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

15 September 2017

Summary Minutes

Participants:

PPTA (Plasma Protein Therapeutics Association): B. Santoni, K. Petrovsky, Joshua M. Penrod, Mary Gustavson, Stephan Walsemann.

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

PPTA[1] had requested the meeting with DG SANTE B4 to present their views on changes that they consider should be made to the EU legislation on Blood.

1. Following the introduction of the participants, DG SANTE explained to the PPTA representatives that the Commission is not currently working on a revision to any of the blood Directives. The current initiative is limited to evaluating the existing legislation, with a view to establishing whether it has achieved its original objectives and whether it is still fit for purpose. Any decisions regarding possible revision of the legislation can only be taken after the completion of the evaluation[2]. Nonetheless, DG SANTE thanked PPTA for thinking ahead and agreed to listen to their ideas, noting that the proposals might also provide pointers to issues that should be considered in the current evaluation.

2. PPTA outlined the background to the proposals they had developed for legislative amendments, noting that they aimed to address the following objectives and concerns perceived by their members:

    i. Lack of a differentiation between blood and blood components for transfusion and plasma;

[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.

ii. The need for clear definitions
iii. The need for EU definitions for Voluntary Unpaid Donation (VUD) and compensation
iv. The need to encourage plasmapheresis development
v. The need to confine self-sufficiency to blood components for transfusion and interpret in light of today's reality
vi. The need to adapt regulatory and technical requirements to technological and scientific progress.

3. PPTA then presented their proposals, addressing Directives 2002/98/EC and 2004/33/EC. They had also reviewed Directives 2005/61/EC, 2005/62/E and 2011/28/EU but, at this time, reported no particular concerns regarding those Directives.

4. For Directive 2002/98/EC, PPTA considered that 4 recitals should be revised and 2 new recitals should be added. These amendments would address topics such as scope, to reflect recent European Court of Justice judgements, community self-sufficiency, to limit the concept to blood and blood components for transfusion, and adding a requirement to encourage plasmapheresis to enhance the availability of plasma for the manufacture of medicinal products, in light of increasing clinical need for these products.

5. Amendments to a number of Articles in Directive 2002/98/EC were also proposed, some of which reflected the comments on the recitals above. Others addressed amendments to definitions and the introduction of new definitions. The latter included plasma of different types collected in different ways and for different purposes as well as the introduction of definitions for different types of blood establishments; different inspection/control measures and the application of a 'risk-based approach' in-line with draft proposals from EMA that are currently under discussion. PPTA considers that the 'voluntary and unpaid donation' (VUD) concept is strongly embedded in Europe but needs to be defined and to allow for compensation. PPTA proposed definitions for 'VUD' and for 'compensation' that would include compensation for expenses and inconveniences within the concept of VUD, similar to the provisions of the Tissues and Cells Directive 2004/23/EC.

6. For Directive 2004/33/EC, PPTA stressed that technical requirements need flexibility to allow changes in relation to developing science and technology. They reiterated their proposals to include additional definitions and also propose amendments that differentiate between donors of blood and blood components for transfusion and donors of plasma for manufacturing in terms of acceptance and deferral criteria. Some general modifications for donor deferral for all types of blood and plasma donors were also proposed, e.g. the removal of cornea transplantation as a risk factor and deferral criterion for transmissible spongiform encephalopathies and the acceptance of donors with a history of tattoo or body piercing where it has been performed by a qualified practitioner using single use sterile needles.

7. With regard to the recent amendment of Directive 2005/61/EC to include a reference to the Good Practice Guidelines developed by the Commission services in collaboration with EDQM (Council of Europe) and published by EDQM, PPTA expressed the view that the EDQM Guide to the Preparation, Use and Quality Assurance of Blood and Blood Components should be seen as mainly relevant for blood transfusion as the input of the plasma for manufacturing stakeholders has been

very limited. In general, PPTA considers that the Commission should maintain its role of harmonising and updating technical requirements.

8. PPTA indicated that they did not wish to publish detailed proposals as they are still under development and may change over time.

9. DG SANTE thanked PPTA for their inputs at this meeting, as well as their submission to the recent Open Public Consultation for the evaluation of EU legislation on blood and tissues and cells[3].

[3] Further information on the Evaluation of the legislation on blood, tissues and cells: https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en