Plasma-Derived Medicines

Uniquely Saving Lives

PPTA

THE POWER OF PLASMA

Patients with extremely rare diseases depend on access to plasma-derived medicines to save and sustain their lives. Plasma-derived medicines are different from pharmaceutical pills and tablets.

The differences begin with the starting material, plasma obtained from healthy donors, which over a time period of up to 12 months is manufactured into high value therapies. **PPTA's primary focus is to maintain access to all plasma-derived medicines that are lifesaving for rare disease patients with no other treatment options.**

Plasma-Derived Medicines: Uniquely Saving Lives

Treating Rare Diseases

Plasma is the straw-colored liquid portion of blood. It contains hundreds of proteins, such as antibodies to fight diseases and clotting factors to control bleeding. If a person has insufficient levels of any one plasma protein, his or her body cannot carry out certain vital functions, causing a variety of chronic and life-threatening medical conditions.

Plasma-derived medicines are unique biologic medicines that treat people with plasma protein deficiencies and dysfunctions. These disorders occur in a very small patient population and belong to a group of rare diseases. In Europe, a disease is considered rare if it affects 1 individual in 2,000.[1]

Your blood is:

- **55%** PLASMA
- **44%** RED BLOOD CELLS
- **1%** WHITE BLOOD CELLS & PLATELETS

Your plasma is:

- **92%** WATER
- **7%** PROTEINS
- **1%** OTHER SOLUTIONS

Examples of proteins in your plasma:

- IMMUNOGLOBULINS (ANTIBODIES)
- CLOTTING FACTORS
- C1 ESTERASE INHIBITOR
- ALPHA-1 PROTEINASE INHIBITOR

European Patients in Need of Plasma-Derived Medicines (Estimates)*

CAUSES & SYMPTOMS

PRIMARY IMMUNODEFICIENCY DISEASES (PID)

- Caused by missing or malfunctioning immunoglobulins (antibodies)
- Antibodies control the immune system and prevent illness
- Patients are chronically ill from severe, persistent, recurrent infections

375,000[2]

CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP)

- Cause not certain; immune system attacks nerve coating
- Messages from the brain aren't delivered to the body if nerve coating is damaged
- Patients experience progressive weakness, loss of limb function, and disability

62,000[3]

HAEMOPHILIA

- Caused by missing or malfunctioning clotting factor protein
- Clotting factors control bleeding
- Patients cannot regulate bleeding (joint damage is common)
- Can be fatal if bleeding occurs in brain or vital organs

150,000[4]

HEREDITARY ANGIO-OEDEMA

- Caused by missing or malfunctioning C1 esterase inhibitor protein (C1-INH)
- C1-INH helps control inflammation
- Patients have oedema (severe swelling)
- Can be fatal if airway obstructed

15,000[5]

ALPHA-1 ANTITRYPSIN DEFICIENCY

- Caused by missing or malfunctioning Alpha-1 Proteinase Inhibitor
- Alpha-1 Proteinase Inhibitor protects the lungs
- Patients have chronic emphysema and liver damage

75,000[6]

*Based on European population of 750,000,000.

Plasma-Derived Medicines: Uniquely Saving Lives

Made From Plasma

Donated Plasma Is A Limited Starting Material

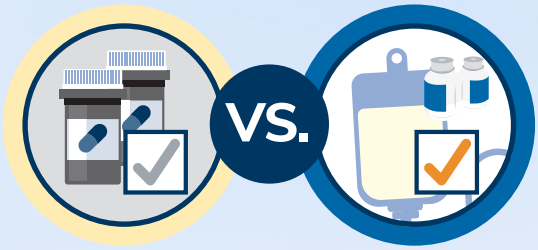
The starting material for plasma-derived medicines is not an infinite resource. Rather than using synthetic or chemical ingredients, plasma-derived medicines are made using human plasma. Plasma cannot be made synthetically in a laboratory. Plasma and its lifesaving proteins can only be voluntarily donated by people who so generously give their time to donate.

PHARMACEUTICALS
Production begins with synthetic or chemical ingredients.

PLASMA-DERIVED MEDICINES
Production begins with a biological starting material (human plasma).

Authorization

EMA certifies establishments which collect plasma for manufacturing through the Plasma Master File (PMF) certifications, and thus qualifies its collection processes as to ensure they are carried out in line with the European regulations. In addition, each of these establishments is under separate supervision of the local and national regulatory authorities. In the European Union, all plasma-derived medicines are either centrally authorized by the European Medicines Agency (EMA), or by Member States' National Regulatory Authorities before they can be marketed.



