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PPTA
Plasma Protein Therapeutics Association

Together toward a broader European plasma donation ecosystem

New thinking & approaches to plasma donation to benefit Europe's patients

Medicines made from human-donated plasma are essential for some 300,000 patients across the EU who rely on them every day to treat a variety of rare, chronic, and life-threatening conditions[1].

Public health evidence suggests that European countries will have an increasing need for plasma-derived medicines needed to treat their patients.

European countries need more plasma: new approaches to donation will help

The use of plasma-derived medicinal products (PDMPs) by European patients has grown steadily over the past decade. To address this evolving clinical need, public health decision makers will need to evolve their policies to ensure a safe and stable supply of plasma donations, which are needed to manufacture these life-saving treatments.

Several European countries have put in place new approaches to plasma donation that encourage more sustainable access to plasma. They have networks through which locally-donated plasma is given in mixed public-private donation centres.

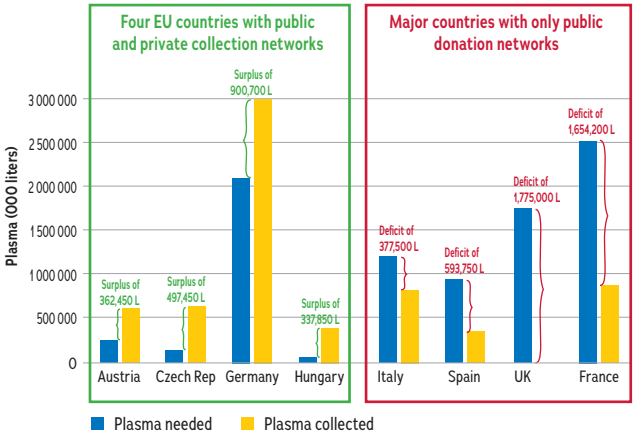
For many conditions that plasma-derived medicines treat, patients have no alternative treatments.

Where does Europe's plasma come from?

Today, some 38% of the plasma used to manufacture PDMPs for EU patients comes from the U.S.[2].

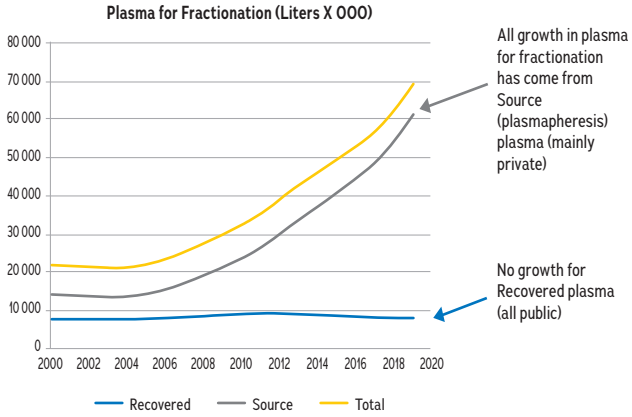
European countries have different options to build systems for safe and stable plasma donations. Options include fully public systems; and combined public-private plasma donation networks.

The EU's plasma deficit and our need for more plasma



Today, the EU has a shortfall of 5.15 million litres of the plasma needed to manufacture life-saving plasma-derived medicinal products. For example, over the past 10 years, the use of immunoglobulins – the most commonly used plasma-derived medicines – has almost doubled. A European Commission survey (2014) shows that demand for plasma derivatives needed for medicines is increasing by some 8% yearly.

Some European countries have created effective public-private plasma donation networks



Countries with a combined public-private donation model contribute the most plasma that is donated in the EU. The public sector has shown little growth in plasma collection over the past decade. In contrast, over the same period, private plasma donation centres have delivered most of the EU's increased plasma collection that is required to meet the growing clinical need for PDMPs.

PER PATIENT PER YEAR:

MORE THAN **1200:** Plasma donations to treat ONE PATIENT for HAEMOPHILIA.

MORE THAN **900:** Plasma donations to treat ONE ALPHA-1 PATIENT.

MORE THAN **130:** Plasma donations to treat ONE PATIENT with a PRIMARY IMMUNE DEFICIENCY.

Public-private plasma systems can coexist

In the European Union, 56% of plasma is collected by public and NGO blood collection services, mainly recovered from whole blood donations.

The private sector collects 44% of Europe's plasma, but only from four countries – Austria, Czech Republic, Germany, and Hungary – using direct plasma donation (plasmapheresis)[3].

In these countries, private plasmapheresis donation centres coexist with public services that collect whole blood and plasma. They collect four times more plasma per 1000 inhabitants compared with other EU countries[4]. The European Commission highlights that plasma donation by plasmapheresis is more efficient, when compared with recovering plasma from whole blood donations[5].

Will opening more plasma donation centres reduce whole blood donations in a country?

