

Plasma collection in Europe: a priority for the Alpha-1 Europe Alliance

Position paper

Update: September 2026

Executive Summary

For people living with Alpha-1 Antitrypsin Deficiency (AATD or Alpha-1), plasma-derived augmentation therapy remains the only treatment specifically developed for their condition. Ensuring a stable supply of plasma is therefore an important condition for uninterrupted care.

Europe relies heavily on plasma collected outside its borders, particularly in the United States. This dependency exposes patients to potential supply vulnerabilities and highlights the need to strengthen European plasma collection capacity. The EU Regulation on Substances of Human Origin (SoHO) provides a historic opportunity to address this challenge by encouraging Member States to improve both donor protection and the resilience of plasma supply.

The [Alpha-1 Europe Alliance \(A1EA or Alliance\)](#) supports a balanced approach that increases plasma availability without compromising donor safety or ethical standards. Expanding plasma collection should involve modernising public collection services while allowing responsible private operators to contribute under robust regulatory oversight. Public and private systems should be viewed as complementary tools for achieving sufficient plasma collection in Europe.

Protecting donors must remain central to any policy. This includes evidence-based donation limits, regular health monitoring, immunoglobulin testing, donor registries to prevent excessive donations across centres, and continued research on the long-term safety of plasmapheresis. Reasonable compensation for the inconvenience associated with donation also contributes to donor attraction and retention, provided that appropriate safeguards prevent exploitation.

The Alliance also emphasises the importance of ethical consistency. Countries choosing not to allow compensated plasma donation should ensure that their own collection systems are capable of meeting domestic demand through alternative approaches. Relying on plasma imported from countries using practices considered unacceptable domestically creates an ethical contradiction that should be addressed.

Ultimately, the objective is clear: Europe should ensure a resilient, patient-centred plasma collection system that prevents shortages, supports long-term access to plasma-derived therapies, protects donors, while strengthening European self-sufficiency and health safety.

About the Alpha-1 Europe Alliance

The Alpha-1 Europe Alliance is a collective voice representing fourteen national organisations of individuals living with Alpha-1 Antitrypsin Deficiency across Europe.

Our mission is to advocate for access to timely diagnosis, individualised care, and holistic therapies, while raising awareness, promoting research, and empowering Alpha-1 national patient organisations. With a vision of a better and longer life for all those affected by Alpha-1 in Europe, we strive for optimal treatment, access to care, and ultimately a cure.

For more information, please visit our website: <https://alpha1europe.org/>

1. Introduction

Alpha-1 Antitrypsin Deficiency (AATD or Alpha-1) is a rare genetic condition that can lead to severe lung, liver and, in very rare cases, skin disease. For people who develop lung disease, augmentation therapy has been the only treatment specifically developed for Alpha-1 for more than three decades. Based on a plasma-derived medicinal product (PDMP), it works by replacing the Alpha-1 Antitrypsin protein that is missing or present at very low levels, helping to protect the lungs from further damage and to slow the progression of emphysema.

Without this protection, lung tissue can continue to be destroyed over time, leading to worsening breathlessness, loss of lung function and, in the most severe cases, respiratory failure or the need for lung transplantation. As the damage already caused to the lungs cannot be reversed, continued access to augmentation therapy is particularly important for patients who rely on it. Ensuring its availability depends on a sustainable, safe and ethically robust plasma supply.

However, Europe continues to face a structural challenge: significant dependency on plasma collected outside the EU, particularly in the United States. This reliance exposes European patients to potential supply disruptions and highlights the need to strengthen plasma collection systems across Europe.

For patients living with AATD, policy discussions on plasma collection must remain grounded in a single priority: ensuring uninterrupted and sustainable access to therapies, avoiding additional mental burden to patients caused by uncertainties of supply.

The Alpha-1 Europe Alliance (A1EA) believes that Europe can and must pursue a pragmatic, patient-centred approach that simultaneously:

- Ensures donor safety
- Increases plasma collection capacity
- Protects patients' access to therapies
- Maintains ethical standards

2. Policy context

2.1. EU SoHO Regulation

The EU Regulation on Substances of Human Origin (SoHO)¹ aims to modernise the regulatory framework governing the donation, testing, processing, storage, and distribution of human-derived substances. It provides a renewed policy framework for plasma collection in Europe and explicitly recognises both the importance of donor protection and the need to ensure availability of processed substances of human origin, including plasma, for patients who need them.