The authorization procedure for plasma-derived medicines is different and more complex in comparison to the traditional chemical compounds.

Plasma Collection

Plasma is collected from healthy, committed donors through a process called plasmapheresis, during which the liquid portion of the blood is removed and red cells and other blood components are returned to the donor. The body replaces plasma more quickly than red cells. This is why plasma can be donated more frequently than whole blood.

Importantly, the frequency of plasma donations is regulated by national health authorities. Donor safety and related donor health parameters (such as protein levels) are monitored regularly, as per national regulations, to ensure that donor health is maintained.

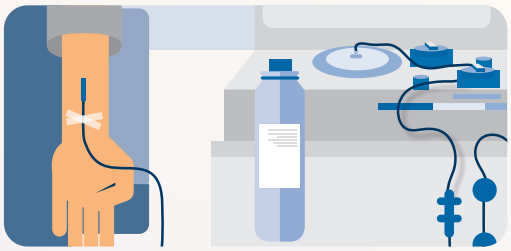
PPTA members collect plasma in more than 190 donation centers in Europe. After collection, the plasma donation is frozen and shipped to a state-of-the-art facility for manufacture into lifesaving plasma-derived medicines.

ESTIMATED DONATIONS NEEDED FOR ONE PATIENT FOR ONE YEAR:

