Platform of Plasma Protein Users

# POSITION PAPER ON A POTENTIAL REVISION OF THE BLOOD DIRECTIVE

PLUS is the platform of plasma protein users representing patient organisations including the Alfa-1 Federation Europe, the European Haemophilia Consortium (EHC), the GBS/CIDP Foundation International, the International Patient Organisation for C1 Inhibitor Deficiencies (HAEI), the International Patient Organisation for Primary Immunodeficiencies (IPOPI), the ITP Support Association and the World Federation of Haemophilia (WFH).

Collectively these seven organisations represent the views of more than 110,000 known patients in Europe and they represent persons with conditions with a probable European prevalence of over 650,000. These patients are affected by rare plasma-related disorders. For many of these conditions, plasma-derived medicinal products are the only treatments available.

PLUS is following with great interest the discussions regarding European and international policy on blood and plasma collection and plasma-derived medicinal products. PLUS welcomes the efforts of the European Commission in involving patient organisations in the assessment of the existent legislation pertaining to the blood and plasma field.

More specifically, with regards to a potential revision of the Blood Directive, PLUS respectfully submits the following key recommendations:

- **Differentiation in policy and legislation of blood collection and plasma collection**.
  - It is important to recognize that there are major differences between whole blood collection and the collection of plasma that is used for fractionation (Creativ Ceutical report on EU overview of the landscape of blood and plasma). The Council of Europe sets the limits of blood donations to 4-6 times per year (women-men limits respectively) and up to 33 donations per year for plasma. A plasma donation will allow for the collection of average 750 ml of plasma for fractionation, whilst a blood donation will allow for the collection of 200-250 ml of plasma. Plasma donors also are repeat donors, which allows for optimal monitoring, screening and traceability.
  - PLUS firmly believes the time has come to make a clear distinction between blood collection and plasma collection and between labile blood products and stable plasma products.
  - Labile blood products have short shelf lives and are mostly used locally. They do not undergo manufacturing procedures. Plasma-derived medicinal products are finished stable pharmaceutical products, which undergo a complex production process that ensures optimal safety, efficacy and much longer shelf lives (up to several years). By definition they are fit to circulate freely at the international level.
  - Plasma-derived medicinal products are also unique medicines, which therefore present differences between different brands and will be tolerated differently by patients who therefore need an optimal range of plasma products within a given country.
  - Currently, the 'Blood Directive' only covers the collection and testing for plasma for fractionation. PLUS feels that a clear distinction between blood components for transfusion and plasma for fractionation should be reinforced. In fact, it is the understanding of PLUS that at the moment most plasma that is collected through whole blood collection cannot be used as source material for the production of medicinal products as it does not comply with European pharmacopoeia requirements. It seems therefore that there is already a natural distinction between the two types of collection and that

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reinforcing differentiation may contribute to increase the collection of plasma for fractionation and guaranteeing a sustainable access to these therapies for European patients.

- **Ensuring that patients have plasma-derived medicinal products available through their free circulation as pharmaceutical products**.
  - The European Union legislation so far adopted has made a major contribution to the achievement of the objective of the free and safe movement of medicinal products for human use and the elimination of obstacles to trade in such products (Recital 2, Directive 2004/27/EC).
  - Member States are allowed to apply more stringent requirements for the standards of quality and safety of plasma-derived medicinal products (Treaty on the Functioning of the EU, Title XIV, Art. 168.4a) to ensure the well-being of patients in need of these treatments.
  - The European Medicines Agency has clearly stated there is no difference in terms of safety between paid plasma donations and unpaid blood donations (EMEA/CPMP/BWP/1818/02).
  - A future EU legislation revision should ensure that high quality and safe plasma-derived medicinal products are available for patients throughout the European Union, with no obstacles to free movement of such products.

- **Ensuring availability of plasma for medicinal products for all patients, through the coexistence of non-compensated and compensated donation**.
  - The large majority (70%) of plasma-derived medicinal products are produced from compensated plasma donations, which undergo and meet strict regulatory requirements.
  - The global demand for plasma products has consistently gone up over the past twenty years. It is foreseen that 37.6 million litres of plasma (recovered and apheresis) will be required in 2018 to meet the global demand (Marketing Research Bureau).
  - For most of the conditions treated by plasma-derived medicinal products, there is no alternative treatment available.
  - A radical change in the system only based on voluntary unpaid blood donations would not be able to meet the demand of patients, would reduce access and choice of treatment options and would be subject to a larger likelihood of shortages, should any problem occur with the national supplier.
  - Only by ensuring the co-existence of voluntary and compensated plasma donations can the growing demand of patients in need of plasma-derived medicinal products be met.
  - Patients represented by PLUS face constant pressures towards accessing their treatment due their high costs and the economic pressures faced by European governments'. PLUS is concerned that setting a goal of self-sufficiency (as mentioned in the recital of the Directive) may limit patients' access to plasma-derived treatments. In fact, Member States may feel compelled to bring down treatment levels in order to achieve the goal of self-sufficiency.

PLUS believes that patients must be the absolute focus of the blood and plasma sectors in healthcare. We believe that the interest of the patients must be paramount in policy-making around issues pertaining to their health and life-saving treatments. We therefore look forward to continuing our work with the European Commission to ensure that future legislative or policy developments in the area of blood and plasma-derived medicinal products ensures the best treatment for patients across the European Union.

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