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By e mail: [antti.maunu@ec.europa.eu](mailto:antti.maunu@ec.europa.eu)

Mr. A. Maunu  
Acting Head of Health Law and International  
Health Law and International (C6)  
European Commission  
Directorate General for Health and Consumers (SANCO)  
B-1049 BRUSSELS

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SUBJECT: 2nd report on voluntary and unpaid donation of blood and blood components

Dear Mr. Maunu

We have read with great interest the "2nd report on voluntary and unpaid donation of blood and blood components" that outlines the current situation in the Member States, including Croatia and Norway.

PPTA commends the Commission and your unit in particular for this Report and would like to address some of the issues it raises.

As was duly noted in the Report, a majority of the plasma fractionation facilities in Europe are privately owned. PPTA prides itself on the fact that our members are expanding their fractionation capacity, both in Europe and globally, they are growing their networks of plasma collection centres as well as the amount of plasma collected.

In 2010 PPTA members collected over two million litres of plasma in European Union Member States and worked with many countries to fractionate their plasma. Our members fractionated more than 20 million of litres of plasma including both plasma recovered from whole blood donations and source plasma from apheresis donations. In many cases this is working cooperatively with national blood services and governments, often as a contribution to national self-sufficiency programmes.

PPTA is concerned that Europe should be responding to the expanding patient need for plasma proteins. Precise figures are difficult to identify, but experience over the last twenty years indicates consistent growing demand. An annual increase of between 5% and 10% has been recorded over this period. Although this has been partly possible thanks to more efficient fractionation, for example with average immunoglobulin yields increasing from less than 3 grams per litre of plasma in the 1990s to an average of over 4 grams rising to nearer 5 grams today, much of this increasing patient need has been met through more plasma donations. It should importantly be noted that patient and physician groups representing conditions

treated with plasma proteins consistently report that even in Europe there is still significant under treatment or no treatment at all for some!

One myth which though not specifically addressed in the Report is relevant and worthy of note. Specifically, it is asserted by many that voluntary compensated plasma donation programmes have the effect of reducing the effectiveness of blood donation programmes by competing for donors with a negative impact on the quantity of blood collected for transfusion purposes.

PPTA challenges the assertion that the coexistence of two independent collection systems, one for blood and the other for plasma could create a risk of shortage in supply. On the contrary, recently available data and years of experience demonstrate the mutual benefit of the coexistence of both systems.

PPTA notes that the countries with plasmapheresis based on voluntary, compensated plasma donors have successful blood donation programs. Blood donation rates in Austria, the Czech Republic, Germany and the USA are higher than most countries that do not host plasma collection programs. There is little evidence that one sector is interfering with another's donor base and collection activities, except in a positive way.

Independent reports clearly indicate that there is a positive impact on blood supply in the four countries with voluntary, compensated plasma donor programs. The European Directorate for the Quality of Medicine and HealthCare's 2006 Report<sup>1</sup>, notes that in Austria and Germany, countries with long and successful histories of plasmapheresis, the level of blood donation is high compared with most other listed countries. Austria and Germany have whole blood donation rates of 56.3 and 57.9 donations per 1,000 population. Only three out of 37 countries: Cyprus, Denmark and Greece have higher rates than Austria. It can reasonably be asserted that an active donation program with voluntary compensated plasma donors correlates with higher rates of blood donation.

Further support for this assertion is provided in the recent report from the Czech Republic: "Activity of health care institutions in the section of transfusion services in the Czech Republic in 2009", published 19 August 2010<sup>2</sup>. This Czech report records the blood donation record in each of the Czech Republic's fourteen regions. Eleven regions increased the number of blood donations between 2007 and 2009, while in three regions blood donations declined. Importantly, in ALL the regions, where the eleven plasma donation centres operate (where donors are compensated for their costs and inconveniences) blood donations have actually increased. In the three regions where blood donations have gone down there is no plasma donation program.

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<sup>1</sup>van der Poel CL, Janssen MP, Behr-Gross ME, The Collection, Testing and Use of Blood and Blood Components in Europe - 2006 Report Page 22 Table 2 - Collection of whole blood, autologous blood and blood components, available at [http://www.edqm.eu/medias/fichiers/The\\_Collection\\_Testing\\_and\\_Use\\_of\\_Blood\\_and\\_Blood\\_1.pdf](http://www.edqm.eu/medias/fichiers/The_Collection_Testing_and_Use_of_Blood_and_Blood_1.pdf)

<sup>2</sup> <http://www.uzis.cz/en/fast-information/activity-health-care-institutions-section-transfusion-service>

This is consistent with PPTA's observations elsewhere in the world.

PPTA is also interested in one of the focal points of the report - namely the section on incentives. This section clearly reports that there are forms of 'accepted' incentives in a majority of the participating countries. This issue greatly affects the amount of plasma that can be collected by Member States. PPTA commends a flexible and pragmatic approach to incentives.

The report states that there is no evidence of a regular shortage of blood and blood cells, but at the same it is widely acknowledged that there is divergence in the level of clinical treatment in the use of blood components in Member States. Demand for blood and blood components for transfusion has been relatively stable for some years.

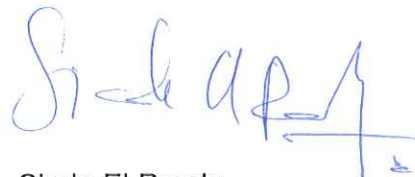
For plasma proteins, the clinical need is also divergent, but it has consistently grown annually and is likely to continue to do so in the foreseeable future. Member States need plans that anticipate this growth and which encourage more donations of plasma for fractionation. In 2011 Europe is less self-sufficient than it was in 1989 when plasma derivatives first came under the pharmaceutical legislation. Collecting more plasma for fractionation and manufacturing it efficiently is very important.

Overall, we would like to thank you and your unit for this report and look forward to working with you further in the future. PPTA and its members have the experience and knowledge that will be very valuable in this area of healthcare and consumer protection. The sustained availability of high quality plasma proteins is a consumer protection issue and as such PPTA commends SANCO for its active engagement with relevant patient groups.

Kind regards,



Charles Waller  
Vice President, Europe  
PPTA



Siada El Ramly  
Director, Health Policy  
PPTA Europe

CC: Mr Stefaan Van Der Spiegel  
Dr Brita Kaltenbrunner Bernitz