130: PRIMARY IMMUNODEFICIENCY DISEASES

900: ALPHA-1 ANTITRYPSIN DEFICIENCY

1200: HAEMOPHILIA



Plasma-Derived Medicines: Uniquely Saving Lives

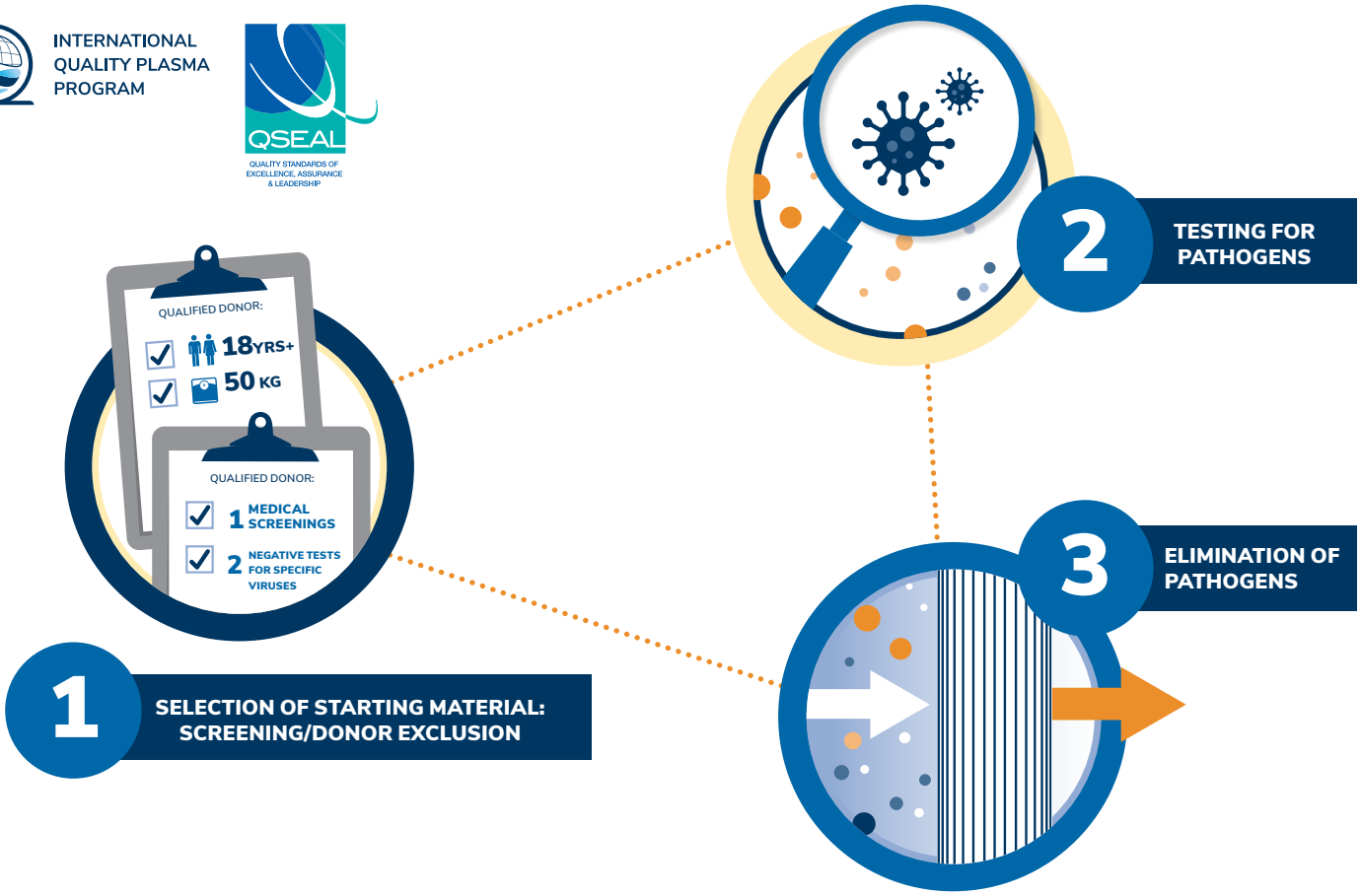
Constant Vigilance for Safe Products

Plasma-derived medicines require constant vigilance for safe products. There are three types of safeguard measures used in plasma donation and manufacturing to ensure safe plasma-derived medicines:

Voluntary industry standards often exceed regulatory requirements.

INTERNATIONAL QUALITY PLASMA PROGRAM

QSEAL
QUALITY STANDARDS OF EXCELLENCE, ASSURANCE & LEADERSHIP



Current manufacturing protocols are extremely effective against pathogens.

The industry has a record of safety from pathogens for more than 30 years.[7]

Evolving Protocols

Unlike traditional pharmaceuticals or other biologics where standard quality assurance practices are sufficient, plasma-derived medicines' safety protocols are constantly evolving due to new and emerging pathogens.

Companies continuously perform tests to demonstrate that their viral inactivation and removal steps work on new pathogens. For instance, over the years, companies have dedicated substantial time and resources to research coronaviruses, ensuring they pose no threat to the safety of plasma-derived medicines. The industry continuously invests in research and development and safety protocols are constantly evolving to keep the plasma supply safe from new and emerging pathogens.

Plasma-Derived Medicines: Uniquely Saving Lives

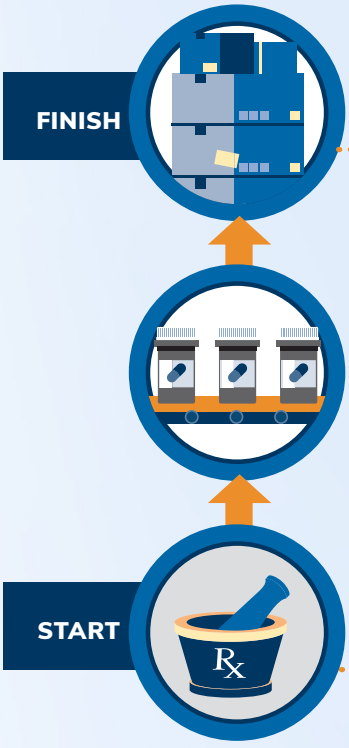
Uniqueness[9]

Plasma-Derived Medicines are Highly Complex to Manufacture

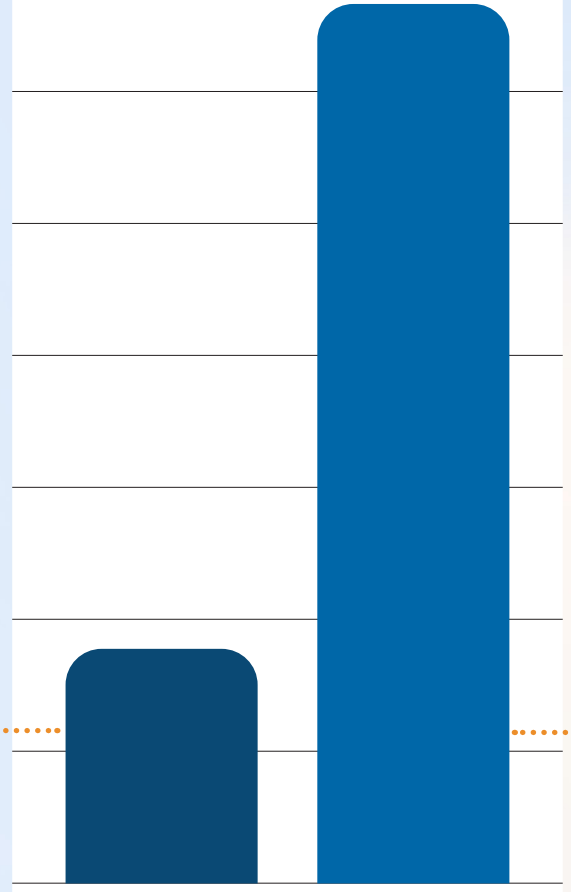
Plasma-derived medicines take **UP TO 12 MONTHS** to manufacture. Companies must adhere to rigorous regulatory requirements to ensure manufacturing consistency and pathogen safety.

