SfEE

NATIONAL FRAMEWORK FOR PLASMA-DERIVED THERAPIES

HEALTH POLICY PROPOSALS FOR ENSURING THE ADEQUATE SUPPLY OF PLASMA-DERIVED THERAPIES AND SAFEGUARDING PUBLIC HEALTH

Chalandri, October 2025

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Chalandri, 13 October 15, 2025

I. PURPOSE

The Hellenic Association of Pharmaceutical Companies (SFEE) welcomes the initiative of the Ministry of Health (MoH) to recognize the need for establishing a new National Regulatory Framework for Plasma-Derived Therapies (Plasma Proteins). With the overarching goal of supporting the Ministry's crucial mission, SFEE – through this document – submits a set of policy proposals concerning the new National Framework for Plasma-Derived Therapies. These proposals are the result of a comprehensive dialogue among key stakeholders, including the medical community, patient representatives, and the pharmaceutical industry. They represent an evidence-based set of actions, drawing on best practices successfully implemented in other European countries, while fully considering the characteristics and needs of the Greek Healthcare System. The key objectives of these proposals are: to ensure the adequate supply of plasma-derived therapies, and to safeguard public health, preventing potential critical shortages and ensuring uninterrupted access for more than 21,000 patients in Greece, both in the short term (2026) and in the medium term (subsequent years).

Plasma-derived therapies are fundamentally distinct from other categories of medicines, a fact which highlights the need for a specialized regulatory approach. Therefore, ensuring their adequate supply and patient access requires targeted health policy measures, separate from those applied to community or conventional pharmaceuticals. The following section presents the key factors differentiating plasma-derived therapies from other types of medicinal products.

II. DIFFERENTIATION OF PLASMA-DERIVED THERAPIES FROM OTHER CATEGORIES OF MEDICINES

The table below outlines the key differences between plasma-derived therapies and conventional pharmaceutical molecules.

Criterion	**Plasma-Derived Therapies**	**Conventional Pharmaceutical Molecules**
Raw Material	Human plasma collected from healthy volunteer donors	Chemically synthesized or biotechnologically produced compounds
Possibility of Artificial Production	Artificial or synthetic plasma and its derivatives cannot be produced	Fully produced in laboratories via chemical or biotechnological synthesis
Dependence on Plasma Donations	Requires 130–1,000 plasma donations per patient per year, depending on the disease (see Annex, Diagram 1)[iii,iv]	No donations required – produced entirely through synthesis
Production Duration	7–12 months from plasma collection to product release[v] (see Annex, Diagram 3)	Typically weeks or a few months, depending on the molecule
Production Yield	Very low – approximately 4–8 g of immunoglobulin per 1,000 ml of plasma (see Annex, Diagram 2)	High yield with capacity for large-scale production
Production Cost	Around 57% of the total cost relates to raw materials and manufacturing processes (see Annex, Diagram 3)[iv,v]	Around 14% of the total cost relates to raw materials/production
Therapeutic Indications	Used for rare and life-threatening diseases[1], with no alternative treatments (see Annex, Diagram 1)	Used across a wide range of conditions, often with multiple therapeutic alternatives
Biological Nature	Complex biological products (proteins, immunoglobulins, coagulation factors)[2]	Small molecules with well-defined chemical structure and stable pharmacokinetics
Risks / Challenges	Dependence on plasma supply and donor availability, complex viral/pathogen testing, high production costs	Less dependent on external factors; main challenges include toxicity and adverse reactions

III. PLASMA-DERIVED THERAPIES: ESSENTIAL MEDICINES FOR THE EU AND GLOBAL HEALTH

- A significant number of plasma-derived therapies[2] are included in the "Union List of Critical Medicines"[xvii] issued by the European Commission in collaboration with the European Medicines Agency (EMA), and the Heads of Medicines Agencies (HMA).This list identifies medicines whose continuous supply is considered a priority within the European Union, supporting the resilience of healthcare systems and ensuring that patients are protected from serious health risks resulting from shortages.
- Immunoglobulins are listed in both: the World Health Organization (WHO) Model List of Essential Medicines[ii] and the EMA's List of Main Therapeutic Groups (MTGs)[i] relevant to crisis preparedness and response. These designations officially recognize plasma-derived therapies as essential medicines, vital for meeting critical therapeutic needs and ensuring continuity of care in both ordinary and crisis conditions.

1. Indicatively: Haemophilia A & B, von Willebrand Disease, Hereditary Angioedema (HAE), Primary and Secondary Immunodeficiency (PID/SID), Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Multifocal Motor Neuropathy (MMN), Idiopathic Thrombocytopenic Purpura (ITP), Kawasaki Disease, Guillain-Barré Syndrome, Alpha-1 Antitrypsin Deficiency (AATD), etc.

2. Human prothrombin complex, Coagulation factors VII and XIII, Human Hepatitis B Immunoglobulin, Immunoglobulins, Albumin and Clotting factors

