PLASMA PROTEIN THERAPEUTICS ASSOCIATION

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Ensuring Patient Access and Open Strategic Autonomy in Europe:

PPTA's Recommendations for the Critical Medicines Act

Plasma Protein Therapeutics Association (PPTA) calls on policy makers to ensure that the Critical Medicines Act includes tailored provisions that address the unique characteristics of plasma-derived medicinal products (PDMPs).

About PPTA

Plasma Protein Therapeutics Association (PPTA) is a dynamic trade association that represents a unique sector of the biologics and biotechnology industry. PPTA represents the leading manufacturers of lifesaving plasma protein therapies as well as more than 1,000 human plasma donation centers.

A one-size-fits-all approach towards all critical medicines would not address the complexities of the diverse pharmaceutical supply chains.

Critical Medicines Act

Recommended Policy Actions.
PPTA recommends reflecting the following elements in the Critical Medicines Act:

- Prioritise patient access over rigid national inventory requirements, recognising that medicines, such as PDMPs, have unique characteristics. These include: non-seasonal demand; production dependent on voluntarily donated human plasma in limited availability, short shelf life, lengthy manufacturing timelines that cannot be easily scaled up. While PPTA acknowledges the importance of appropriate inventory, distinct limitations must be accounted for.

- Recognise the distinctive characteristics of specific medicinal supply chains, especially medicinal products derived from substances of human origin. Differentiation is particularly relevant for Article 2 and Recital 15 to support effective implementation.

- Ensure continuous dialogue with manufacturers of all medicine classes included in the Union's list of critical medicines. Given the broad scope of the Act, it is essential that the Critical Medicines Group regularly consults industry representatives. In doing so, special attention should be given to the balance between national stockpiling and patient access since excessive stockpiling at the national level can unintentionally reduce availability for patients across the EU.

- Encourage Member States to establish procurement programmes as well as pricing and reimbursement frameworks tailored to the distinct nature of the PDMP supply chain. Cost containment measures, including price and reimbursement capping should consider exempting PDMPs given their unique characteristics. For example, Portugal applies a PDMP-specific tax at 2.5%, significantly lower than all other medicines at 14.3%. In Greece, immunoglobulins and albumins are exempt from the clawback measures.

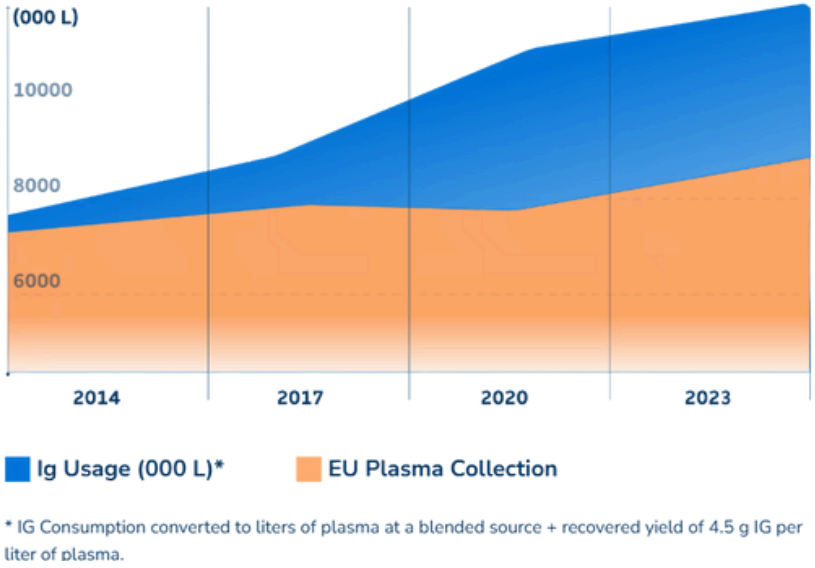
- Collaborate with the PDMP industry while implementing the Critical Medicines Act to ensure patients' uninterrupted access to medicines.

Plasma-Derived Medicinal Products (PDMPs)

Plasma-derived medicinal products are unique biological treatments made from voluntary human plasma donations. They are used to treat patients with rare, chronic, and life-threatening conditions such as bleeding disorders, immune deficiencies, and autoimmune diseases.

Plasma-Derived Medicines Sector & European Union

- Most plasma-derived medicines are listed on the **Union List of Critical Medicines**.
- **300,000** rare disease patients in the EU depend on PDMPs for survival. The use of immunoglobulins (Ig) has nearly doubled in the last decade due to improved diagnosis.[1]



* IG Consumption converted to liters of plasma at a blended source + recovered yield of 4.5 g IG per liter of plasma.

40% of the plasma used to manufacture PDMPs is imported from the United States.

- In 2023, **9.3 million litres** of plasma for fractionation were collected in the EU, with **50%** sourced from private centers in four Member States (Austria, Czechia, Germany, and Hungary) and the remaining **50%** from the public sector across 27 countries.[2]
- **50%** of PDMP's global manufacturing and **40%** of its global workforce are based in Europe. **Since 2022**, the industry has made significant investments in R&D, collection and manufacturing capacity in Europe to ensure that patients have access to lifesaving treatments.

Why Are Plasma-Derived Medicinal Products Unique?

01 Plasma is recognised as a **critical substance** of human origin in the SoHO Regulation

02 The Critical Medicines Act applies to all medicines from the Union list of critical medicinal products, including nearly all PDMPs

03 The production of PDMPs is **dependent on the voluntary** donation of human plasma, a starting material in limited supply

04 PDMPs are **not interchangeable due to natural variations** in plasma and differences in their production processes

05 Plasma for fractionation **cannot be synthesised in a factory** or laboratory

06 The patient need for PDMPs is not seasonal but has been **steadily growing**

07 Manufacturing of PDMPs cannot be **easily scaled up**

08 PDMPs have a **short shelf life**

09 Manufacturing of PDMPs is a lengthy process**, taking up to 12 months**

Plasma-derived medicines are essential far beyond rare diseases. They are also used in everyday medicine, emergency and critical care, and preventive medicine. Hospitals and clinics use these treatments to treat animal bites, burns, shock, trauma, and rhesus (Rh) incompatibility during pregnancy. They are essential in cancer supportive care, organ transplants, cardiac procedures, major surgeries, liver treatments, and many more.

For More Information

Visit euneedsmoreplasma.com or email info@pptaglobal.org.

1 The Marketing Research Bureau, 2023.
2 The Marketing Research Bureau, 2025.