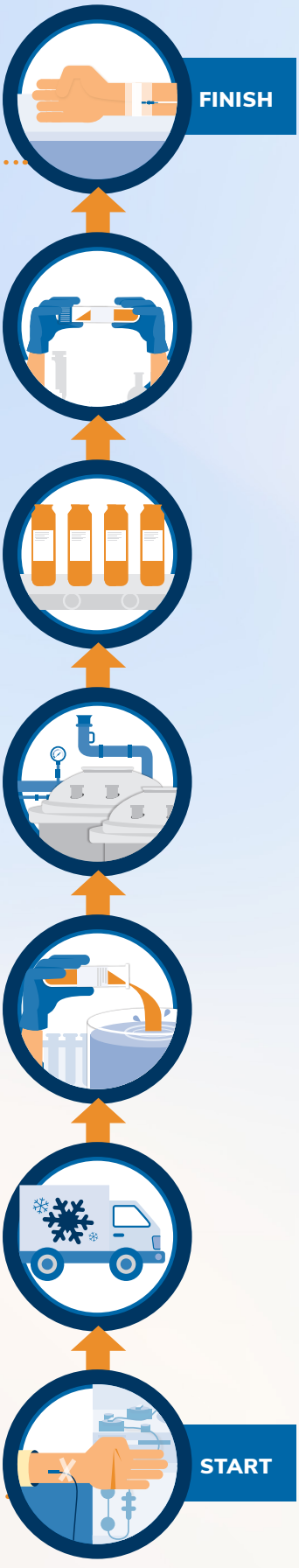
COSTS ATTRIBUTED TO MANUFACTURING & RAW MATERIALS[10]

14% PHARMACEUTICALS **VS.** **57%** PLASMA-DERIVED MEDICINES



PHARMACEUTICALS





PLASMA-DERIVED MEDICINES

Plasma-Derived Medicines: Uniquely Saving Lives

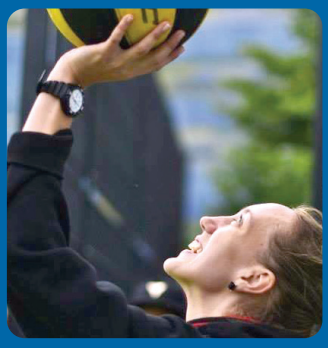
Value to Patients

As different policies to slow health spending are debated, it is critical to maintain access to lifesaving treatments for rare disease patients. A one-size-fits-all policy does not work for plasma-derived medicines as these biologics are not interchangeable.

Plasma-derived medicines increase life expectancy, improve quality of life, and reduce life-threatening complications for individuals with plasma protein deficiencies or abnormalities.

Frank, individual with Alpha-1 Antitrypsin Deficiency

"Without treatment, I think my life would be quite different. [...] I know today that I am treated for nine years and my lungs are stabilized, that means I can do some sports, I can do my daily work as I would like to. I have a high quality of life because I have a lot of mobility, I can go wherever I want, I don't need a wheelchair, I don't need oxygen and I know also that tomorrow I will have the same quality of life as today."

