Plasma Protein Therapeutics Association

25 June 2008 tapani.piha@ec.europa.eu
Ref.: DG SANCO08005

Mr. Tapani Piha
Head of Unit
European Commission
DG Sanco, Unit C6: Health Law and International
B-1049 Brussels

Dear Mr. Piha,

Subject: Call for tender SANCO/2008/C6/012 on Testing Methods and Testing Laboratories

The Plasma Protein Therapeutics Association (PPTA)[1] recently became aware of the European Commission's call for tender ref.SANCO/2008/C6/012 concerning an analysis and comparison of testing methods and testing laboratories in the EU and third countries for the biological markers specified in the blood and tissues and cells Directives.

PPTA understands, welcomes and supports the purpose behind the Commission's call for tender which is to conduct an analysis on how testing methods and testing laboratories are authorized and validated for the application of the Community standards and specifications as set in the relevant Commission Directive in order to ensure the highest standards of quality and safety for substances of human origin as well as to address differences in national requirements.

PPTA strongly believes however that plasma and plasma-derived medicinal products should be considered on a separate basis than other substances of human origin such as blood and tissues and cells. It is important to understand that plasma-derived medicinal products are intrinsically different from other substances of human origin such as red cells, thrombocytes (etc.). These differences lie in the way plasma is collected, in 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 Code 2001/83 EC. A combined analysis and description with blood and tissues and cells in a single report could end up in producing misleading conclusions by assuming that what applies to labile products of human origin would also apply to

[1] PPTA is the primary advocate for the world's leading producers of plasma protein therapies. The medicines produced by PPTA members are used to treat patients suffering from rare, mostly chronic, life-threatening and/or life-impairing plasma protein disorders and serious medical conditions including bleeding disorders (e.g. Haemophilia), immune system deficiencies (e.g. Primary Immunodeficiencies), auto-immune diseases (e.g. Guillain-Barré Syndrome, Idiopathic Thrombocytopenic Purpura), Alpha-1 Antitrypsin Deficiency, burns and shock.

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

plasma protein therapies, which in contrast are stable medicinal products with a shelf life of several years.

PPTA strongly believes that a separation between plasma-derived medicinal products and cellular blood components and tissues is needed in the context of this tender as well as in upcoming European Commission's relevant reports and/or legislation. Recognizing the important differences of plasma and plasma-derived medicinal products which are linked to their unique collection, production and supply and demand patterns in future European Commission's dossiers and actions will be key to sustaining an appropriate supply of these life-saving and life-enhancing therapies for the patients who need them in the EU.

PPTA would like to respectfully request a meeting with the Commission's relevant services to address this important issue in a detailed discussion.

Yours sincerely,

Charles Waller
Vice-President, Europe

CC : Thomas Brégeon, DG Sanco

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