In particular, Article (62) stipulates that *"Member States shall (...) consider all reasonable efforts for achieving a sufficient, adequate and resilient supply of critical SoHO with a view to appropriately meet recipients' needs, and to contribute to European self-sufficiency"*.

In its recital (58), the Regulation emphasises that "compensation should be able to be acceptable to prevent SoHO donors being financially disadvantaged by their donation".

Article 54 underlines that *"Where Member States allow for the compensation of living SoHO donors, (...) the conditions for such compensation shall be established in national legislation"*.

When combining the principles of the Regulation, a clear dual objective can be established for European policy: (1) ensuring sufficient and reliable access to plasma-derived therapies for patients (2) while safeguarding donor health. The SoHO framework also leaves room for Member States to define operational models for plasma collection, including how to organise donation systems to ensure sufficiency.

¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202401938

2.2. Global plasma supply and policy environment

Currently, most of the plasma used to manufacture PDMPs originates from the United States. Therefore, changes in U.S. policy, trade frameworks, or supply conditions could have direct consequences for European supply, thereby negatively impacting European patients. Strengthening plasma collection capacity in Europe is a matter of health security and strategic autonomy.

2.3. Patient Perspective

Patients with Alpha-1 already face substantial challenges related to:

- Ill-health
- Diagnosis delays
- Treatment access inequalities
- Reimbursement restrictions

It is important to ensure that plasma collection issues do not add additional mental burden and uncertainty for patients relying on PDMPs. The central objective must remain clear: ensuring uninterrupted access to life-supporting therapies.

3. Achieving plasma self-sufficiency in Europe

The A1EA supports the development of sustainable plasma collection systems across Europe, based on best practices that ensure both donor protection and sufficient supply.

This requires:

3.1. Expansion of plasma collection capacity

European countries should support the installation and scaling of modern plasma collection infrastructure. Well-regulated co-existence between public and private plasma collection systems should be considered as a tool to increase collection capacity and strengthen plasma supply. Experience shows that countries relying exclusively on public collection models face greater challenges in meeting demand and avoiding plasma shortages.

Public systems should therefore be reorganised and modernised so that plasma collection becomes a clear health-system priority. This may include expanding collection points, increasing staffing, investing in dedicated equipment, and improving donor pathways and territorial accessibility.

There is evidence from four European countries (Germany, Austria, Hungary and Czech Republic) demonstrating that a mixed system can support donors' participation and allow for more flexible collection capacity, as well as broader geographical coverage within a country reaching to areas that are traditionally left behind (such as rural areas).

3.2. Strengthening responsible private collection

Private plasma collection operators can play an important role in expanding capacity. National legislations should enable responsible private participation while ensuring strong safeguards.

Possible measures include intensifying public information campaigns that highlight the benefits of plasma donation and raising public awareness of donor health monitoring, as well as patients' needs.

The A1EA deeply cares about donors' health and strongly supports donors receiving regular health checks and any other necessary support associated with donations. Donors' safety must be supported in collaboration between public authorities and private operators.

We believe that private collection is complementary to - and not a substitute for - sustained public-sector commitment to plasma collection capacity.

3.3 Compensation for donor's inconveniences

The A1EA recognises that plasma donation requires time, travel, and personal commitment. Reasonable and proportionate compensation for inconvenience can be a legitimate mechanism to support donor retention and encourage participation, ultimately ensuring stable plasma supply for patients who need it.

Importantly, robust safeguards must be put in place to ensure that compensation does not lead to exploitation of donors or unsafe donation practices. These safeguards could include:

- Centralized registration of donors, as recently introduced in Hungary
- Control of immunoglobulins to identify too frequent donations.

Compensation, however, should be seen as one possible component of a broader effective plasma strategy, not as a substitute for adequate public planning, investment, infrastructure and donor accessibility.