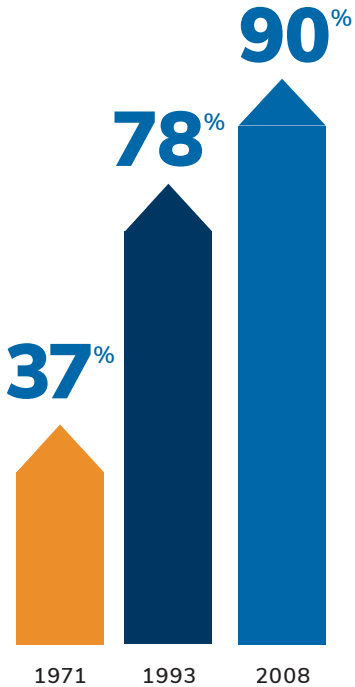


Janika, individual with Common Variable Immune Deficiency (PID disorder)

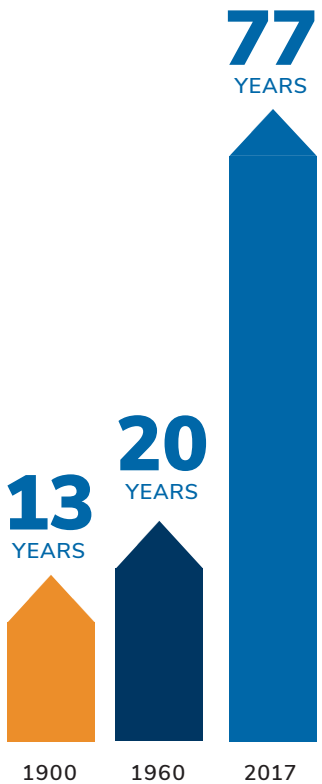
"I was sick a lot and missed out on plenty of things kids my age were doing at that time. During my first year in college my condition worsened pretty fast, I couldn't keep up with others, and I was often on antibiotics.

I received a diagnosis (CVID) in 2008 and my life changed completely once I began receiving immunoglobulin subcutaneously. I remember waking up in the morning and feeling full of energy like I honestly had never felt before. I am truly grateful for receiving a real chance at life."

10-year survival rate of patients with COMMON VARIABLE IMMUNE DEFICIENCY, by year[11]



Life expectancy of a patient born with HAEMOPHILIA, by year[12]



Plasma-Derived Medicines: Uniquely Saving Lives

Non-Interchangeability

One-size-fits-all policies are unsuitable for plasma-derived medicines and endanger patient health. Each therapy is non-interchangeable due to the pharmacologic and manufacturing differences that exist across different brands and patients' unique response to the treatments.

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

"[...] Take into account that human normal immunoglobulin therapeutic products differ from one another in terms of production processes, which might have an impact on specifications and clinical performance." [13]

IRIS

"Immunoglobulins are not interchangeable with each other, they are not generic medicines, prescribers must have long-lasting and readily available preparations."[14]

Health Canada

"Intravenous Immunoglobulin (IVIG) preparations are not considered identical, and no consideration can be given to approve a specific IVIG product, based on the proven safety and efficacy in established indications for other marketed IVIG products."[15]

IPOPI
INTERNATIONAL
PATIENT ORGANISATION
FOR PRIMARY IMMUNODEFICIENCIES

"It is important to realize that there is no single immunoglobulin (Ig) product or method of administration that is suitable for all PID patients. [...] All countries and immunodeficiency centers should have access to a wide spectrum of Ig products, to provide optimal treatment for all immunodeficient patients." [16]

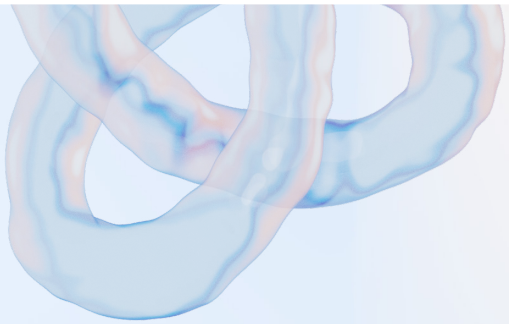
Department of Health

"Although the active ingredient in IVIg - purified immunoglobulin - is the same from brand to brand, there are considerable differences in the manufacturing processes used. This results in individual products that cannot be used interchangeably."[17]