IV. CURRENT SITUATION – INTERNATIONAL AND NATIONAL OVERVIEW

Criterion	**International Context**	**Greece**
Availability of Plasma Proteins	The supply of plasma proteins does not meet global healthcare needs. In Europe, production lags behind demand[vi] by approximately 38% (see Annex, Table B).	Public Entities[3], patients, and healthcare professionals (physicians) report difficulties in access and limited availability of plasma-derived therapies. Reduced doses and extended dosing intervals often result in (a) critical treatment conditions[4] and (b) the need to resort to more costly alternatives, such as plasmapheresis[4]
Demand	Annual increase of 6% for plasma proteins and 9% for immunoglobulins[vii] (see Annex, Diagram 4).	No publicly available national data.
Production Costs	Sharp increases observed in 2022: +26% in Europe, +15% in the United States.[xii]	Greece has no domestic production of plasma-derived therapies.
Policies to Encourage Plasma Collection	Several countries have adopted policies: a) promoting both public and private plasma collection, b) investment in plasmapheresis infrastructure, and c) efficiency improvements in donation systems.	No national policies or measures to promote plasma collection. Public awareness is limited.
Impact of Plasma Shortages	Shortages increase pressure on the global supply chain and raise the cost of raw materials.	Persistent immunoglobulin shortages (known colloquially as the "immunoglobulin crisis"). Patients often must resort to alternative, more expensive treatments, such as plasmapheresis.
Per Capita immunoglobulin Consumption	Increasing steadily across EU and non-EU countries[vii], (see Annex, Diagrams 5–7)	Based on 2020 published data (66 kg /million), Greece remains below the EU average (78 kg/million) and ranks among the lowest in Europe. Indicatively: Spain 116 kg/million, Italy 111 kg/million[vii], [see Annex, Diagrams 5 (2020), 6 (2016-2018), 7 (2023)]
Nominal (Ex-Factory) Price Increases of Plasma Products	Prices have risen by up to 55% in many EU countries (e.g. Austria, Cyprus, Czech Republic, France, Germany, Italy, Spain, Latvia, Lithuania, the Netherlands, Poland, Romania, Slovakia, Sweden, and the United Kingdom).	Plasma-derived therapies and vaccines are excluded from national price revisions, to safeguard public health and ensure adequate patient supply. As a result, ex-factory prices have remained frozen, with the exception of one adjustment in August 2024.
Exemption or mitigation from automatic return mechanisms	Several countries globally and within the EU exempt plasma-derived products from automatic return mechanisms, or significantly mitigate their negative effects — e.g. Belgium, Romania, Portugal, Ireland, Turkey, and the United States.	There is no formal exemption for plasma-derived therapies from mandatory return mechanisms. In certain cases, these therapies are included in closed budgets, which does not guarantee a priori exemption from clawback & rebate obligations.
Plasma Collection	Both public and private collection systems operate under structured programs. Countries are investing in new plasmapheresis centers, technology upgrades, and donor incentive campaigns to improve self-sufficiency and meet demand.	Zero per-capita plasma donations (see Annex, Diagram 10). No private plasma collection, no awareness campaigns, no donor incentives, and no strategic framework for national self-sufficiency.
Private Plasma Fractionation	9 to 10 litres of plasma are fractionated in Europe by private sector operators (see Annex, Diagram 11).	No regulatory or strategic framework exists for private plasma fractionation.

3. According to EOPYY, it is likely that patients resort to alternative therapeutic options, the cost of which is neither recorded nor clearly defined.

4. According to the medical community: (a) There are significant shortages in intravenous therapies used for acute cases, while the situation is considerably better for subcutaneous therapies, which are mainly used for chronic conditions.(b) Furthermore, the use of off-label medicines in public hospitals is considered of utmost importance, in contrast to private hospitals, where this practice is not applied and patients are referred to the public sector. (c) The shortage of immunoglobulin has led to the emergence of what is referred to as the "immunoglobulin crisis" phenomenon, due to its critical role in the treatment of severe cases.

Criterion	**International Context**	**Greece**
Private Plasma Collection & Donor Compensation	Austria, Czech Republic, Germany, and Hungary account for over 55% of total plasma collected in Europe for fractionation. These countries permit plasma donor compensation, following strict ethical and safety standards (see Annex, Diagram 12).	No national framework or plan for private plasma collection or compensated donations.

V. STAKEHOLDERS' PERSPECTIVE: PHYSICIANS AND PATIENTS ON THE LIMITED AVAILABILITY OF PLASMA THERAPIES IN GREECE

According to the medical community:

a) There are significant shortages of intravenous plasma-derived therapies, which are primarily used for acute cases, while the situation for subcutaneous therapies, typically prescribed for chronic conditions, is relatively better.

b) The broad use of plasma-derived therapies for the management of multiple diseases, particularly within public hospitals, is considered crucial. In contrast, private hospitals generally do not apply these treatment protocols, and patients are instead referred to public hospitals for treatment.

c) The persistent shortage of immunoglobulin is a cause of deep concern among healthcare professionals and patients alike, due to its essential role in treating severe and life-threatening conditions. This shortage has even been described as the "immunoglobulin crisis"

The lack of adequate availability of plasma-derived therapies inevitably leads to the adoption of alternative therapeutic interventions, in order to maintain treatment continuity for affected patients. However, the National Organization for Health Care Services Provision (EOPYY) currently lacks sufficient data regarding the alternative treatment approaches used as substitutes for plasma-derived therapies, and the associated costs on a case-by-case basis. Furthermore, there is no clear overview of the extent or variety of these alternative practices. As a result, it is impossible to accurately estimate the financial burden arising from the shortages of plasma-derived therapies.

VI. POLICY PROPOSALS

In accordance with Article 168 (1) of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union, Member States must ensure a high level of human health protection in the definition and implementation of all policies and activities. The same obligation derives from Article 21 (3) of the Greek Constitution.

Given the current situation in Greece, it is imperative to secure the availability of plasma-derived therapies in the national market, with the overarching objective of protecting public health through uninterrupted patient access to these vital treatments.

Ensuring adequate patient access to plasma-derived therapies provides significant medical[xiii,xiv,xv] and socioeconomic benefits both for healthcare systems and for patients themselves[i,iv] e.g reduced annual hospitalizations, shorter hospital stays[xvi] (see Annex, Diagram 8). At the same time, it contributes to relieving the burden on the National Healthcare System — an outcome that certainly cannot be achieved if patients are undertreated or deprived of their therapies.

To achieve these objectives, SFEE proposes the following set of measures to be incorporated into the new National Regulatory Framework for Plasma-Derived Therapies, ensuring alignment with European best practices and modern health policy standards:

A. Revision of Reimbursement Policies for Plasma-Derived Therapies

a. Implementation of rationalized policies for plasma-derived therapies, for cases where: a) there is a documented inability of the country to secure sufficient quantities, based on the the relevant monitoring mechanism (see bullet B) and data derived from Patient Registries and/or National Studies (see bullet A), b) for the correction of listed prices in Greece, when these deviate negatively (i.e. are lower) from the levels that would result from the application of an appropriately adjusted price revision rule.

b. Establishment, through legislative provision, of a permanent and dedicated supplementary budget (as in the Heparin case, 2020) for specific categories of plasma-derived therapies — for example, immunoglobulin G and albumin.

B. Assessment of Actual Patient Needs in Greece and Quantification of the Existing Gap Between Demand and Supply of Immunoglobulin G and Other Plasma-Derived Therapies

a) Utilization of Real-World Data (RWD) through the implementation of nationally designed studies

b) Activation of a national patient registry for individuals receiving immunoglobulin G[5], alongside the simplification of bureaucratic procedures for its procurement

c) Establishment of additional patient registries for other diseases requiring plasma-derived therapies (where it is clinically necessary).