4. Safeguards to protect donors

Ensuring donor safety and ethical standards must remain a central pillar of plasma collection policies in Europe. Transfer of already existing best practices could significantly improve the current situation, while ensuring at the same time protection of patients and donors.

4.1. Avoid crowding out of blood donation

Plasma collection systems must be designed so that they do not negatively impact whole blood donation. Countries have successfully implemented policies to manage this balance. Examples include:

- plasma collection centres primarily located in urban areas
- mobile blood collection centres operating in rural regions.
- requirement of at least one blood donation per year before eligibility for plasma donation.

Such policies can help maintain a balanced donor ecosystem.

4.2. Avoid exploitation of donors

Donor protection requires scientifically grounded safeguards. These measures include:

- Strict, evidence-based limits on maximum donation frequency
- Health monitoring protocols
- Long-term safety research on plasmapheresis donation.

International initiatives and research programs continue to assess donor health outcomes across different donation frequencies.

4.3. Donor monitoring systems

The A1EA supports the establishment of national and/or European donor registries. Indeed, such systems would help prevent excessive donation across different centres and improve donor safety. It is an important step to enhance traceability and oversight.

Several countries have already started implementing such systems.

4.4. Monitoring IgG levels

Regular monitoring of immunoglobulin G (IgG) among plasma donors is an important safety measure. Countries such as Germany already require periodic measurement of Ig levels to ensure donor health is protected.

5. Ethical responsibility and international solidarity

Countries that oppose compensation models for plasma donation face an important ethical responsibility. If they choose not to collect plasma using compensated donation models, they should ensure that sufficient plasma is collected domestically using methods considered ethically acceptable within their national frameworks.

This also means that countries relying predominantly on public collection models should ensure that their collection systems are appropriately equipped to deliver sufficient plasma collection in practice, through adequate planning, funding and operational capacity.

It would be inconsistent for countries to reject compensated plasma donation domestically while relying on plasma collected abroad under systems, they consider ethically problematic. Therefore, these countries have the moral obligation to fulfil their national needs by establishing a collection system that they find ethically acceptable. The A1EA therefore encourages a coherent ethical approach to plasma sourcing.

6. Key recommendations

The A1EA calls on policymakers to:

6.1. Strengthen European plasma collection to respond to patients' needs

- Expand plasma collection capacity across Europe
- Support coexistence of public and private collection systems
- Reorganise and sufficiently resource public plasma collection systems, including infrastructure, staffing, donor access and dedicated plasmapheresis capacity.

6.2. Protect donor safety

- Implement national donor registries
- Establish evidence-based donation frequency limits
- Monitor immunoglobulin levels regularly

6.3. Support responsible donor participation

- Recognise reasonable compensation for donor inconvenience
- Develop public awareness campaigns on plasma donation

6.4. Protect blood donation systems

- Introduce intelligent regulatory mechanisms preventing crowding-out effects

6.5. Ensure ethical policy coherence

- Countries opposing compensated donation should ensure sufficient domestic plasma collection for their patients through a system they find ethically acceptable.

7. In conclusion

Plasma-derived medicinal products are essential therapies for many patients in Europe, including patients with Alpha-1 Antitrypsin Deficiency and people living with other rare diseases. Ensuring a safe, ethical, and sustainable plasma supply requires pragmatic policies that protect donors while guaranteeing patients' access to life-improving and life-saving treatments.

This requires not only enabling complementary public and private collection models but also ensuring that public plasma collection systems are sufficiently organised and resourced to make a meaningful contribution to plasma sufficiency.

The Alpha-1 Europe Alliance stands ready to collaborate with policymakers, healthcare professionals, plasma collection organisations, and patient communities to build a resilient and patient-centred plasma ecosystem in Europe.

Ultimately, increasing plasma collection in Europe must go hand in hand with ensuring that the plasma collected is effectively transformed into the plasma-derived medicinal products patients depend on, including Alpha-1 Antitrypsin products, and that those medicines are made available to patients in a reliable and sustainable way.

Even if the scope of this paper focuses on plasma collection and supply in Europe, the overall plasma policy must address the full chain from collection to production and patient access.



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