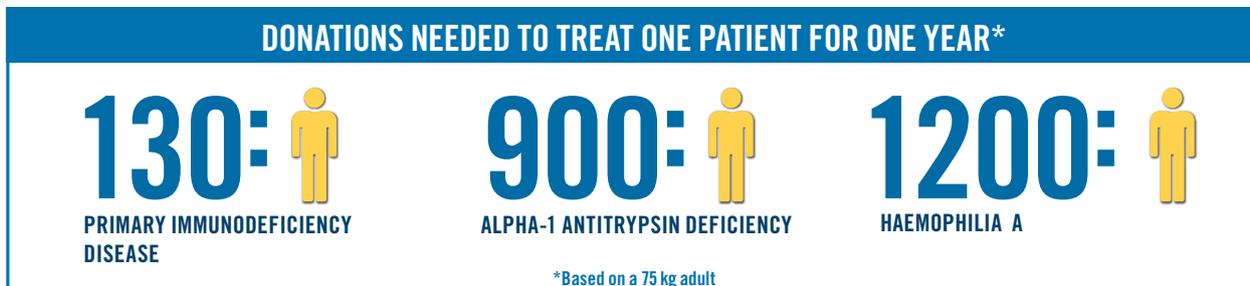


Compensating plasma donors

The current state of plasma donation for plasma-derived medicinal products in the EU

Plasma-derived medicinal products (PDMPs) help patients living with a range of rare diseases that can only be treated by these therapies.



- In the EU, 56% of plasma is collected by public and NGO blood collection services and this is mainly recovered from whole blood donations. The private sector collects 44% of plasma in Europe, but from only **four countries** (Austria, Czech Republic, Germany, and Hungary), via **plasmapheresis**. This equates to 62% of the EU need.
- To cope with the growing clinical need for PDMPs, **the EU is reliant of 38% (or 5.15 million litres)¹ of plasma from the U.S.**

Plasma can be obtained in two ways:

1

By **'direct' donation** in dedicated plasma centres that use the **'plasmapheresis'** process (source plasma). This process is mainly used by **private plasma donation centres**. Here, the donor's blood runs through a medical device that separates plasma from other blood cellular components, which are then returned to the donor.²

2

By **separation** from **whole blood donation** in the public blood centre (Red Cross, NGOs etc.) system (recovered plasma). After the blood donation, blood is separated into different components; plasma is one of these.

Compensation policies and practices

A report by the European European Commission highlights that **23 countries in the European Union provide some form of compensation to plasma donors**: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Malta, Poland, Romania, Spain, Slovenia and Sweden.

These compensation examples address **expenses** incurred and recognise the **inconvenience** related to donating, following the principle of **Voluntary Unpaid Donation** (VUD).

EU countries have different approaches that are all compatible with the principle of VUD. Some apply fixed-rate allowances, others reimburse specific expenses or compensate people with time off from work, tax reductions, vouchers, or by other means.

Compensation includes:

- Reimbursement of medical costs
- Compensation for effort and inconvenience linked to loss of earnings
- Free physical check-up
- Food vouchers
- Time off work
- Reimbursement of travel costs
- Small tokens
- Refreshments

Compensation practices in Austria, Czech Republic, Hungary, and Germany

In Austria, Czech Republic, Germany and Hungary, private plasma donation centres offer **fixed-rate allowances**, in compliance with the **VUD principle**.³ This approach is supported by:

- European Commission Report on implementation of the Voluntary Unpaid Donation Principle⁴
- EU Tissue & Cells Directive (2004/23/EC, art. 12.1.)⁵
- German Transfusion Law, article 10.⁶
- Council of Europe DH Bioethics Guide Committee on Bioethics (DH-BIO), article 23, 24.⁷
- Nuffield Council Guide on Bioethics 8 and the German Transfusion Law⁸

Experience shows that offering a “fixed-rate allowance” is the most efficient form of compensation for collecting plasma.

Why should plasma donation be compensated?



Plasma donation via plasmapheresis requires a commitment in terms of the amount of time spent in the donation process.



Donating plasma takes longer than giving blood and is a more complex process.

To collect more plasma across Member states and reduce the EU’s reliance on U.S. plasma, PPTA proposes that the revision of the EU Blood Directive should specify that “an allowance that is limited to making good the expenses and inconveniences related to each specific type of donation” is compliant with Voluntary Unpaid Donations or Voluntary Non-Remunerated Donations.

This approach is considered ethically acceptable by bioethical bodies such as the Council of Europe Committee on Bioethics (DH-BIO)⁹ and the Nuffield Council on Bioethics.¹⁰

About PPTA

The Plasma Protein Therapeutics Association is the global industry trade association with a strong European presence representing the private sector manufacture of plasma-derived medicinal products (PDMPs) and privately-owned plasma donation centres, including more than 160 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 worldwide.

References

1 Marketing Research Bureau, 2021.

2 "COVID-19: Commission supports blood services to increase COVID-19 convalescent plasma collection." 11 January 2021.

https://ec.europa.eu/commission/presscorner/detail/en/ip_21_50.

3 The concept of 'fixed-rate' compensation is defined in the DH BIO Interpretation Guide of the Principle of Prohibition of Financial Gain.

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4 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. <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52016SC0130>.

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9 Idem reference 7.

10 Idem reference 8.