C. Establishment of a Procedure for the Timely and Preventive Evaluation of the National Supply Adequacy of Plasma-Derived Therapies for the Following Year(s)

Establishment of a mechanism through which the National Health Authorities will assess, in a timely manner (e.g. at least six months before the end of each year), whether the quantities of immunoglobulin G and albumin that Marketing Authorization Holders (MAHs) and/or local representatives are able to supply to the country for the following year(s) are sufficient to meet national demand.

D. Establishment of modern policy measures that will:

a) encourage plasma donations through structured plasmapheresis programs,

b) Enable public–private partnerships for the production and processing of plasma-derived therapies and

c) Attract investments related to the creation of new plasma collection centers (see Annex, Diagram 1)

E. Strengthening Cooperation and Establishing a Dialogue Mechanism with International Organizations (e.g PPTA), SFEE, as well as with pharmaceutical companies that have experience in the production and distribution of plasma-derived medicinal products.

5. Press Release Ministry of Health: https://www.moh.gov.gr/articles/ministry/grafeio-typoy/press-releases/6513-apofash-ypoyrgoy-ygeias-basilh-kikilia-gia-th-xorhghsh-paragwgwn-aimatos-ap-039-eytheias-sta-panepisthmiaka-kai-idiwtika-nosokomeia

VII. CALL TO THE STATE

Taking into account the exceptional global health and economic circumstances, and with a strong sense of responsibility toward the patients in our country who depend on stability and continuity in their treatment, we urge you to address this matter and take the necessary actions to ensure the uninterrupted access of thousands of patients in Greece to plasma-derived therapies.

Sincerely,

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ANNEX

Diagram 1: **Categories of Plasma-Derived Therapies and the Diseases for Which They Are Used as Treatments**

PDMP class	Conditions Treated

Coagulation factors:
Essential for blood clotting, used to treat genetic bleeding disorders and surgical bleeding.
	• **Bleeding Disorders**
	  • **Haemophilia A and B**
	  • **Von Willebrand disease (VWD)**
	  • **Rare clotting factor deficiencies**
	• Bleeding from trauma
	• Over dosage of anticoagulants or bleeding-causing toxic substances
	Liver disease

Immunoglobulins:
Essential for defense against infectious agents and regulation of immune system; used to treat genetic diseases with defense deficits against foreign pathogens (e.g. viruses, bacteria), as well as autoimmune and inflammatory conditions.
	• **Immunodeficiencies**
	  • **Primary (PID)**
	  • **Secondary (SID)**
	• **Neurological diseases**
	  • **Chronic inflammatory demyelinating polyneuropathy (CIDP)**
	  • **Acute inflammatory demyelinating polyneuropathy (Guillain Barré)**
	  • **Multifocal motor neuropathy (MMN)**
	• **Haematological**
	  • **Primary immune thrombocytopenia (Idiopathic thrombocytopenic purpura) (ITP)**
	• **Inflammatory diseases**
	  • **Kawasaki disease**

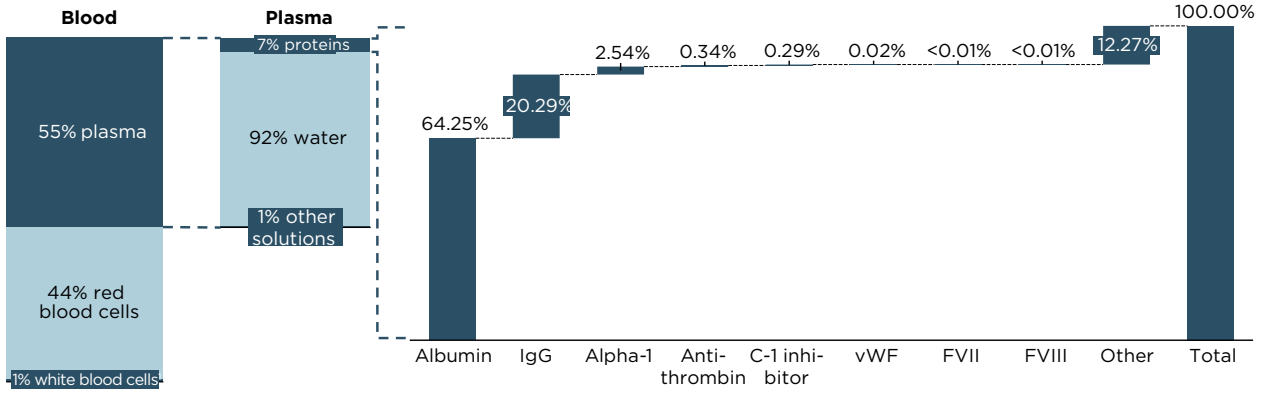
Hyperimmune Globulins: Prevention and treatment of specific infections and other indications.	• Rabies, tetanus, hepatitis, cytomegalovirus, varicella-zoster virus • Rh factor complicated pregnancies • Organ transplants

PDMP class	Conditions Treated
Alpha-1 Proteinase Inhibitors: Protects tissues from enzymes of inflammatory cells.	• **Alpha-1 antitrypsin deficiency (AATD) (genetic emphysema)**
Albumin: The major plasma protein, regulating blood volume and providing many essential non-oncotic functions.	• Cardiac surgery • Liver disease • Severe infections • Emergency and surgical medicine (shock, severe burns and during surgery)
C1-esterase inhibitor: Controls spontaneous activation of complement system as a part of the immune system.	• **Hereditary angioedema (HAE)**

Diagram 2: **Plasma and Its Components**

Composition of blood and plasma

Percent of components that a litre of blood consists of



Note: IgG = immunoglobulin G, alpha-1 = alpha- 1 antitrypsin, vWF= von Willebrand factor, FVII/FVIII = factor VII/VIII. The category 'Other' includes fibrinogen, prothrombin, alpha-2 macro, FIX, FXI, and more. 1) White blood cells and platelets.

