Plasma Protein Therapeutics Association

Ref: DGSanco12007 **by email**
14 September 2012

SANCO-FEES-PHARMACOVIGILANCE@ec.europa.eu

European Commission
Directorate General for Health and Consumers (SANCO)
Unit D5 'Medicinal Products – Authorisation, EMA'
B-1049 BRUSSELS

Subject: Introduction of fees to be charged by the EMA for Pharmacovigilance

Dear Madam, Sir;

PPTA appreciates the opportunity to comment on the Concept Paper on the Introduction of fees to be charged by the EMA for Pharmacovigilance. Please find our comments below:

Consultation item #1: We disagree that the review of a standard report should be charged with the same amount as a Type II Variation. In our view, the fees for PSURs evaluation should be adjusted to the amount of cases to be evaluated instead of years of marketing the product. We propose collecting the number of cases processed by each company per year and aggregate them in order to have ranges of number of cases and identify related fees; this would be consistent with the EMA approach to base their fees on workload. The fees should be adjusted to a reasonable amount and according to the real workload.

The time frame of two years has to be better defined. How are products handled that are on the market, but are subject to a MA, for example because another indication is added? Will the 2 years start with the first MA or does the clock restart with the second MA.

We do not see the rationale that products on the market for more than 2 years would generate more workload, than products on the market for less than two years. We believe that the safety profile of a product increases the longer it is on the market.

Consultation item #2: PPTA welcomes in principle the option to allow grouping of different MAHs. But it should be taken into account that certain data might be confidential and should not be disclosed to other MAHs participating in the grouping, unless participants have established a commercial agreement. If not, data submission in a grouping should be performed individually through a single portal, and EMA would then aggregate and evaluate the data. Feed-back should only be provided to the original owner of the data and not to the entire group.

Also, a fee of 500 € per MAH seems too high when compared to the fees foreseen for the scientific assessment.

Consultation item #3: We believe that a fee of 80,300 € is exaggerated when compared to the potential fees for a new MA in a small group of countries. We understand fees may vary substantially depending on the countries involved; however, the fees for a PASS should not be higher than half the fees paid for the MA application.

Consultation item #4: See response to consultation item #2.

Consultation item #6: See comments to consultation Item #2.

Consultation item #7: PPTA would agree with the proposed fees covered under this consultation item, if the other fees are reduced according to our proposals outlined above, specifically the fees for PSUR. If these fees remain unchanged we would request to reduce the PhV fees, because otherwise the sum of fees is inflated and in no relation to the service provided.

Finally, we would like to request clarification on the wording of the second paragraph on page 10: *"This fee should be charged for the assessment of the PSUR irrespective of the route of authorisation (centralised/decentralised/national) of the products concerned. This fee would be a new type of fee which does not currently exist."* We understand that this paragraph only refers to products nationally licensed in more than one Member State as stated in the first paragraph in section 3.1..

We hope that you will find or comments constructive and remain at your disposal for further discussion.

Sincerely Yours,

Ilka von Hoegen

Dr. Ilka von Hoegen
Senior Director, Quality and Safety