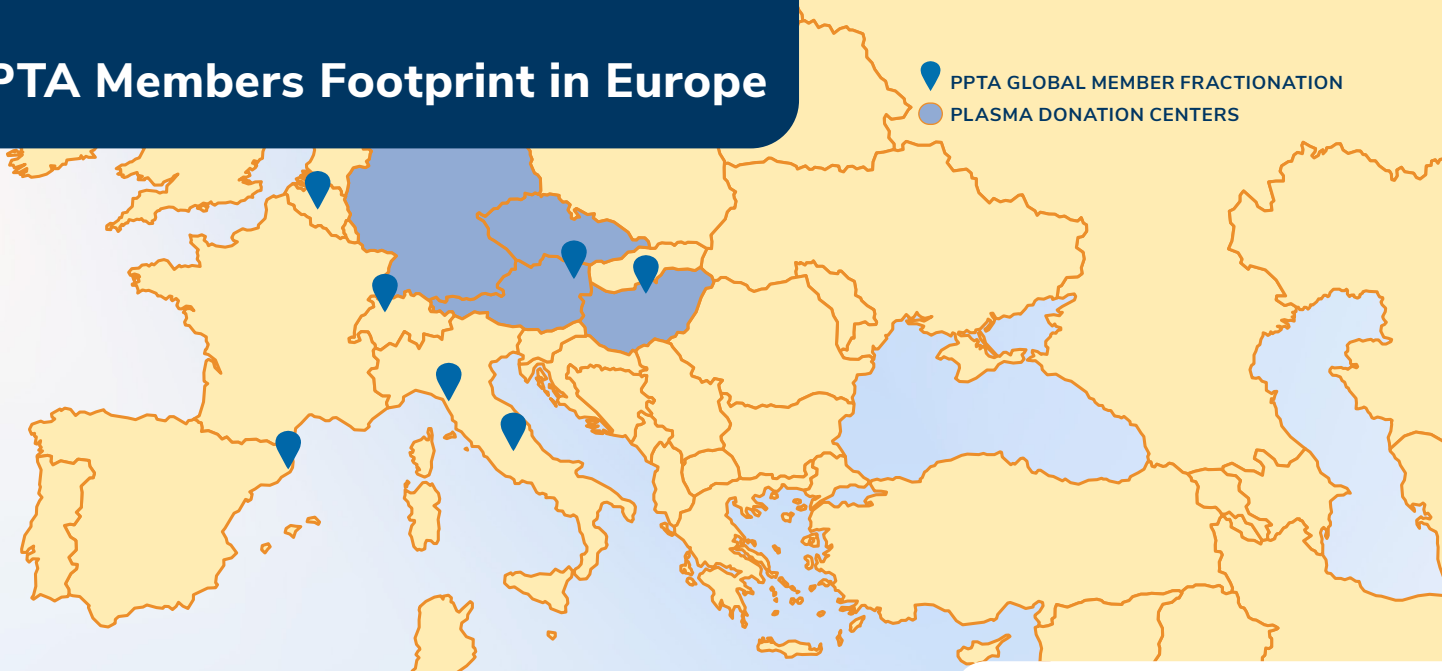
NATIONAL
BLEEDING
DISORDERS
FOUNDATION

"It is critical that the bleeding disorder community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed."[18]

