PPTA
Plasma Protein Therapeutics Association

30 November 2010
Reference: PSSC10028

BY E-MAIL

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Mr. Antti Maunu
(Acting) Head of Unit "Health Law and International"
Directorate General for Health and Consumers
European Commission

Subject: West Nile virus: meeting in Thessaloniki, January 2011

Dear Mr. Maunu,

The Plasma Protein Therapeutics Association (PPTA) is writing to you pertaining to the summary report of the recent joint meeting of the Competent Authorities and the Regulatory Committee on Blood and Blood Components. In the report it was stated that it is expected that an increasing number of cases of West Nile virus will be reported in 2011. It is planned to create a subgroup to develop a preparedness plan for next year's anticipated West Nile virus outbreak and have a first meeting in January 2011.

After the introduction of West Nile virus into the US in 1999, blood transfusion transmissions were first observed in 2002, at which point the FDA contemplated introducing measures with regard to blood safety and supply, such as NAT testing of whole blood donations and possibly also plasma for fractionation. PPTA took an active part in the discussions of appropriate measures for human plasma for fractionation, the starting material for plasma protein therapies, and provided an abundance of scientific evidence on the virus inactivation capacity of the manufacturing process for plasma protein therapies for relevant model viruses of West Nile virus as well as West Nile virus directly. On the basis of the provided evidence the US FDA finally decided that West Nile virus NAT testing was not indicated for plasma for fractionation.

We would like to also reassure European Authorities about the safety of plasma protein therapies with regard to West Nile virus and share our scientific evidence and experience. Therefore, we would respectfully like to propose that a member of PPTA's Pathogen Safety Steering Committee, our scientific expert group, is given the opportunity to present at the first meeting of the subgroup in Thessaloniki. We believe that we can contribute relevant information for decision making processes pertaining to appropriate safety measures for plasma protein therapies related to West Nile virus in the interest of patients depending on these often life-saving medicinal products.

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Please find attached a presentation that was given by the PSSC to the FDA in 2003 to provide you with information on the virus reduction capacity of the manufacturing process of a wide range of plasma-derived products. An update of this data can be presented, demonstrating, based on a risk assessment, a high safety margin regarding WNV for plasma-derived products without West Nile virus NAT testing.

We hope that our proposal will find your approval and remain at your disposal for further discussions at any time of your convenience.

Sincerely Yours,

Ilka von Hoegen

Dr. Ilka von Hoegen
Senior Director, Quality and Safety

Enclosure: Clearance of West Nile virus in plasma therapies, presentation to the FDA Blood Products Advisory Committee. March 13, 2003

Cc: Rita Poleczki

About PPTA:

The Plasma Protein Therapeutics Association (PPTA) is the trade association and standards-setting organization of the world's major producers of plasma derived and recombinant analogue therapies. PPTA's members include, Baxter, Biotest, CSL Behring, Grifols, Kedrion and Talecris. Between them they provide the majority of the world's needs for plasma protein therapies, including clotting factor therapies for individuals with bleeding disorders, immunoglobulins to treat complex diseases in people with immune deficiencies, and a range of other plasma protein therapies including fibrin sealant and alpha-1 anti-trypsin.