusion Law, article 10 - [https://www.gesetze-im-internet.de/tfg/\\_10.html](https://www.gesetze-im-internet.de/tfg/_10.html)
- <sup>vi</sup> Commission staff working document on the implementation of the principle of voluntary and unpaid donation for human blood and blood components as foreseen in Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC – More info: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52016SC0130>
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