PPTA
Plasma Protein Therapeutics Association

25 April 2006
Reference: DGENT06008

BY E-MAIL
Peter.Arlett@cec.eu.int
Martin.Terberger@cec.eu.int

Dr. Martin Terberger
Dr. Peter Arlett
Commission of the European Communities
DG Enterprises
Rue d'Arlon 88
1049 Brussels

SUBJECT:European Commission Pharmacovigilance Workshop with Industry

Dear Dr. Terberger, dear Dr. Arlett,

Thank you very much for the opportunity to participate in the European Commission Pharmacovigilance Workshop with Industry on 21 April 2006. PPTA appreciates the opportunity to provide input to this important initiative and to learn about the positions of other industry representations, which we support particularly with regard to a more transparent and harmonised EU Pharmacovigilance approach.

We believe that the early involvement of interested parties, such as patients, physicians and industry, in the decision making processes to develop Commission regulations is important. In 2004 and 2005, we have written to the Commission jointly with other associations representing manufacturers of biological products to request that the "Commission Regulations (EC) No 1084/2003 and (EC) No 1085/2003" and the related "Guideline on dossier requirements for Type IA and Type IB notification (July 2003)" should be revised, because of the serious negative impact on biological products. We have been notified in March 2006 that the Commission is now starting to reflect on a possible revision of these texts. In view of the success of the recent workshop on pharmacovigilance, we would respectfully like to propose a similar workshop in the near future to discuss the variations regulations and to provide the industry perspective and experience with the current system for variations. We believe that sharing this information with you and your colleagues at an early stage will be helpful for your internal discussion and accelerate the urgently needed revision process of these documents.

We hope that our proposal will find your consideration and we remain at your disposal for further discussions.

Yours sincerely,

Ilka von Hoegen

Dr. Ilka von Hoegen
Director, Regulatory Affairs

Cc: Mr. Nicolas Rossignol

Boulevard Brand Whitlock, 114/5 · 1200 Brussels BELGIUM · tel : +32.2.705.58.11 · fax : +32.2.705.58.20
VAT: BE453 837 462 · e-mail: pptaeu@pptaglobal.be · www.pptaglobal.org
PPTA Offices in Brussels · Washington · Annapolis · Tokyo