EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation
B4 – Medical products: quality, safety and innovation

Meeting between PPTA and DG SANTE B4

19 June 2018

Summary Minutes

Participants:

PPTA (Plasma Protein Therapeutics Association): Jan Bult, Karl Petrovsky, Mary Gustafson, Stephan Walsemann, Jean Marie Vlassembrouck.

DG SANTE (Unit B4 Medical products: quality, safety, innovation): S. Van der Spiegel, D. Fehily, I. Pucinskaite-Kubik, R. McGeehan.

PPTA[1] had requested the meeting with DG SANTE B4 primarily to present their views on what they see as shortcomings in the EU legislation on Blood.

1. Following the introduction of the participants, PPTA presented a short video they have produced as part of the "How is Your Day" campaign to promote plasma donation. The campaign was launched in Budapest at the International Plasma Protein Congress in March and in Washington at the Plasma Protein Forum shortly before this meeting. The videos will be shown at events in a number of other EU countries, at conferences and via social media. The videos can be viewed at www.howisyourday.org. The campaign aims to educate on the importance of plasma donation and the lifesaving medicinal products (PDMPs) derived from it. The campaign contains a number of plasma donor and PDMP patient testimonials.

2. DG SANTE updated the PPTA representatives on progress with the ongoing evaluation of the legislation[2]. In general, the process is on schedule and the final report should be published by the end of 2018 or early in 2019. PPTA expressed its positive impression on how the external study is being conducted by ICF consulting Ltd. PPTA had been interviewed and invited to focus group discussions by ICF.

[1] PPTA members run more than 700 plasma collection centres globally. In the EU they represent an alliance of 14 collection organisations that collect 2.4 million litres of plasma (2014 data) at 97 centres in Germany, Austria, Czech Republic and Hungary.
[2] DG SANTE plan to conclude the evaluation by the end of 2018.

3. PPTA presented a short paper they had developed that outlined what they consider the most important shortcomings in the current legislation. They informed DG SANTE that they have considered, for many years, that a revision of the blood legislation is required, as soon as possible, to address those shortcomings. They have raised these concerns at a political level and they intend to continue to ensure that those in decision-making positions are aware of the issues at stake for the plasma industry.

4. The three top priority issues for PPTA, in relation to the legislation, were the following:

   i. the lack of adequate provisions to encourage all EU Member States to establish or increase plasma collection for PDMP manufacture;

   ii. a lack of key definitions of plasma components;

   iii. the lack of a definition of compensation of source plasma donors.

5. PPTA considers the first priority issue to be critical in the context of the failure of the EU to achieve sufficiency of plasma for its PDMP needs. This is important so that Europe can support the global annual market growth. PPTA sees an urgent need for more state-of-the-art quality source plasma collection. They see this being achieved with co-existence between the public sector, with voluntary unpaid non-compensated donations, and the private sector, with voluntary unpaid but compensated donations, so that the EU will do its share to ensure the availability of PDMPs.

6. DG SANTE informed PPTA of the intention to work with EDQM (Council of Europe) on the topic of plasma supply as it has been raised by many stakeholders as a major concern. PPTA expressed their understanding for this initiative but stressed their concern that EDQM should continuously and transparently guarantee key stakeholder involvement in its work, as the EU Commission does.

7. The second priority for PPTA addresses what is seen as a need for definitions of plasma components, including components intended for transfusion versus for manufacturing into plasma derived medicinal products (PDMPs), so that requirements can be appropriately tailored. PPTA stressed that they do not support any proposal to separate plasma for PDMP manufacture from the blood legislation.

8. The third concerns the concept of compensation that PPTA argued should be included within the voluntary unpaid donation (VUD) concept, as is currently the case in article 12 of the Directive 2004/23/EC on the safety and quality of tissues and cells. They pointed out that many of those EU Member States that do not give monetary compensation to plasma donors do, in reality, compensate them via tax benefits, paid days off work in the public sector or even with monetary compensation when the plasma collection facility is in another Member State.

9. On the topic of the risk that increasing plasma collection might pose a threat to the supply of blood and blood components for transfusion, PPTA indicated that there is no evidence available of this 'crowding out' phenomenon. They reported that there is, however, some evidence that increased plasma collection has caused an increase also in whole blood collection in some countries. PPTA also pointed to the possible impact of urbanisation, which reduces the number of

younger donors in rural areas, where a large part of the whole blood has traditionally been donated.

10. PPTA reported that they have been meeting with the authorities in some EU Member States to discuss national issues related to plasma collection, tendering of processing services, supply and availability of plasma derivatives. PPTA considers that some Member States conduct public tenders that do not account for the uniqueness and non-interchangeability of PDMPs while others exempt PDMPs from tendering and mandatory discount rules. These cost-containment practices raise economic challenges for manufacturers and can create significant PDMP access concerns. As some of these efforts might be complementary to ongoing Commission work, PPTA agreed to keep the Commission informed on progress of these discussions.

11. PPTA confirmed their message at previous meetings regarding their preference to remove detailed technical requirements from EU legislation. They would prefer to see such requirements in guidance that can be updated in an efficient and timely manner and which should preferably be adopted by the EU, which they consider utilizes transparent consultation processes, as well as including regularly the relevant stakeholders.

12. DG SANTE thanked PPTA for their inputs at this meeting.