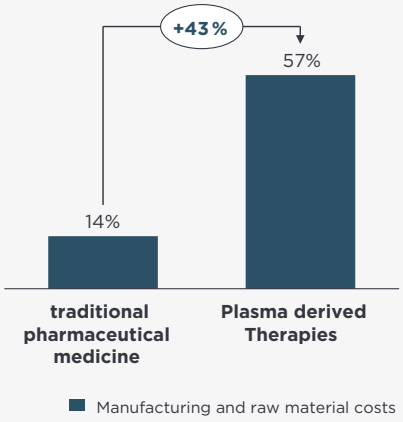
Source: PPTA (2020a) and Burnouf (2008)

Notes: 1) PPTA, https://www.pptaglobal.org/plasma / 2) PPTA (2020a)

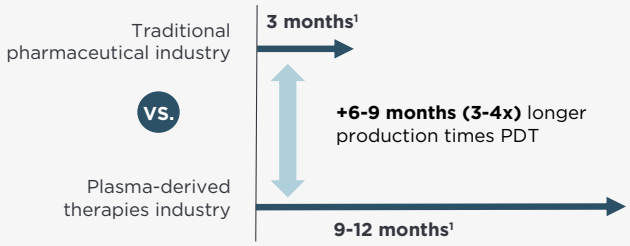
Diagram 3:**Manufacturing of Plasma-Derived Therapies – Cost and Production Time Structure in Comparison with Conventional Drug Molecules**

PDTs vs traditional pharmaceuticals: Cost of raw material and manufacturingis much higher & production more time consuming[1]

43% higher costs of raw material and manufacturing PDT vs traditional medicine



3-4x longer production times (+6-9 month) for Plasma-Derived Therapies vs traditional pharma



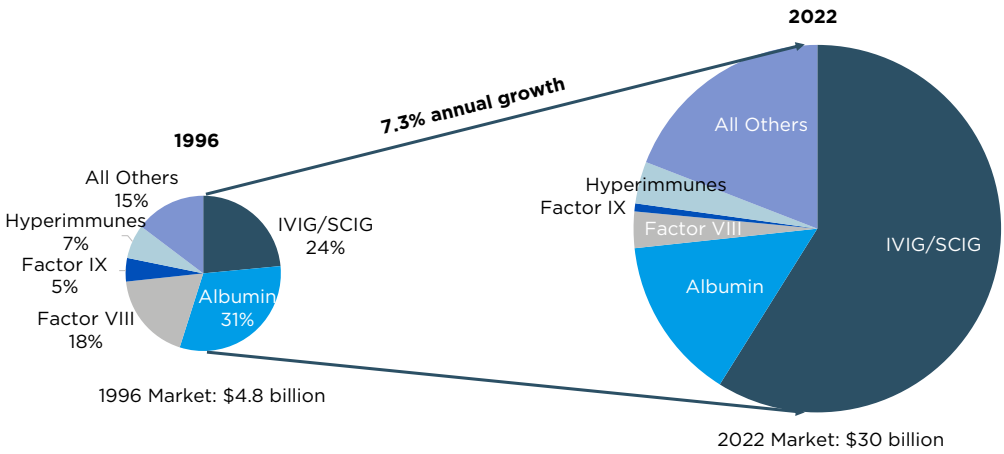
Sources: 1. Kluszczynskiet al., (2021) White Paper Key Economic and value considerations for PDMPs
Available at: https://www.vintura.com/news/white-paper-key-economic-value-considerations-plasma-derived-medicinal-products-pdmps-europe/

PDT: Plasma-derived therapy

Diagram 4: **Market Growth Trend of Plasma-Derived Therapies (1996–2022)**

Global supply of plasma therapies is not keeping up with growing patient need

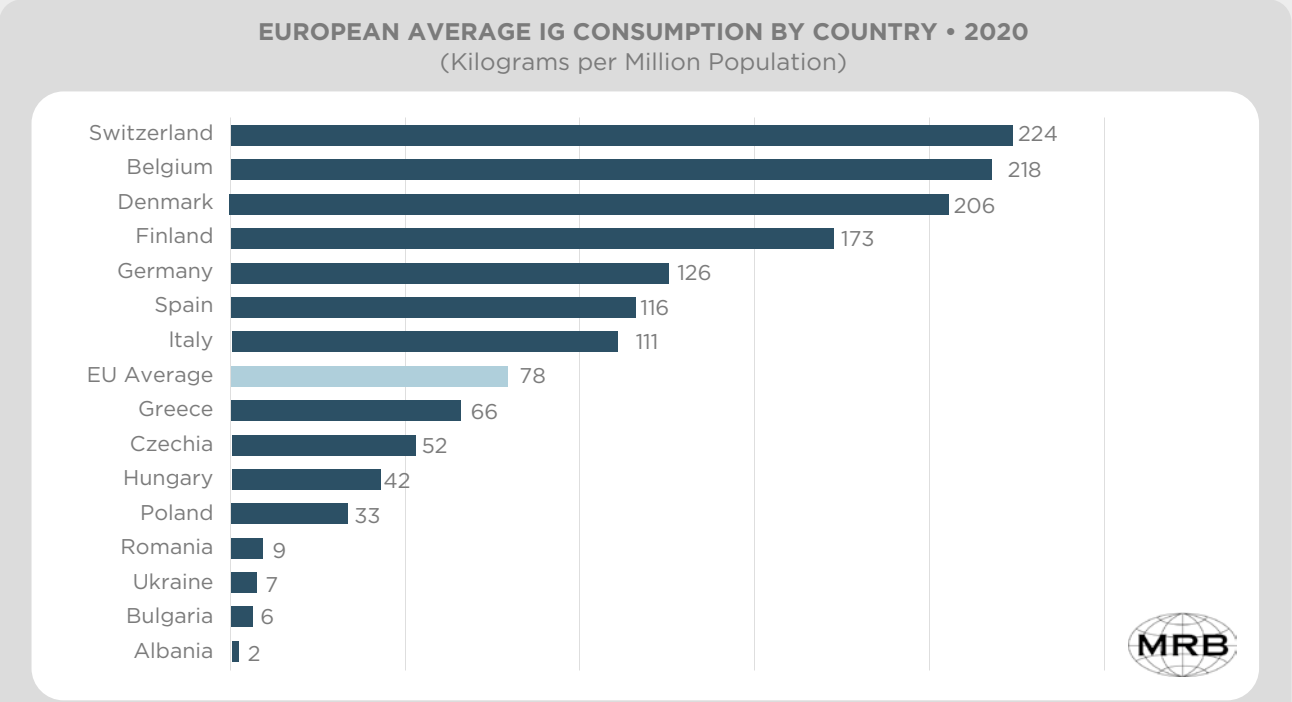
26 Years of worldwide plasma proteins market growth (without recombinant products)



