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

20 June 2016

Summary Minutes

Participants:

PPTA (Plasma Protein Therapeutics Association): B. Santoni, S. Walsemann, K. Petrovsky

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

PPTA[1] had requested the meeting with DG SANTE B4 to (i) provide their views on the Commission reports on the implementation of EU legislation on Blood, (ii) receive information on the envisaged evaluation of the EU legislation on Blood, (iii) inquire about a possibility to participate in the meetings with Competent authorities for Blood and (iv) provide a feedback on the 'ethical label' being proposed by some Member States for medicinal products derived from plasma.

1. After the introduction of the participants, PPTA expressed appreciation for the recently published Commission Blood Implementation reports[2]. The participants elaborated on the results of the reports which concluded that the legislation has generally been implemented in a satisfactory manner, and the Commission highlighted that there are gaps and challenges that should be explored in an evaluation of the functioning of the Blood Directive, 14 years after its adoption.

2. According to PPTA, a clearly defined regulatory environment in the EU is essential to ensure that companies can better function. The association stressed their view that due to the lack of clear provisions including on definitions in the EU legislation , a regulatory lacuna is created.

[1] PPTA members run 600 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] http://ec.europa.eu/health/blood_tissues_organs/docs/com_2016_224_en.pdf
http://ec.europa.eu/health/blood_tissues_organs/docs/swd_2016_130_en.pdf

3. PPTA suggested that it will submit recommendations to Commission services regarding potential adaptations of the Blood Directive. It also suggested that it would be useful to distinguish between blood and blood components/plasma in the legislation. In this context, PPTA inquired about the state of play of an envisaged evaluation of the Blood legislation.

4. SANTE B4 informed PPTA that plans for such an evaluation are being considered and that it might be launched in the third quarter of 2016. In case of an evaluation of the legislation, the interested stakeholders will have a possibility to provide their comments. The evaluation may also include an external contract to support some aspects of the process. In general, the evaluation process will follow the procedure defined in the Better Regulation package and include ample opportunities for public as well as targeted consultation. The evaluation should be completed towards the end of 2018.

5. DG SANTE informed that during the evaluation process, the Commission services will be open to collect input provided by a broad spectrum of stakeholders including PPTA.

6. PPTA reiterated their interest to participate in the meetings with National Competent Authorities for Blood and Blood Components (NCAs). DG SANTE B4 informed them that the meetings of NCAs are closed meeting but it had explored the possibility with the NCAs of holding separate meetings with stakeholders where specific topics would be addressed.[3] It was considered that, when appropriate, certain stakeholders could be invited to such meetings on the basis of the agenda topics. Following the requests of NCAs to clearly define the scope of eligible stakeholders, the Commission services will prepare draft terms of reference for the selection and participation of the stakeholders. After finalising terms of reference, the Commission services will launch an open call for interest. SANTE B4 also noted that such meetings will be formalised and summary minutes will be published on the Public Health section of the Commission's Europa website.

7. PPTA expressed their concerns regarding the possible implementation of an 'ethical label' for medicinal products derived from plasma by at least one Member State. The association noted that if the Member State was to go ahead with such regulation, this would provide information of the "ethical" (i.e. unpaid) origin of the blood or plasma donation not only to the patients but also hospital public buyers, pharmacists, prescribing doctors, nurses and patients. As a result, it might constitute an element of a promotional nature and become a criterion for gaining increased access to market. SANTE B4 took note of their views and proposed to share concrete information, if available, with the Commission services including DG GROW.

8. Other discussion points touched upon included a request for a preliminary ruling by the European Court of Justice on EU Blood VAT exemption. According to PPTA, the recently issued Opinion of the Advocate General suggests that plasma is to be regarded as blood and thus should be exempted from VAT[4]. The association noted that in case the Court of Justice will follow the opinion issuing a ruling, this would have a number of negative practical implications as plasma would be VAT exempt. When supplying plasma to manufacturers, collectors would not be able to

[3] http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20160526_ag_en.pdf
[4] http://curia.europa.eu/juris/document/document.jsf?text=&docid=179326&doclang=EN

recover the VAT they have spent on equipment and disposables and would, consequently, be financially disadvantaged. Some of the plasma collecting organisations might encounter financial challenges and Europe might become even more dependent on the US plasma. DG SANTE B4 took note.

9. In summary, PPTA urged that it is necessary to have an adequate legislative framework and regulatory environment in the EU which enables plasma collectors to develop their activities. Therefore, PPTA would welcome an evaluation of the existing legal framework for Blood and subsequently a possible revision of the directives. DG SANTE B4 noted that plans for an evaluation are underway, leaving all options for possible next steps open, and that this process will include ample opportunities for public and targeted consultation.