PPTA
Plasma Protein Therapeutics Association

13 December 2010
Reference: DGSanco10009

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Subject: Revision of Annex XIV; manufacture of medicinal products derived from human blood or plasma

Dear Mr. Maunu,

PPTA has noted with great interest the report on the joint meeting of the competent authorities and the Regulatory Committee on Blood and Blood Components held 27 & 28 October in Brussels. We refer specifically to the conclusion that the draft Annex XIV should progress without making any statement on import criteria for plasma fractionation programmes for third countries, other than referring to the import criteria set out in the Blood Directive and its implementing measures. In 2009, when the revised Annex XVI was published, PPTA raised concerns about the proposed provisions for contract manufacture of plasma derived medicinal products from plasma from non-EU countries, when the finished product is intended for patients in the country where the plasma was collected. Please find our previous correspondence attached (DGENT09005, DGENT09006).

Although we appreciate the conclusion to remove the restrictive requirements from the Annex XIV as a sign, that our concerns were taken seriously, we believe that now a situation has been created, where a lack of regulatory guidance will also present a threat to contract manufacture.

Therefore, we would return to our initial proposal for paragraph 9.1: *"Plasma sourced in, or imported into the EU from third countries and used for contract fractionation for plasma derivatives and/or for commercial products to be marketed outside the EU must comply with current WHO- and national requirements in the country of origin. Also the fractionation process can comply...."*

For Paragraph 9.2 we propose to modify the wording as follows:

"Depending on the outcome of a thorough risk management process and taking into consideration possible differences in epidemiology, validated cleaning procedures and other appropriate measures should be adopted when plasma/intermediates of different origins is processed at the same plant."

We believe that regulatory guidance on contract manufacture will provide national Competent Authorities with reassurance about the safety of the incoming material, by

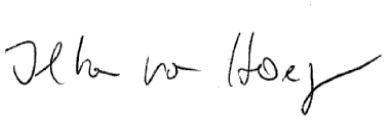
providing a regulatory framework, which is complimentary to the risk-based approach the manufacturer needs to apply to ensure that plasma entering their facilities is of appropriate quality and safety, which in their own interest.

Again, we would like to reiterate the abundance of experience and the good safety record of contract manufacture performed by PPTA member companies. To keep this well established process as efficient as it is right now, sensible regulatory guidance for contract manufacture is needed. We believe that ignoring contract manufacture in the GMP Annex XIV will cause national Competent Authorities to implement measures that may be even more restrictive and unhelpful.

We are also aware about the resolution of the Sixty-third World Health Assembly on Availability, Safety and Quality of Blood Products, which aims at better use of blood products and plasma for fractionation from developing countries. Since most of the globally available fractionation capacity and the relevant know-how are located within the EU and the US, these countries have to rely on the willingness of EU and US companies to fractionate their plasma.

We hope that you will find our arguments convincing and we would be more than happy to meet with you for further discussion of this very important issue.

Sincerely Yours,



Dr. Ilka von Hoegen
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Enclosures: DGEN09005, DGENT09006