PPTA
Plasma Protein Therapeutics Association

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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,

We noticed that the proposed "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" does unfortunately not allow any exceptions for medicines which are administered only by health care professionals (e.g., intensive care medicines like Human Albumin solutions or thrombolytics). Furthermore, there are no exceptions for medicines for target patient groups that have regularly undergone special training before administering their special therapies.

The latter applies particularly to coagulation factors used for treatment of various haemophilia diseases (e.g., haemophilia A, haemophilia B, or von Willebrand's disease) as well as to immunoglobulin G preparations for intravenous or subcutaneous administration (IVIG or SCIG) in patients suffering from antibody-deficiency conditions. These kinds of products have to be administered intravenously or by subcutaneous infusion, respectively. This is usually done by health care professionals. For many prophylactically treated patients however, home treatment is made possible, but only after special training by health care professionals at the beginning of the therapy.

The special training includes intensive education of the patient about his or her type of disease (inherited, chronic, etc.) and learning to reconstitute any lyophilised products, perform venipuncture and inject the medication intravenously or learn self-infusion of subcutaneous immunoglobulin, respectively. The package leaflet, training brochures, CD´s etc. provided by manufacturers, specialised Treatment Centres and/or patient organisations are an essential part of this educational process.

As in the case of the above mentioned medicinal products, the intensive training prior to and during the initial phase of the therapy ensures the familiarity of the patient and/or relevant care-person(s) with the disease, the drug and its administration. The performance of a Readability test according to the above mentioned Guidance and the "Guideline on the readability of the label and the package leaflet of medicinal products for human use" is not appropriate for these target patient groups and for this kind of medicinal products, respectively.

We therefore strongly recommend excluding from this Guidance/Guideline all hospital-only medicinal products / intensive care medicines (namely Human Albumin solutions and thrombolytics) as well as those patient groups, who have undergone a special training or education before taking a medicine in self administration, as outlined above.

In addition, the aspect of specially trained patient groups should also be added to the exceptions listed in the "Guidance concerning the Braille requirements for labelling and the package leaflet", which currently only mentions "products which are only intended for administration by health care professionals".

To illustrate that, we would like to give a calculation example:

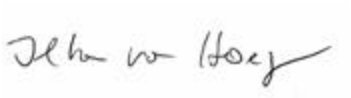
The diseases that are treated with, e.g., coagulation factors, are very rare diseases. As an example, the most frequent haemophilia disease, i.e., haemophilia A, occurs in 1:10.000 people only, resulting in a probability of 0.0001 that a German would suffer from haemophilia A. There are about 160.000 blind persons in Germany, which results in a probability of 0.02 for any German being blind. Therefore the probability of a German person to suffer from haemophilia A and blindness at the same time is as little as 0.000002.

It is furthermore absolutely unrealistic that a blind haemophiliac or blind patient suffering from antibody-deficiency conditions would be trained for home treatment. The relevant treatment's application would be carried out by health care professionals or care-persons of the patient, who are specifically trained as outlined above.

The Guidance should therefore also exempt all medicinal products from Braille labelling that can practically not be self-administered by blind or partially sighted patients.

As the measures to be taken to fulfil the above mentioned Guidances are very time and cost intensive without contributing to the welcomed spirit of the regulations, we would highly appreciate it if our comments are taken into consideration.

Yours sincerely,



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