EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate B - Health systems, medical products and innovation

Meeting between IPFA and DG SANTE B

15 September 2016

Summary Minutes

Participants:

IPFA (International Plasma Fractionation Association): P. Strengers, F. Rossi, Y. Charpak

DG SANTE, Directorate B (Health Systems, medical products and innovation): A. Rys, S. Van der Spiegel

IPFA had requested this meeting in order to express concern on possible shortages in plasma derivatives (PD), and discuss potential causes and possible strategies to address this concern.

1. After the introduction of the participants, IPFA presented its membership (not-for-profit fractionators and national blood services), as well as its main principles (Voluntary non-remunerated blood donors, not-for-profit, focus on public health, safety and quality). IPFA is a global organisation, and within the EU liaises regularly with the European Medicines Agency, the EU Commission and the Council of Europe.

2. IPFA focused on the complementarity in products supplied by Blood Establishments: on the one hand blood (components) for transfusion, on the other hand plasma for manufacturing/fractionation into Plasma-derived Medicinal Products (PDMPs). As the latter are subject to pharmaceutical legislation, an expectation exists from the Blood Establishments to organise all collections in line with Good Manufacturing Practices (GMP), also whole blood collection from which plasma is recovered. This expectation creates sensitivities and tensions in the public sector, however in practice the requirements laid down by GMP might not differ much from those in e.g. the Council of Europe Guide for Blood. IPFA agreed to make a comparison between both, so that points of difference and similarity are clear.

3. IPFA also pointed to the different approaches in authorisation of plasma collection and manufacturing of plasma derivatives in the EU (focused on end-product) compared to in the US (focused on production processes). This complicates any effort to harmonize requirements and GMP standards for these activities.

4. These differences in recognised quality standards cause a significant amount of recovered plasma not to be useable for manufacturing of plasma derivatives, and therefore to be lost. While this might concern only a small number of countries in the EU, it is estimated to be the cause of losing 6 million litres plasma on a global scale. This is a significant amount, compared to 40-45million litres of plasma which was fractionated in 2014 (MRB data).

5. IPFA also pointed to a major dependence on plasma collected in the US, where more than 60% of global plasma is collected, mainly through apheresis organised by commercial actors. More than 25% of global sales of PDMPs take place in the EU market, with less than 20% of plasma collected in the EU for these products. Hence EU patients, treated with and dependent of PDMPs, are strongly dependent on plasma collected in the US.

6. Several factors were mentioned which might interrupt this supply and create shortages for EU citizens, in particular epidemiological outbreaks in the US of infectious agents which might not be inactivated or eliminated in the plasma manufacturing process. Also the possibility of lifting import restrictions for EU plasma and PD in the US were mentioned as a possible future cause for shortages in the EU. This US import restriction was put in place due to concerns regarding variant CJD in Europe, and is raised by other stakeholders for discussion in TTIP. Also China has currently an import ban for immunoglobulins from the EU. However, since several years EU albumin can be imported into China, which has driven global demand.

7. To increase self-sufficiency for plasma in the EU, more plasma collection could be organised by public Blood Establishments, with the involvement and commitment of the Authorities. Several national blood services seem to be developing more of these activities, driven by overall financial pressure and reduced demand for blood (components). This does however require a process organisational change to bring better efficiency, which also can help reduce prices of plasma collected. Such a process is already undertaken in some Member States such as the UK and DK. It was suggested that this topic could be brought forward in an upcoming stakeholder meeting with interested competent authorities. The Commission services will explore this and if needed, involve the European Blood Alliance in possible exchanges. IPFA introduced the concept of *Strategic Independence* of Europe in plasma for fractionation, as well as its designation as a *Strategic Resource*[1].

8. An additional topic that could be explored is the use of priority supply schemes, to be used in case of sudden shortage, which are in place in UK and in FR. The collection of supply data by fractionators is useful but rather to be seen as a monitoring tool, and not a tool that can prevent or address sudden shortages.

9. The Commission services explained that a process of evaluation of the EU blood legislation will be soon launched, with the publication of a roadmap for consultation. They also mentioned plans to call for interested stakeholders to join specific meetings with interested competent authorities to be organised in the course of the evaluation.

[1] Plasma is a strategic resource, Paul F.W. Strengers and Harvey G. Klein: Transfusion Nov 2016, online