There is no evidence to support the perception that the coexistence of public and private plasma donation centres – and compensating donors for their expenses and inconvenience – leads to a decline in whole blood donations[3]. Decreases in the availability of whole blood, which have been noted in some countries, are caused by lower demand for whole blood, according to a European Commission report on implementing legislation on standards and quality of blood and blood components[6].

A recent study[12] of the evolution of the Czech Republic's public-private donation system shows that blood collection volumes and frequency have remained stable as private plasma donation has grown.

Between 2007 and 2010, volumes of whole blood collection remained stable, as private plasma donations increased nearly tenfold – from 6.8 litres per 1000 people in 2006 to 50 litres per 1000 people in 2010.

Austria, Germany and Hungary report that their public-private systems show similar results. Public health officials in these countries have found that compensating donors for their effort and inconvenience is a determining factor in their ability to increase and sustain stable volumes of locally-donated plasma.

Plasma donation approaches are compatible with Voluntary Unpaid Donation principles.

Today, almost all EU countries provide some form of compensation for plasma donors. This compensation covers expenses incurred and recognises the inconvenience related to donating, following the principle of Voluntary Unpaid Donation (VUD)[7].

In four EU countries (Austria, Czech Republic, Germany, and Hungary), private centres apply compensation as a fixed-rate allowance[8**]. This approach follows the thinking of the EU Tissue and Cells Directive and is fully compatible with the Voluntary Unpaid Donation, as recognised in the EU Commission Report on implementation of the VUD Principle[7], the Council of Europe DH Bioethics Guide[9], Nuffield Council Guide on Bioethics[10], and the German Transfusion Law[11].

Making plasma-derived medicines is fundamentally different from synthesised pharmaceuticals

- The essential building block of plasma-derived medicines is human-donated plasma. It cannot be re-created in a laboratory or by synthesis used for small molecule medicines production.
- It takes **1 month** to produce small-molecule pharmaceutical medicines.
- On average it takes **7-12 months** to produce plasma-derived medicines.
- Each plasma-derived medicine has its unique biochemical profile. It is not interchangeable with other treatments. Medicines regulators specify them as treatments for which no generic or substitution treatments exist.

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Overview of compensation for plasma donation costs and inconvenience to donors

In some countries, donors can receive a fixed compensation that is not directly related to actual costs incurred. Some examples:

Belgium's official documents on blood, platelets and plasma refer to voluntary unpaid donations. Donors employed in the public sector are allowed leave from work for the duration of the donation, plus a maximum of two hours of travel.

Denmark's policy specifies voluntary, non-remunerated donations. Regional authorities, which run the Danish public hospitals, give a small fee per donation to the local donor-association to cover administrative and publicity costs.

Estonia's guiding principles mention the possibility of giving incentives to donors of blood and blood components.

Greece says that giving donors small souvenirs, soft drinks and travel costs is compatible with its voluntary and unpaid blood donation rules.

Italy's policy allows public and private sector employees the day off when they donate blood or plasma; donor associations receive specific payments per donation to cover administrative and publicity costs.

Latvia's guiding principles cover incentives to donors of blood and blood components, and policies to promote self-sufficiency of blood and blood components.

Lithuania's guidance covers similar incentives for donors. Depending on the volume donated, donors may receive a compensation of up to two days of average salary.

Finland specifies travel expenses may be reimbursed to the donor, within its voluntary and unpaid framework.

The Netherlands specifies that plasma is to be given by voluntary donors, who may receive compensation, which will not be beyond a reasonable cost of expenses incurred.

Poland's blood and plasma donors are offered a recovery meal and can make a modest tax deduction and, in some cases, two days off work.

Slovakia's incentive policy is enacted by each city; employers may recognise their employees' efforts with a financial bonus or a holiday allowance.

Published by The Plasma Protein Therapeutics Association (PPTA – www.pptaglobal.org), a global industry trade association, representing the private sector manufacturers of plasma-derived and recombinant analog therapies, collectively known as plasma protein therapies, and the collectors of source plasma used for fractionation. Millions of people use these therapies worldwide to treat a variety of diseases and serious medical conditions. PPTA also administers standards and programmes that help ensure the quality and safety of plasma protein therapies, donors and patients.

References

1. 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, and increased use in in cancer treatment-induced secondary immunodeficiency are further contributing to the growing clinical need for PDMPs.
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4. Statement from the European Commission: Coronavirus: European Commission strengthens support for treatment through convalescent plasma. https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1435 (accessed September 2021)
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8. It is the responsibility of each Member State to define the details and conditions for compensation. The concept of 'fixed-rate' compensation is defined in the DH BIO Interpretation Guide of the Principle of Prohibition of Financial Gain https://rm.coe.int/guide-for-the-implementation-of-the-principle-of-prohibition-of-financ/16807af9a3

   ** In all countries where donors are compensated, including countries that apply a fixed-rate compensation, Member States define the conditions.
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12. Lacetera. N and M Macis. Working Paper: "Do paid plasma centers crowd out altruistic donation? Evidence from a natural experiment in the Czech Republic." October 2017.