Plasma Protein Therapeutics Association

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European Commission
Directorate General for Health and Consumers (SANCO)
B-1049 BRUSSELS

Subject: GMP Annex 14: Manufacture of medicinal products derived from human blood or plasma

Dear Mrs Villanueva, dear Mr. Van-Der-Spiegel;

When GMP Annex 14 has been revised in the light of Directive 2002/98/EC and relevant implementing Directives setting standards of quality and safety for the collection and testing of human blood and blood components for all uses, including the manufacture of medicinal products PPTA has been advocating for a favourable regulatory environment for contract manufacture of human plasma into plasma derived medicinal products. In this context PPTA has noted the interpretation of the Competent Authorities on Blood and Blood Components at the meeting on 16 and 17 May 2011.

Although the statements made in the summary report of the meeting (Ref. Ares(2011)902136 - 24/08/2011), see paragraph 4.2. “Follow-up on Annex XIV of EU GMP on manufacture of medicinal products derived from human blood or plasma”) give a certain level of reassurance to manufacturers providing contract manufacturing services to non-EU countries; the lack of legal provisions particularly on national level still leaves a wide range of interpretation by National Competent Authorities (NCAs). In this context, we understand from above mentioned summary report that *“The issue of applying the same quality and safety standards for EU and non-EU countries was highly debated”*. In acknowledgement of these uncertainties PPTA has developed a Position Paper outlining our interpretation of Annex 14 and the provisions for contract manufacture (QOTF11033, copy attached).

PPTA would like to bring this Position Paper to your attention and respectfully proposes that the need for more legal guidance pertaining to the provisions of contract manufacture is addressed at the next meeting of the National Competent Authorities on Blood and Blood Components in April 2012.

We would particularly appreciate legal clarification in the following areas:

- Plasma Quality Requirements for products entirely intended for marketing outside the EU should be specified in such a way that the national requirements of the country of origin have to be fulfilled and compliance with at least the requirements stipulated by the WHO must be ensured.

- Inspections of blood establishments in non-EU countries by EU Authorities are not mandatory for contract fractionation programs.

- When as part of a contract fractionation agreement not all products manufactured from plasma from a non-EU country are returned but are marketed in another non-EU country, regulatory provisions should be comparable or equivalent but not identical to the respective EU requirements and in full compliance with the national license in the country where the product is marketed.

In conclusion, we believe that an obligation for non-EU plasma to comply with EU requirements would jeopardize high quality EU contract manufacturing for non EU-countries having no national plasma fractionation facilities. Such countries, their health systems and foremost their patients in need of plasma derived medicinal products would be deprived from – financially affordable – treatment. These arguments are also applicable if plasma-derived medicinal products from contract manufacture are also provided to another country outside the EU. We understand that EU legislation cannot be imposed on or enforced in non-EU countries.

We hope that our request for legal clarification finds the consideration of the National Authorities on Blood and Blood Components. We remain at your disposal for further discussions on these important matters.

Sincerely Yours,

Ilka von Hoegen

Dr. Ilka von Hoegen
Senior Director, Quality and Safety

Enclosure: PPTA Position Paper QOTF11033