PPTA
Plasma Protein Therapeutics Association

24 April 2006 **BY E-MAIL**
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SUBJECT: PPTA comments on the "Guidance concerning "consultations with target patient groups" for the package leaflet (Article 59(3) and 61(1) of Directive 2001/83/EC as amended by Directive 2004/27/EC" (August 2005)

Dear Dr. Lehmann, dear Ms. Dourdin,

Thank you very much for your willingness to consider our comments on the "Guidance concerning the patients' consultation requirements for the package leaflet (Article 59(3) and 61(1) of Directive 2001/83/EC as amended by Directive 2004/27/EC" in the finalisation process of the document.

As already indicated we believe that the Guidance is very general and broad and not all the requirements laid out in the Guidance are appropriate to all product types. PPTA's member companies would like to share in more detail their experiences, which you will find attached to this letter (DGENT0600x). The examples confirm that Member States are already implementing some of the requirements from the draft Guidance. It is also apparent that there is significant diversity among Member States on package leaflet requirements pertaining to new applications or for variation procedures.

We believe that application of the package leaflet requirements to all products is unwarranted as some products are used by professional who are well aware of the product requirements or by patients who have undergone extensive training by their treating physician.

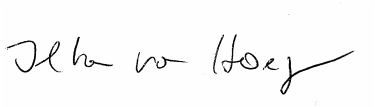
As already indicated in our previous letter, we would respectfully like to propose to exempt all medicinal products from Braille labeling that can practically not be self-administered by blind or partially sighted patients.

Regarding the performance of readability tests we would respectfully like to point out that both Art. 59 (3) and 61 (1) of Dir. 2001/83 as amended state unambiguously "target patient groups". So from a formal legal perspective, we see no basis for

extending the scope of the Guideline to all users, especially not to health-care professionals.

We hope that the attached information will further highlight the significant difficulties imposed by the broad focus of the guideline and the different interpretation by EU Member States. We would like to respectfully request that more precise guidance is developed to avoid a disharmonised situation within the European Union, which is already manifesting itself, and to ensure that the often life-saving therapies our member companies manufacture are available to patients depending on them. We remain at your disposal if you would require further information.

Yours sincerely,



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Enclosure: DGENT06005