Note: Pie charts are drawn to scale

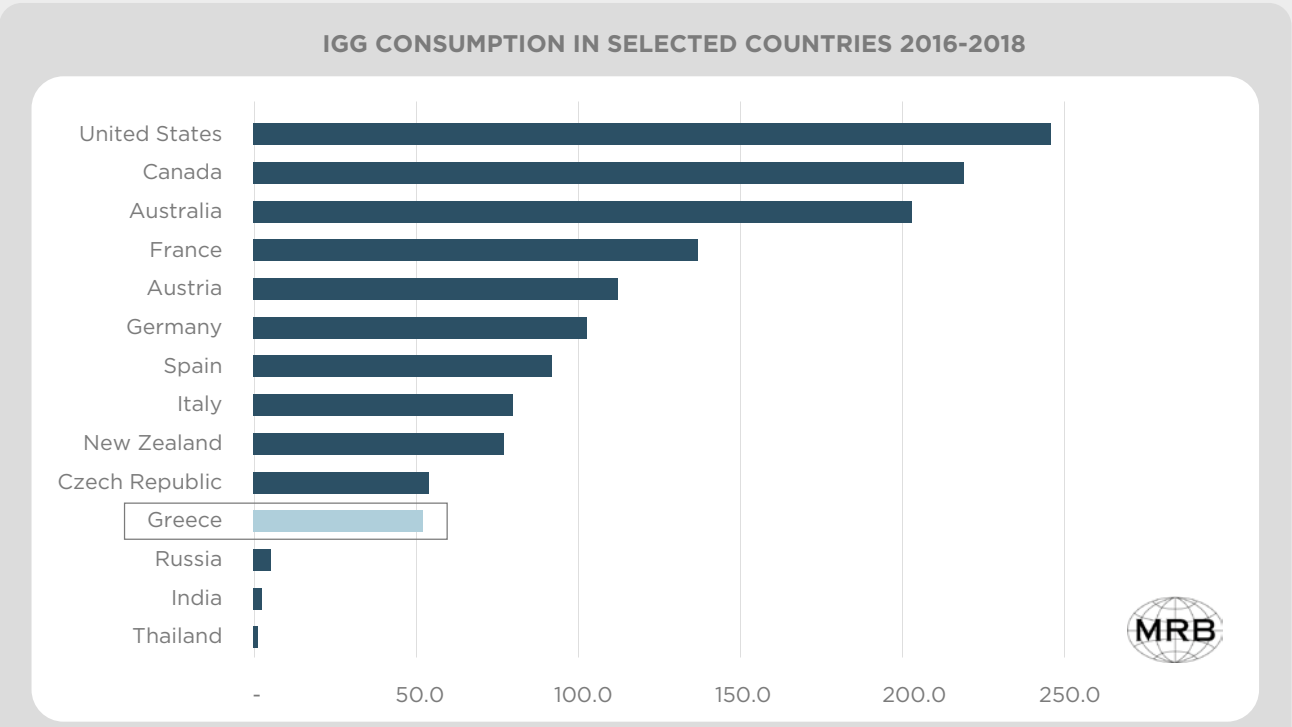
OVERVIEW OF EUROPEAN PLASMA SUPPIY SITUATION, MRB Presentation, IPPC Meering Athens, Greece, April 17, 2024

Διάγραμμα 5: **EU countries Immunoglobulin usage per capita 2020**
Select European countries show wide disparity within Europe on immunoglobulin usage



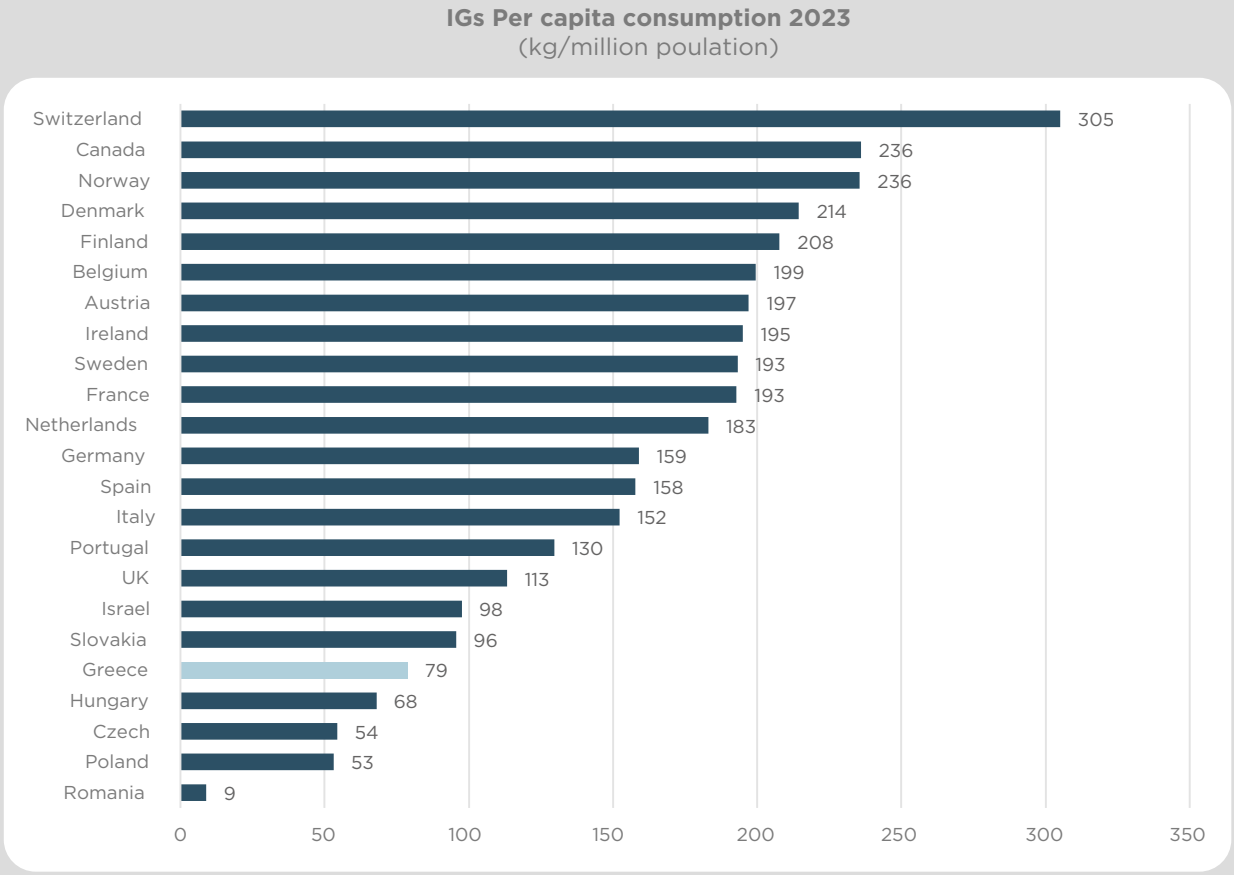
OVERVIEW OF EUROPEAN PLASMA SUPPLY SITUATION, Presentation by Marketing Research Bureau at IPPC Meeting, Athens, Greece, April 17, 2024

Diagram 6



"Plasma-Derived Medicinal Products (PDMPs) and Plasma Supply into the Future", European Blood Alliance and International Plasma and Fractionation Association (EBA-IPFA)", Amsterdam, Netherlands, 14-15 Juanuary 2020.