1. EU Commission proposal for EU Council of Ministers, Recommendation 11.11.2008 for a European action in the field of rare diseases. Definition of a rare disease as having a prevalence of no more than 5 in 10,000 first appeared in Europe in EU regulation 141/2000/EC on orphan medicinal products.
2. International Patient Organisation for Primary Immunodeficiencies (IPOPI) https://ipopi.org/.
3. As calculated by the European Patient Organisation for Dysimmune and Inflammatory Neuropathies (EPODIN) in the April 2026 Advocacy Analytical Report "Executive Synthesis Report CIDP Patient Estimates in Europe."
4. European Haemophilia Consortium (EHC) https://www.ehc.eu/.
5. David M. Lang et al. "International consensus on hereditary and acquired angioedema", Annals of Allergy, Asthma & Immunology, Volume 109, Issue 6, December 2012, Pages 395-402.
6. Orphanet http://www.orpha.net/consor/cgi-bin/index.php.
7. Tabor E. The epidemiology of virus transmission by plasma derivatives: clinical studies verifying the lack of transmission of hepatitis B and C viruses and HIV-1. Transfusion. 2002;42:1159-74.
8. PSSC Statement: Zika Virus and Plasma Protein Therapies. https://www.pptaglobal.org/material/zika-virus-and-plasma-protein-therapies.
9. "The Government recognises the need for specific procurement provisions (in comparison to classical pharmaceuticals) in order to maintain adequate supply of plasma protein therapies [...]." Adapted from UK Department of Health, Changes to the statutory scheme to control the prices of branded health service medicines. Consultation response 2016, article 20, page 9.
10. https://copenhageneconomics.com/wp-content/uploads/2026/03/The-impact-of-plasma-derived-therapies-in-Europe-Copenhagen-Economics-March-2026.pdf
11. Chapel H, Lucas M, Lee M, et al. Common variable immunodeficiency disorders: division into distinct clinical phenotypes. Blood. 2008; 112(2):277–286.
12. Aledort, L. The evolution of comprehensive haemophilia care in the United States: perspectives from the frontline. Haemophilia. 2016; 22(2) 676–683.
13. Council of Europe, Resolution CM/Res(2015)2 on principles concerning human normal immunoglobulin therapies for immunodeficiency and other diseases (Adopted by the Committee of Ministers on 15 April 2015 at the 1225th meeting of the Ministers' Deputies)
14. Immuno-déficience primitive, Recherche, Information, Soutien (I.R.I.S.) Position Statement Summary https://cdn.prod.website-files.com/642d14a4952aaf05561fa4e0/6594417b704030cde0a29ba5_Positionnement_association_IRIS_lg.pdf.
15. Health Canada Effective Date: 2004/08/04 http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/ivig-igiv-eng.pdf
16. Frontiers in IMMUNOLOGY, Primary Immune Deficiencies – Principles of care; Hypothesis and Theory Article, published: 15 December 2014, doi: 10.3389/fimmu.2014.00627
17. Clinical Guidelines for Immunoglobulin Use; the UK Department of Health, 2008, p. 15
18. National Bleeding Disorders Foundation., Medical and Scientific Advisory Council Recommendation #159. https://www.hemophilia.org/sites/default/files/document/files/masac159.pdf.
19. https://copenhageneconomics.com/publication/impact-of-plasma-in-europe/
20. Marketing Research Bureau, presentation Global Plasma Collection - Is there enough?, IPFA-EBA Symposium, February 2026 https://ipfa.nl/wp-content/uploads/2025/06/Global-plasma-collection-Is-there-enough-M.-Hotchko.pdf (accessed April 2026) - slide 8.



PPTA Members Footprint in Europe

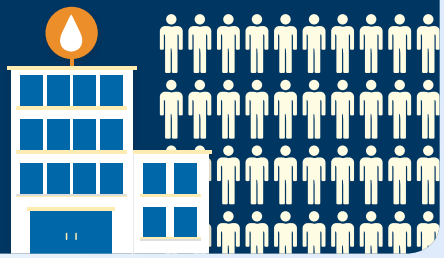


190+
PLASMA DONATION CENTERS

BUT MORE EUROPEAN PLASMA IS NEEDED.

Employment

PPTA members make a substantial contribution to employment, supporting over **25,000** direct jobs across the supply chain in Europe.

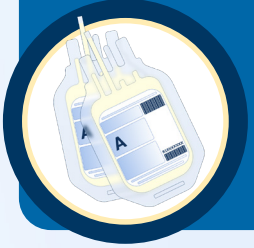


Impact in the European Economy

The plasma-derived medicines industry contributes **€6.6 billion annually** to the European economy, with the cumulative direct, indirect, and induced efforts **totaling €14 billion.**[19]

Volume of Collection (2024)

10 million liters of plasma for fractionation were collected in Europe.[20]



52%
from private collectors in Austria, Czechia, Germany, Hungary.

Donor Commitment

On average, a donor donates **17,5 times per year**, for an hour to an hour and a half.

Europe remains heavily reliant on U.S.-sourced plasma to help meet patient needs, underscoring the urgent need to strengthen local plasma collection and supportive policies across Europe so more patients can access the therapies they depend on.

PLASMA PROTEIN THERAPEUTICS ASSOCIATION

Global Members

GRIFOLS

KEDRION BIOPHARMA

Takeda

European Plasma Alliance (EPA)

The EPA is an alliance of 9 European private sector plasma collectors:

Biolife (Takeda)
Cara Plasma (Grifols)
Europlasma
Haema (Grifols)
Haema Plasma Hungary (Grifols)
Octapharma Plasma
Plasma Place
PlasmaVita
Unicaplasma (Kedrion)

April 2026
pptaglobal.org

Plasma-Derived Medicines: Uniquely Saving Lives

Everyday Medicine

Rh Incompatibility

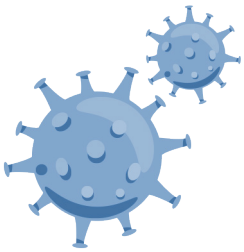
During pregnancy, a mismatch in the type of rhesus (Rh) factor (a protein found on the surface of red blood cells), between a mother and fetus can lead to hemolytic disease of the newborn (HDN). Rh incompatibility occurs when a Rh-negative mother is carrying a Rh-positive fetus. In that case, the mother's immune system sees the red blood cells of the fetus as foreign and develops antibodies which attack them.

