

7 October 2008
Ref.: HPSC08071

MEETING WITH DG SANCO
Tuesday 7 October 2008, European Commission, Brussels

PPTA Position on the
Call for tender SANCO/2008/C6/012 on Testing Methods and Testing Laboratories

PPTA would respectfully like to bring the following points to the attention of the Commission with regards to the above mentioned call for tender:

- PPTA strongly believes that plasma and plasma-derived medicinal products should be considered on a separate basis than other substances of human origin such as blood and tissues and cells in the context of this call for tender as in other European Commission's relevant reports and/or legislation.
- Plasma-derived medicinal products are intrinsically different from other substances of human origin such as red cells, thrombocytes (etc.). These differences lie in the way plasma is collected, in the manufacturing process of plasma-derived medicinal products as well as in the usage patterns of plasma-derived medicinal products which are subjected to the Community Code 2001/83 EC.
- These intrinsic differences are also reflected in the fact that unlike other substances of human origin such as red cells and thrombocytes, human plasma for fractionation is itself subject to a EU Pharmacopoeia monograph (Human Plasma for Fractionation 01/2005:0853)
- As the call for tender refers to the Blood Directive, one could interpret that plasma is included in the scope although the call for tender's objectives mainly refer to Blood and Tissues and Cells establishments. However plasma for fractionation should be expressly exempted from its scope since:
 - Unlike blood and tissues and cells, once collected plasma for fractionation undergoes a long and complex production process. Several viral inactivation steps take place during this production process which contribute to the highest safety of the final product
 - Plasma for fractionation undergoes a centralized approval procedure through the centralized Plasma Master File thereby avoiding variability in national authorization procedures. The PMF is a compilation of all the required scientific data on the quality and safety of human plasma relevant to the medicines, medical devices and investigational products that use human plasma in their manufacture. These data cover all aspects of the use of plasma, from collection to plasma pool.
- A combined analysis and description with blood and tissues and cells in a single report could end up in producing misleading conclusions by assuming that what applies to labile products of human origin would also apply to plasma protein therapies, which in contrast are stable medicinal products with a shelf life of several years.
- Recognizing the important differences of plasma and plasma-derived medicinal products which are linked to their unique collection, production and supply and demand patterns in future European Commission's dossiers and actions will be key to sustaining an appropriate supply of these life-saving and life-enhancing therapies for the patients who need them in the EU.