Diagram 7: **EU and non-EU countries Immunoglobulin usage per capita for 2023**

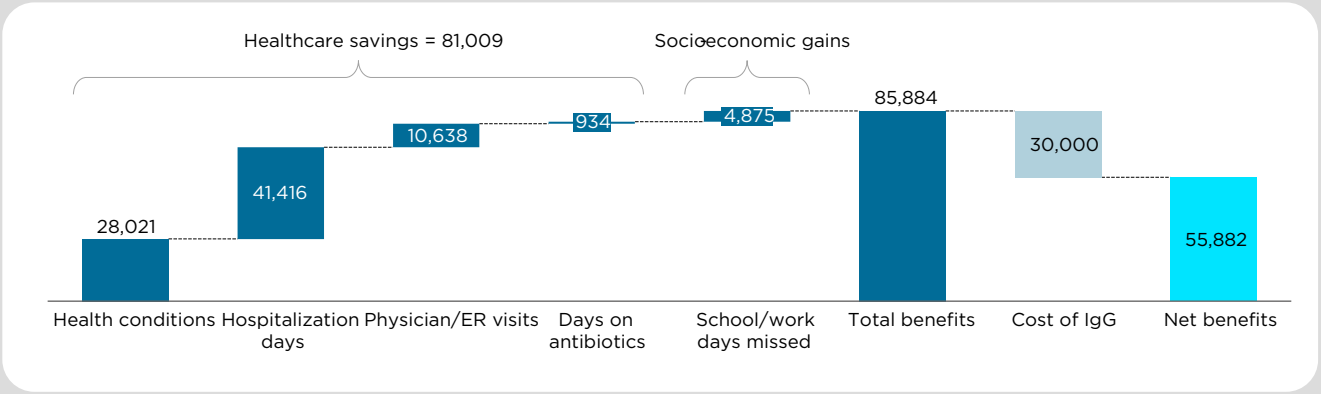


Analysis based on internal data

Indicatively, Greece consistently demonstrates a per capita consumption of immunoglobulin G (66 kg per million population)[vii] which is significantly lower than that of many European countries, below both the EU average and the levels observed in Southern European countries such as Spain (116 kg per million population) and Italy (111 kg per million population), as reflected in published 2020 data (see Annex, Diagram 5).

When comparing the most recently published data (2020, see Annex, Diagram 5) with earlier data (2016–2018, see Annex, Diagram 6), it becomes evident that: (a) there has been a clear increase in per capita immunoglobulin G consumption in a considerable number of EU and non-EU countries, while (b) Greece, based on the policies currently in place, has not succeeded in improving its position in terms of patient access to these indispensable medicinal products (per capita immunoglobulin G consumption: GR = 52 kg per million population, ES = 91 kg per million population, IT = 79 kg per million population). Moreover, according to 2023 data (see Annex, Diagram 7), Greece has now fallen among the lowest-ranking EU countries in terms of per capita immunoglobulin consumption.

Diagram 8: **Significant Socioeconomic Benefits and Reduction of Healthcare Expenditures from Immunoglobulin G therapy**



Note: Data is from the US. Costs of procedures is based on hospital billings. The cost of IgG is similar to that found in Boyle and Scalchunes (2008). Health conditions include persistent otitis media, serious sinus and upper respiratory infections, viral infections, acute bronchitis, bacterial pneumonias, chronic obstructive pulmonary disease, and bronchiectasis.

Source: derived by Copenhagen Economics from results in Modell et al. (2017) on the costs of treating a patient with immunoglobulin and the cost of not treating a patient.

Diagram 9: **Significant Benefits from the Use of Plasma-Derived Therapies**

Disease	Increased life expectancy	Improved quality of life	Infection prevention	Positively modifies disease progression
• Prim. immunodeficiencies (PID) • Sec. immunodeficiencies (SID)* • CIDP • ITP	✓	✓	✓ for PID/SID	✓
• Haemophilia A and B • Von Willebrand disease (VWD)	✓	✓		✓
• Hereditary angioedema (HAE)	✓	✓		
• Alpha-1 antitrypsin deficiency (AATD)	✓	✓		✓

* Diverse causes e.g. infectious diseases and immunosuppressive medication – prevalence not estimated.
Note: European population estimated as 597 million, affected population calculated using prevalence mean values and prevalence for adult CIDP population.

Diagram 10: **Per Capita Plasma Donations by Country in Europe (Litres per 1,000 Inhabitants)**

