PPTA
Plasma Protein Therapeutics Association

19 July 2006 **BY E-MAIL**
Reference: DGENT06009 **georgette.lalis@cec.eu.int**

Ms. Georgette Lalis
Director European Commission
DG Enterprise and Industry
B-1049 BRUSSELS

Subject: PMF and second step procedure in Italy

Dear Ms. Lalis,

PPTA member companies are currently encountering a very serious issue in Italy with regards to the Plasma Master File (PMF) and the second step procedure and we would like to inform you accordingly. Furthermore, we would highly appreciate it if your Directorate could take an official position and avoid an escalation of the threat to the availability of our life saving therapies in Italy.

As you are well aware, the EU Directive (2003/63) officially introduced the concept of the PMF. A PMF holder can request central certification of this documentation on the starting material "plasma" at the EMEA. Once the EMEA has established conformity with regulations, a certificate is emitted which has to be "connected" to national product licenses in the Member States in the so-called second step procedure. This procedure is described in an explanatory note[1] from the Commission. In this document, as well as mentioned in the Directive, no reassessment of the PMF should be performed at national level.

Unfortunately, in Italy, the licensing agency AIFA has requested all PMF holders to certify and prove that the EMEA approved PMF complies with Italian law and therefore introduce a reassessment of the PMF.

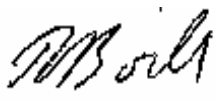
PPTA and its member companies have contacted AIFA but no solution to this issue has been found yet. However, we understand that AIFA as well as PPTA would welcome clarification of the second step procedure and particularly that a reassessment of the PMF evaluation at national level is not allowed.

Due to the urgent situation (AIFA could not approve EMEA certified PMF's in Italy which could lead to shortages of life-saving therapies) we would highly appreciate the intervention of the Commission and clarification on the issue of the second step procedure.

It would be very negative for the PMF concept if suddenly all Member States could come with special requirements once a PMF has been centrally certified which would go against the certification of the PMF at the EMEA.

We hope you will be able to help us with this situation and remain at your disposal should you need any further information.

Yours sincerely,



Dr. René Büchel
Director, PPTA Source

Charles Waller
Executive Director PPTA Europe

1. Explanatory note on PMF and VAMF "Second Step"