Plasma Protein Therapeutics Association

**22 May 2009** thomas.bregeon@ec.europa.eu
**Ref.: DG SANCO09001**

Mr. Thomas Brégeon
European Commission
DG Sanco, Unit C6: Health Law and International
B-1049 Brussels

Dear Mr. Brégeon,

**Subject: Upcoming Report on the Promotion by Member States of Voluntary Unpaid Blood & Tissues and Cells Donations**

Further to our meeting with you and your colleagues on 7 October 2008 and to our more recent discussion during the International Plasma Protein Congress in March 2009 during which we discussed the upcoming report on the promotion of voluntary blood and tissues and cells donations, we would like to share some comments with you which we hope you will take into consideration when drafting the questionnaire that will be used to gather the necessary information from Member States for the elaboration of the report.

We are well aware that the Commission will consult PPTA and other relevant stakeholders when preparing the actual report towards the end of the year, as discussed previously. However we strongly believe that it is very important to differentiate between the collection of blood for transfusion as well as other biological substances and the specialized collection of apheresed plasma for fractionation.

Realizing you will be shortly starting to work on the preparation of the questionnaire we would like to take the opportunity to share the following specific comments with you:

- We feel it is important to re-emphasize that PPTA strongly believes that apheresed plasma and plasma protein therapies should be considered on a separate basis than other substances of human origin such as blood and tissues and cells. Apheresed plasma is intrinsically different from other substances of human origin such as red cells, thrombocytes (etc.). These differences lie in the way plasma is collected, the speed with which it is replaced in the body after an apheresed plasma donation (24-48 hours), the manufacturing process of plasma-derived medicinal products as well as in the usage patterns of plasma-derived medicinal products which are subjected to the Community Directive 2001/83 EC.
- PPTA strongly believes that a clear separation of apheresed plasma for fractionation and plasma protein therapies will be crucial to ensure that the report avoids drawing misleading conclusions by erroneously assuming that what applies to labile products of human origin should also apply to plasma protein

therapies, which in contrast are stable medicinal products with a shelf life of several years and with recognized and accepted viral safety steps which account for the absence of viral transmission since the early 1990s.

- A clearly separated section on apheresed plasma and plasma protein therapies would also help avoid misinterpretations which in the past have often caused unnecessary concerns amongst involved stakeholders.

In order to receive information that can easily be interpreted and integrated into the actual report we would respectfully like to propose that the Commission considers phrasing the questions contained in the questionnaire in a way that will make it clear for the Member States to differentiate between apheresed plasma and plasma protein therapies and other substances such as blood and tissues and cells when reporting their information.

An explanatory introduction to the questionnaire could explain why the Commission believes it is important to differentiate between these categories bearing in mind the intended purpose of the end product. It should be remembered that in Europe PPTA members collected over 1.75 million liters of apheresed plasma in 2008. Internationally, the figure is about ten times higher.

We hope that the above suggestions and comments will be helpful to you. PPTA would be pleased to informally further support and comment on the draft questionnaire.

Yours sincerely,

Charles Waller
Vice-President, Europe

Johan Prévot
Director Health Policy, Europe

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