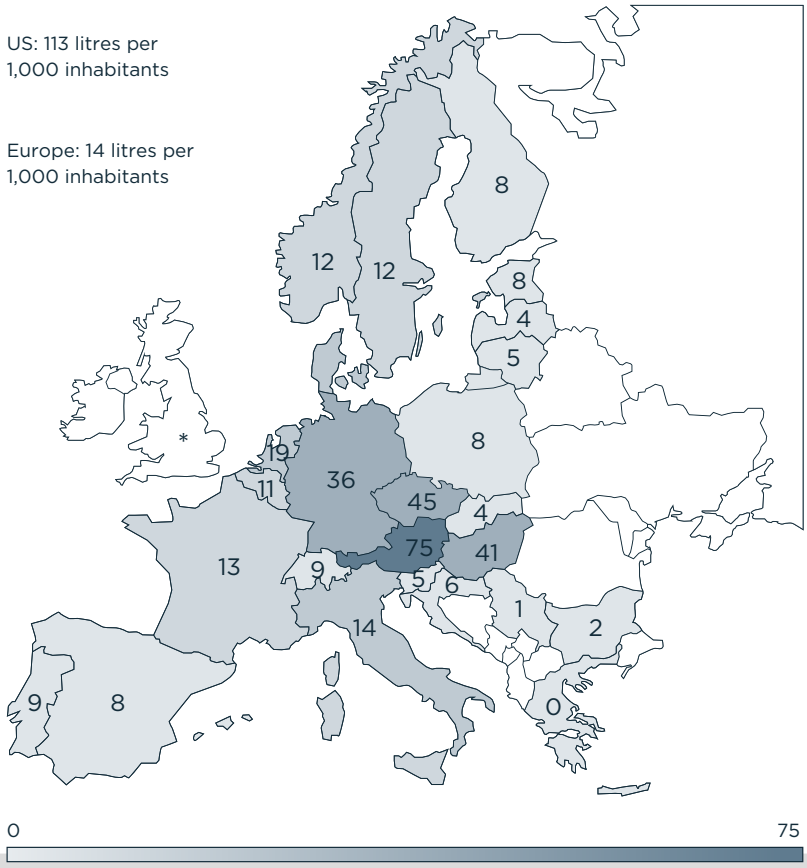
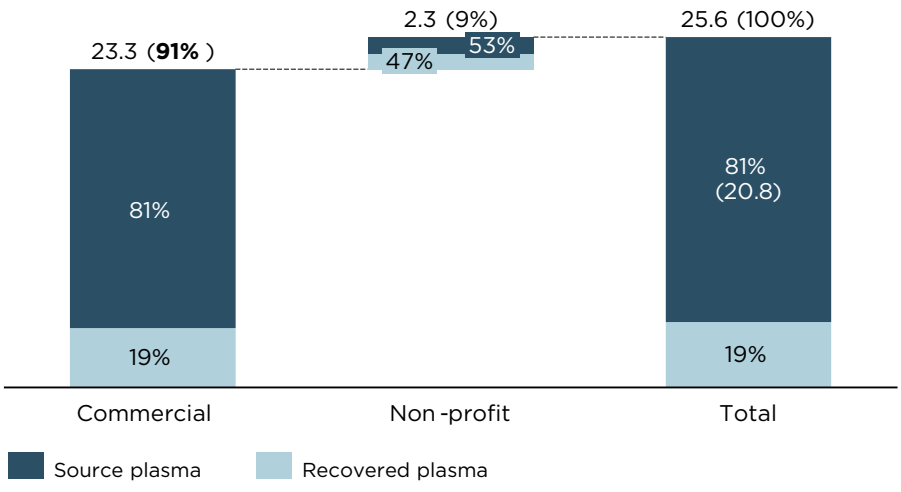
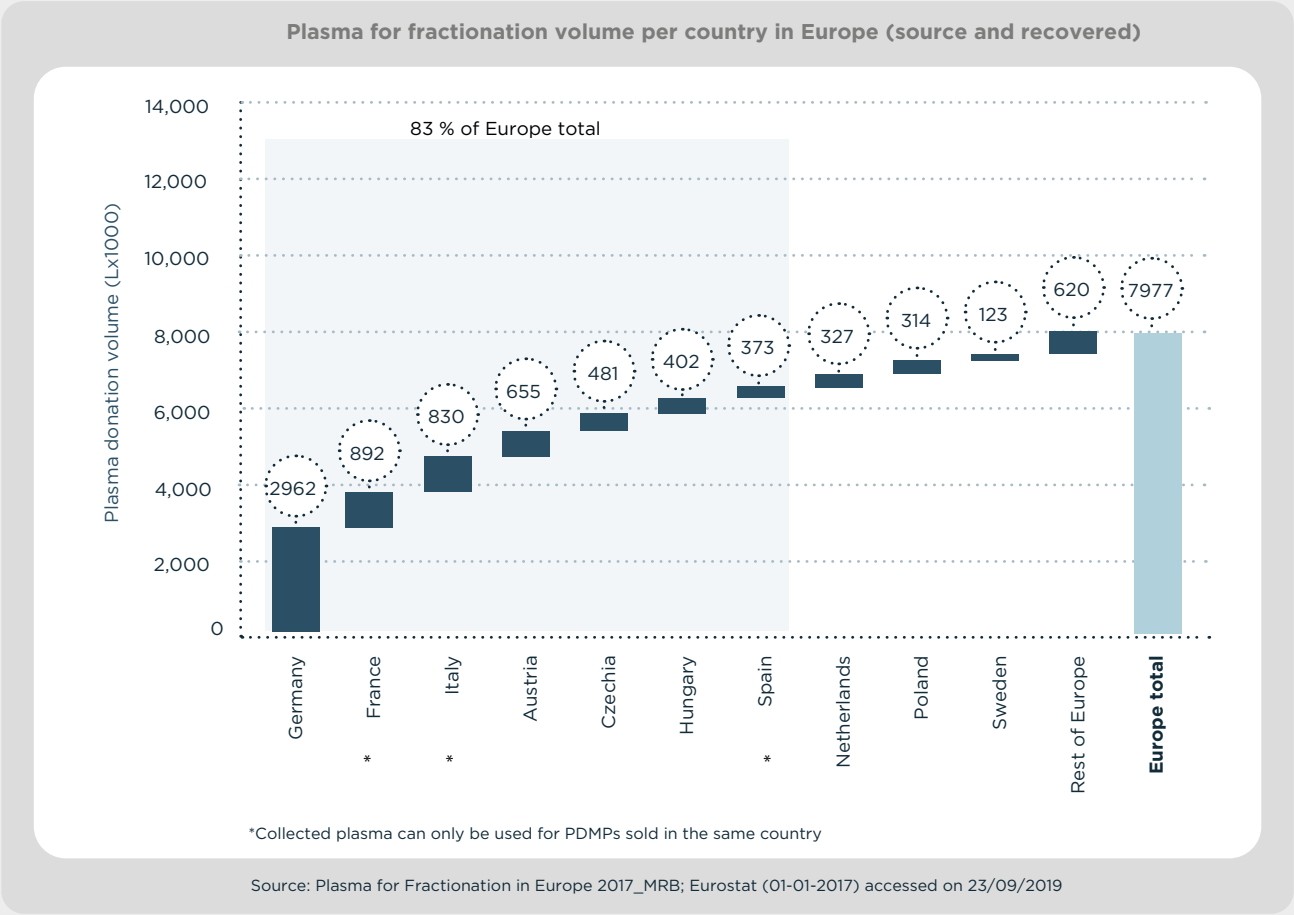


