EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Brussels,
SANTÉ

Meeting between International Plasma Fractionators Association (IPFA) and DG SANTE B4

25 February 2016

Summary Minutes

Participants:

IPFA: Bob Perry, Francoise Rossi, Paul Strengers

DG SANTE (Unit B4): Dominik Schnichels, Deirdre Fehily, Richard McGeehan, Ingrida Pucinskaite-Kubik.

IPFA had requested the meeting with DG SANTE to update them on a number of issues of importance for the field of plasma collection and fractionation in the European Union.

1. DG SANTE opened the discussions by describing the recent reorganisation (effective February 1st 2016) whereby the SoHO team is now in the same unit as two other teams, one working on Health Technology Assessment and one on aspects of pharmaceuticals including clinical trials, GMP and plasma derived medicinal products.

2. The IPFA representatives summarised the role of their association in representing not-for-profit plasma supply and fractionation organisations, with members in Europe, the United States, Japan, New Zealand and South Africa. They promote the supply and fractionation of plasma from mainly non-remunerated donors aiming to ensure that the field is not only market driven but also incorporating an ethical approach. They jointly organise a scientific meeting each year in collaboration with the Paul Ehrlich Institute and they are also in regular discussion and collaboration with EMA, ECDC and the FDA.

3. IPFA stressed that they do not support proposals by others to separate in the EU legislation plasma donation and collection from the donation and collection of whole blood and blood components for transfusion.

4. IPFA explained that their primary concern in relation to the plasma supply situation in the EU is the strong dependence on plasma collected in the US and imported to the EU for manufacture of plasma derived medicinal products (more than 50% of the plasma supply comes from the US).

They consider that the situation should be rebalanced with a significant increase of plasma collection in the EU to safeguard supply in the event that any risk emerging in the US might jeopardise supply for EU patients. Their view is that this should be achieved through a significant reallocation of resources in blood services towards the conversion of whole blood donors to plasma donation, a change that is feasible due to the falling usage of red blood cells across the EU. Such a change would require investment at national level and recognition of the strategic importance of a robust plasma supply in the EU. IPFA hoped that the Commission might be in a position to support an awareness raising initiative to highlight the public health importance of this issue.

5. IPFA noted the ban on the supply of EU plasma (and the products derived from it) to the US and considered that the TTIP negotiations might be used to remove this ban so that the motivation for investing in increased plasma collection in the EU would increase. They noted that their member organisations in the EU are obliged to provide for their patients nationally before exporting, so a removal of the ban would not risk that the products would be sold where the highest price is available.

6. DG-SANTE explained that the legal basis for EU-level actions is largely limited to ensuring safety and quality although there have been successful initiatives in related sectors, e.g. organ donation, where the Commission has facilitated the sharing of good and successful practices of supply between Member States. IPFA noted that the international patient organisations depending on plasma derived medicinal products consider shortage of supply as a serious safety issue.

7. IPFA asked whether there are plans to revise the blood directives as they had expected this might happen in 2015/6. DG SANTE informed IPFA that reports on the implementation of the blood and tissues & cells directives are about to be published (with annexes that provide the results of the surveys conducted with Member States on implementation and on the principle of voluntary and unpaid donation (VUD)). The conclusion of the exercise was that an in-depth evaluation of the legislation might be needed – without pre-judging any potential follow up. The evaluation should hopefully begin soon and is likely to take at least a year and will include public consultation and probably consultation with targeted stakeholders.

8. In a discussion on the principle of voluntary and unpaid donation (VUD) IPFA noted that at an expert meeting at EMA some time ago, screening test results from first time donors were reviewed and reactive results were more common in remunerated donors. Older studies of blood donors also showed a difference in frequency of reactive results. They agreed to provide documentation of this evidence to DG-SANTE following the meeting.

9. IPFA noted that it has been informed during a meeting with the European Medicines Agency (EMA) that discussions are advanced on the implementation of a risk-based approach to inspection of blood establishments and this was confirmed by DG-SANTE. IPFA expressed their support for this approach which should streamline the inclusion of establishments in Plasma Master Files submitted to EMA for authorisation.

10. IPFA were also very supportive of discussions on mutual recognition of GMP inspections between the US and the EU as a measure to reduce the inspection burden on facilities.

11. The need to include provisions for donor protection was supported by IPFA representatives who considered that the directives should ensure that plasma donors are not exploited.

12. IPFA raised concern regarding diverging approaches of Member States to certain donor selection criteria, notably the deferral of men having sex with men (MSM). They are concerned that divergent policies and practices might jeopardise the free movement of plasma and consequently of plasma derived medicinal products. They support the letter sent by Platform of Plasma Protein Users (PLUS) to EMA on February 3rd 2016 following a consensus conference in Portugal in January 2016 where this topic was extensively discussed. They provided DG-SANTE with a copy of the letter (attached).

13. IPFA had provided a statement on Zika virus prior to the meeting. The statement was consistent with the guidance of ECDC that deferral of donors coming from areas of Zika virus risk do not need to be deferred as the virus inactivation steps included in the manufacturing process are adequately robust to eliminate any risk.

14. DG SANTE informed IPFA that DG-SANTE is discussing with the CA SoHO (Competent Authorities for Substances of Human Origin) Expert Group the possibility of organising discussions with stakeholders that would be separate from, but immediately before or after, meetings of the competent authorities so that those authorities interested would able to attend. IPFA will be informed if this proposal goes ahead and may be invited to attend when the topic to be discussed is of particular relevance to their work. IPFA expressed interest in participating in such meetings.