This can cause severe anemia in the fetus or newborn, as well as jaundice as the broken-down red blood cells produce bilirubin. The level of bilirubin in the infant's blood may range from mild to dangerously high. Plasma-derived Rh immunoglobulins (RhIg) administered during pregnancy can neutralize the fetus's Rh-positive red blood cells, preventing maternal sensitization and HDN.

Cancer

Plasma-derived medicines often play a supportive role in the treatment of cancer patients. Plasma-derived immunoglobulins (IG) can be used to address treatment-related immunosuppression and reduce the risk of infections in patients undergoing chemotherapy or radiation. Additionally, plasma-derived clotting factors can help cancer patients who experience clotting disorders or increased risk of bleeding due to their cancer or related treatment.

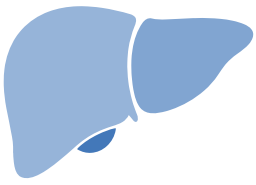
In addition, albumin is also used as a carrying agent for some cancer medications, due to it being preferentially internalized by tumor cells. This can prolong the half-life of otherwise rapidly cleared drugs and promote their accumulation within tumors.



Liver Conditions

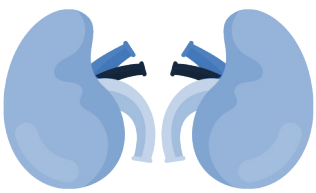
Plasma protein therapies such as albumin and prothrombin complex concentrates can be beneficial in managing complications associated with liver conditions. Albumin infusions help maintain fluid balance, stabilize blood pressure, and reduce the risk of abnormal swelling and fluid buildup in patients with cirrhosis.

Some liver disease patients experience an impairment in their own body's ability to produce clotting factors and can require fresh frozen plasma or plasma derived clotting factors to manage and prevent bleeding.



Organ Transplantation

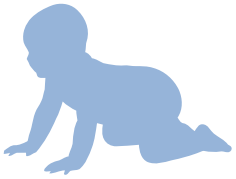
Transplant recipients are at high risk of graft rejection, which occurs when the recipient's immune system attacks and begins destroying the transplanted tissue or organ. To prevent this, recipients are often given immunosuppressive medications, leaving them vulnerable to opportunistic infection. Plasma-derived immunoglobulins can bolster the immune system and minimize the risk of infections, making them an important adjunct in post-transplant care.



Everyday Medicine

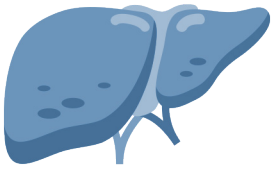
Pediatric HIV

Children infected with HIV often experience immune system deficiencies that predispose them to infections. Plasma-derived immunoglobulins help provide passive immunity and boost these patients' ability to fight infections.



Hepatitis B

A plasma-derived medicine with hepatitis B antibodies, called Anti-HBV IG, can help protect people from hepatitis B virus (HBV). Anti-HBV is used as a postexposure preventative measure in individuals who are at risk of acquiring HBV, including healthcare workers and first responders treating a patient with HBV, as well as babies born to mothers with the virus.

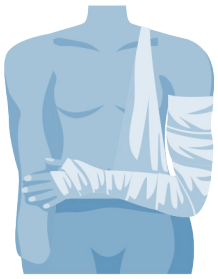


Severe Burns

Severe burns can lead to life-threatening complications, including fluid loss and infection. Plasma-derived medicines, such as albumin, can help replenish lost fluids in burn patients. Additionally, fibrin sealants derived from plasma can help in wound healing and reduce the risk of infections.

Shock and Trauma

In cases of shock and trauma, the rapid loss of blood can result in acute clotting disorders. Plasma-derived clotting factors like Factor IX may control bleeding and restore normal clotting function. Administering these factors to trauma patients can be effective in preventing excessive blood loss.



Tetanus

The presence of antibodies and immunoglobulins in plasma equips it to neutralize harmful substances and infectious agents. In cases where individuals are bitten by animals or sustain deep cuts, there is a risk of tetanus infection, which can be life-threatening. Anti-tetanus immunoglobulin (IG) provides antibodies that protect against this infection.