Diagram 11: **Plasma Processed in Europe – Volume (1,000,000 Litres) and Percentage Share**



Source: MRB (2018), data from 2018

Diagram 12: **Volume of Plasma Collected for Fractionation per European Country – Source and Recovered Plasma**

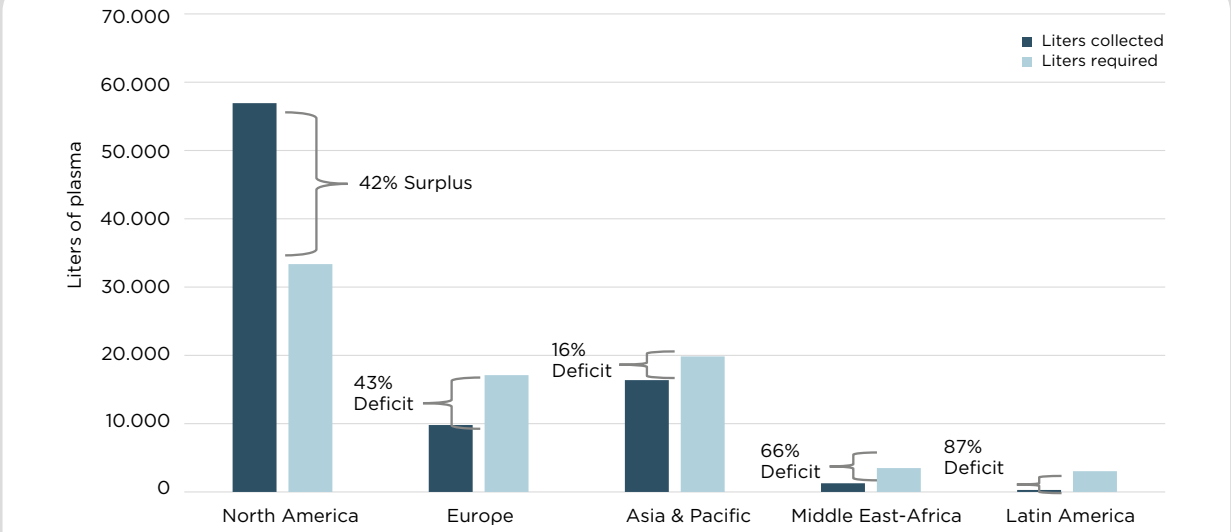


Source: Plasma for Fractionation in Europe 2017_MRB; Eurostat (01-01-2017) accessed on 23/09/2019

Table A: **Country cases – The combined Public/Private approach**

	AUSTRIA	CZECH REPUBLIC	GERMANY	HUNGARY
Population	88 million	11 million	83 million	10 million
Approach	Combined system: Austrian Red Cross collects plasma from whole blood donations; direct plasma donation at local level by Red Cross and private sector plasma donation centers.	Combined system: Public blood/plasma system from whole blood donations; direct plasma donation at local private sector plasma donation centers.	The German system has three pillars, active in both whole blood and plasmapheresis donation; Red Cross collection centers; municipal and hospital centers; private donation centers.	Combined system: National blood/plasma system from whole blood donations; direct plasma donation at local prrvate sector plasma donation centers.
Public Plasma system	Whole blood collection for transfusions is exclusively public; by Red Cross and national hospitals. A small amount of plasma collection is public.	Public system for blood collection - reserved to blood banks and hospitals	Whole blood and plasma collection: centers established at city, communal level and in hospitals and by the Red Cross.	Government -run whole blood collection.
Local plasma donation system	Plasma donors give in local centers; owned by mix of international and national companies.	Plasma donors give n local centers; owned by mix of international and national companies	Plasma donors give in local centers; owned by mix of international and national companies.	Plasma donors give in local centers; wned by mix of international and national companies
Local plasma donation centers	**20 centers nationwide**	**50 centers nationwide**	**80 centers nationwide** **Local donation centers in 11 Lander**	**35 centers nationwide**
Legislation on donation frequency	- 50 plasmapheresis donations/year - 3 donations in a 2-week period - 2 donations in 7 days - 1 donation in 72 hours - Max 700 ml/donation (without coagulant)	- Plasmapheresis donation not more than every 14 days - Max 650 ml/donation(without coagulant) - Not more than 151 /week/person - Total plasma donation/person/year: max 251	- 60 plasmapheresis donations in 12 months - 2-day interval between donations Between 650ml-850 ml per donation (Depending on donor weight)	- 33 plasmapheresis donations in 12 months - 1 donation within 72 hours - Max 800ml per donation including coagulant
Total plasma collected/ donated per year	- 590,000 liters, in slight decline - 67 liters per capita	- 500,000 liters - 45 liters per 1000 inhabitants	- 3.1 million liters per year - 36 liters per 1000 inhabitants	- 600,000 liters per year - 41 liters per 1000 inhabitants
Incentives	Financial compensation implicitly allwed. but financial profit explicitly not allwed	Financial compensation allowed. capped at €12 per donation to cover donor costs (linked to minimum wage and varies per year); can be deducted from personal income tax.	Financial + non-financial compensation authorized for local donation centers.	Financial compensation allowed - capped at €10 per donation - linked to minimum wage and can vary per year.
Observations	Liberal blood donation law. Allows covering of doner expenses, and similar costs as part of voluntary unpaid compensation. Advertising for plasma donation is allwed. Per capita collection is highest in Europe, second to US, globally.		Liberal plasma donation law. Donors can be compensated fa both whole blood and plasma donations. Non-compensation allowed as well. Plasma donation volumes in Germany are relatively flat (not growing). Advertising fa blood/plasma collection is allowed (not fa compensation).	This national framework is a good «ample of public/ private collaboration to encourage stable donation of whole blood and plasma in sufficient quantities. Plasma donation law fa local plasma centers requires each donor to also donate whole blood fa transfusion once yearly, uncompensated.

Table B: **Plasma supply vs Immunoglobulins needs & the EU deficit (2023)**



ONLY NORTH AMERICA (US) IS SELF-SUFFICIENT IN PLASMA ON A REGIONAL BASIS, ALL OTHER MARKETS RELY ON US COLLECTED PLASMA TO FILL THEIR DEFICIT

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Position Paper on Plasma-Derived Therapies

A joint initiative of patient organizations, the medical community, and the pharmaceutical industry

Chalandri, October 2025

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