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 the CSL, PPTA and DG SANTE B4

21 January 2016

Summary Minutes

Participants:

CSL: R. Gatermann, M. Roll.

PPTA Europe: B. Santoni, J. Penrod, K. Petrovsky.

DG SANTE: D. Schnichels, S. Van der Spiegel, R. McGeehan, D. Fehily.

The meeting was organised by the Plasma Protein Therapeutics Association (PPTA) and was held at the CSL Plasma Collection Centre in Frankfurt. It was preceded by a tour of the centre.

1. CSL presented its activities as a global speciality biotherapeutics company with annual revenue of more than 5.5 billion US dollars and more than 14,000 employees worldwide. They run more than 120 plasma collection centres (CSL Plasma) in Europe (11 in the EU of which 9 are in Germany) and North America, employing in total more than 5,000 employees, and have 8 manufacturing sites (CSL Behring) in the US, the EU (Germany: 2,300 employees) and Australia. They also operate 2 logistics centres (one in the US and one in Germany), where plasma is stored before being sent for fractionation, and 2 testing centres (one in the US and one in Germany).

2. The 8 plasma collection centres in Germany have a total of 236 beds, they open for around 520 hours per week per centre, employ 300 individuals in total and collect around 360,000 litres of plasma from 40,000 donors each year. A donor can donate up to 45 times a year with at least 2 days between donations in accordance with German law. Donors receive 19-22 EURO (depending on the volume collected) for each donation. Although donors were described as having a wide range of profiles (level of education, profession etc.) and to be motivated to help others, it was also considered that the compensation is important for them and it was noted that an increase in the minimum wage in 2015 caused a fall in donation numbers.

3. PPTA presented the role of their members in plasma collection. Their 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. This compares with over 32 million collections in 2014 collected by their members in the US, which, extrapolated, would be around 26 million liters. Germany is the largest plasma collector in the EU collecting 1.85 million litres by apheresis and 1.2 million from recovered plasma in 2014, 60% of which is collected by private/industry owned centres.

4. While a steep increase in plasma collection over the last 10 years has been observed in the US, the increase in Europe has been much less and is limited to apheresis collection, with recovered plasma remaining the more important source (59%), in contrast to North America where 92% of plasma for fractionation is now from apheresis collection. In contrast, the EU has a higher manufacturing capacity (23 million litres) compared with the US (15 million litres) resulting in a steady flow of plasma from the US to the EU. It was noted that EU plasma, and the products derived from it, are not accepted in the US due to concerns regarding variant Creutfeldt Jacob disease (vCJD).

5. PPTAs voluntary standards (IQPP and QSEAL) are applied in collection centres as well as fractionators and are verified through a certification programme. The standards address issues related to donor management and centre management.

6. On the topic of donor compensation, PPTA presented data to demonstrate that countries with mixed systems (uncompensated and compensated: US, Austria, Germany, Czech Republic) collect 32 – 66 litres per 1000 population while those with exclusively uncompensated programmes (Australia, Netherlands, Denmark, France, Sweden, Belgium) collect 15.5 – 21.5 per 1000 population.

7. In the view of PPTA, to prohibit the offer of compensation is to fail to respect the autonomy of the donors.

8. PPTA noted that source plasma collection centres are subjected to multiple inspections by authorities (FDA and EU authorities), PPTA auditors (IQPP certification), purchasers of source plasma and others. They promote that the US and EU authorities should recognise each other's authorisations to reduce the inspection burden.

9. In summary, PPTA argued that it is necessary to greatly develop plasma collection in the EU to meet clinical demand for products and that the private collectors should be supported rather than hindered by the regulations. They consider that parallel working between the public and private sectors has been shown to be the most cost effective for the healthcare system.