PPTA
Plasma Protein Therapeutics Association

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European Commission

DG Enterprise and Industry
Unit F2, Attn: Sabine Atzor

Office BREY 10/069

BE-1049 Brussels

Belgium

SUBJECT: Pharmaceutical Excipients Consultation

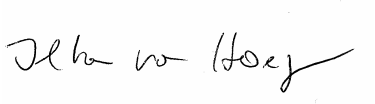
Dear Dr. Atzor,

Thank you very much for the opportunity to submit comments to the draft "*Specific conditions of the application of the principles and guidelines of good manufacturing practice for certain excipients"*.

Our comments focus on the definition of excipients in the current draft, which, in our interpretation would cover all auxiliaries and materials used in the manufacturing process. In contrast, the CHMP *"Guideline on excipients in the dossier for application for marketing authorisation of a medicinal product"* (EMEA/CHMP/QWP/396951/2006) defines excipients as those used for the formulation of the final product. We strongly agree with the definition in the EMEA document and we would therefore respectfully like to propose to either reword the definition section for excipients in the current draft, or introduce the text from the EMEA document also for the sake of harmonisation of European Union regulations.

We hope that you will find our proposal constructive and acceptable. We remain at your disposal if you would require further information.

Yours sincerely,



Dr. Ilka von Hoegen
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