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Plasma Protein Therapeutics Association

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Risk factors: new treatment indications & external influences affecting Europe's stable access to plasma

Over the past three decades, European patients have benefited from stable access to plasma-derived medicines manufactured in Europe, delivered through national health systems, and based on a significant portion of plasma imported from US donors.

Today, the need for more plasma to produce medicines is growing. Improved and early diagnosis is helping more patients access treatment and medical research provides evidence for new indications for plasma-derived medicines.

At the same time, global emergencies such as the COVID-19 pandemic and geopolitical shifts driven by evolving national health priorities trade issues that may restrict the exchange of blood components and plasma protein therapies, may upend the current global balance for plasma exports and imports. What are the risk factors for Europe's public health policies?

External issues & risks – plasma in the geopolitical landscape

Ensuring stable plasma donations for this critical resource

Plasma and its derived medicines are a critical health resource that patients in every country need to manage and a wide range of critical health conditions.

Plasma is partly recovered from blood given to the national blood bank system, by donors giving plasma directly and partly imported from donors in other countries. In this light, emerging medical treatment trends and shifting politics that can affect the global health landscape risk disrupting access to the donated plasma – especially for plasma that is imported.

The sudden emergence of COVID-19 is an important lesson for plasma donation planning and risk management policies. While the donation situation in Europe has remained predictable over the years, the pandemic shows the reality of how the donation landscape can change rapidly and without warning. Overnight, the lockdown across Europe and globally in 2020 has severely reduced the number of donors and donations. The result was fewer donations of blood and plasma in most European countries.

Factors influencing increased need for plasma and derived medicines

The need for plasma to produce plasma-derived medicines has been growing steadily in recent years, driven by several factors:

- The increased precision of medical diagnostics means that more people are identified with conditions that these medicines can treat.
- More people are being diagnosed early and those under treatment are living longer.
- More clinical evidence is emerging to show the benefits of plasma-derived medicines to treat patients with a variety of disorders.
- Increased awareness helps lead early identification of rare diseases in many patients that can benefit from plasma-derived medicines.
- Progress of medical research[29] that identifies new areas where these medicines will bring life-changing and saving treatments, for example:
  - Immunoglobulins to boost immunity and prevent infections in patients with secondary antibody deficiencies caused by chemotherapy or immunosuppressive therapy.
  - Immunoglobulins in patients in pre- and post-allogeneic haematopoietic stem cell transplant.
  - Plasma to produce hyperimmune treatments that are highly effective against hepatitis A, measles, chickenpox and rubella. Plasma-derived medicines also show potential to control other types of viral infections; and for ‘passive immunity’ treatments, where plasma-based antibodies are given directly to patients.
  - Albumin to treat patients with decompensated cirrhosis.

National security – plasma in the geopolitical landscape

Growing interest in exploring the use of plasma and convalescent plasma for new treatments could open new treatment globally for plasma and its derived medicines – beyond the medicines specified today by countries' health services.

This new interest in the potential wider uses of plasma-derived medicines is evolving the thinking on how much plasma a country needs and where it will come from. These factors and the debate in public health systems on plasma's effectiveness for treating COVID-19 has placed this material as critical resource on countries' political and medical agendas. Some examples:

US national security plan. The 2012 US Presidential Order on National Defense Resources Preparedness calls for national health resources to be prioritized over the supply of foreign needs and contracts in the event of a national emergency. The health resources specified include drugs, biological products, medical devices, health supplies, services and diagnostic equipment. In a pandemic, plasma would be covered, raising the risk that exports could be curtailed.[30]

COVID-19
The efficacy of plasma and its derived medicines as a treatment for COVID-19 have not been conclusive. To date it has shown to be effective only in the very early stages of the disease. Responding to the COVID-19 public health urgency in the pandemic's early days, some countries granted Emergency Authorization for plasma use. This has raised interest in the potential of convalescent plasma to treat the virus.

- This emerging situation, coupled with the use of plasma in treating Ebola, has heightened the perception that plasma can be considered to help manage future outbreaks – creating more interest among countries in securing a national plasma supply. This thinking may affect the global landscape for plasma donation in the medium term, and countries may include strategies to secure more plasma donations in their future pandemic preparedness plans.
- **US Food & Drug Administration – temporary authorization for plasma transfusions in COVID patients.** In mid-2020, the FDA authorized the emergency use of plasma donated by patients previously affected by COVID-19, for transfusions to treat affected patients.[31] This was updated in March 2021 in a further Emergency Use Authorization by the FDA.[32] It allows that COVID-19 convalescent plasma can be obtained from licensed blood establishments from donors in the US or its territories.

European Union policies/regulations on plasma self-sufficiency

The EU Blood Directive and related policies EU refer to an 'open strategic autonomy on starting materials for the manufacturing of medicines and to reduce the dependency from third countries' (see EU pharma and trade strategy).