The Platform of Plasma Protein Users (PLUS) Consensus meeting has put together all the interest groups from the blood and plasma community. It is an important platform to create common views on key aspects of the sector.

On Jan. 14-15, 2016, PLUS organized a consensus conference in Estoril, Portugal in order to address several important ongoing issues for the Blood and Plasma community. The EU Blood Directive and its potential future evolution as well as the latest MSM (men who have sex with men) deferral policy changes were among the topics discussed during the meeting.

The meeting was chaired by Brian O’Mahony from PLUS and William Murphy from the Irish Blood Transfusion Service. PLUS was represented at the meeting by Alpha 1 Global, EHC (European Haemophilia Consortium), HAEI (Hereditary Angioedema International), IPOPI (International Patient Organisation for Primary Immunodeficiencies), and WFH (World Federation of Hemophilia). The different stakeholders invited were: the American Plasma Users Coalition (A-PLUS), represented by HAEI and the National Hemophilia Foundation (NHF); the European Blood Alliance (EBA); the European Plasma Collectors Committee (EPCC); the International Federation of Blood Donor Organizations (IFBDO), the International Plasma Fractionation Association (IPFA) and the Plasma Protein Therapeutics Association (PPTA).

The dialogue among the stakeholders was open and productive. While consensus statements were published in 2010, 2011, and 2012, the goal of this meeting was not to publish a paper but to find common ground to establish recommendations. The concept of the meeting is, of course, to leverage the knowledge and views of all participants in order to develop and deliver messages with one voice. This perfectly...
illustrates the principle that the effect of a joint action is stronger than the sum of isolated separate actions. Follow up meetings will be conducted in May 2016 and January 2017.

THE EU BLOOD DIRECTIVE
Although there is not yet a revision of the Blood Directive 2002/98/EC (the famous one setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components) adopted 13 years ago, there are ongoing questions in the sector and at the EU Commission level on the future of this Directive. Does the Directive still meet its purpose? Does it meet the needs of the sector (donors, patients, collection centers, industry) and does it still match with the current status of knowledge and science?

Sebastian Rohde from Rohde Public Policy started this section of the meeting by providing visionary insight into the EU health care policy environment, explaining the changing public health environment and the possible consequences of a future revision. Mr. Rohde provided an excellent overview of this environment in the Fall 2015 edition of The Source in his article, “The Continuous Path of Changes in Healthcare: EU Member States.” Following Mr. Rohde’s presentation, a representative from each group presented their viewpoint on the current Blood Directive and its potential evolution. Specifically, each group talked about the need to better differentiate between blood and plasma in the Blood Directive.

During the discussion, PLUS specifically highlighted the disparities in diagnosis, treatment, and care within the EU. Throughout the different presentations, it was quite clear that all interest groups believed that improvements can and need to be made in the EU to contribute to the global plasma supply while keeping in mind the growing clinical demand. This was already mentioned in the 2011 consensus paper but the recommendations of this session will focus on how this can be addressed in the Blood Directive. There were also several interest groups highlighting the need for an improvement of definitions (e.g.: plasma, plasma for transfusion, plasma for manufacturing, plasmapheresis) and policy concepts (e.g.: voluntary unpaid donation, sufficiency). It was also quite obvious that the Blood Directive isn’t a tool that allows regular and easy revision of technical requirements.

Since its launch, operations have been impacted locally according to how the Blood Directive has been implemented by the member states, creating different levels of satisfaction among the different blood and plasma collectors. On the national level, the different choices made by the member states in terms of establishing plasma collection standards or policies did not move in the direction of more harmonization. Although the goal of the EU Commission is obviously to improve in the EU, the reality is often different. This is due to the subsidiarity principle allowing countries to implement different policies in some specific domains. This was well illustrated during the meeting by the differences in MSM policies in the EU Member States.

Of course, the participants noted if the Blood Directive is revised, there is always a certain significant amount of uncertainty about how the EU Parliament will vote, the Blood Directive’s finished form, and what the consequences will be for the sector and particularly for patients.

While keeping all of this in mind, the group committed to continue its work to finish a set of recommendations in the coming months.

The next steps will focus on consolidating the input of the different groups so that the consensus document can be finalized. The PLUS stakeholder group represents the most comprehensive set of experts with regard to the EU regulations and its effects on their specific area. All are motivated to deliver the best quality and the best care. This group has overcome its differences to develop several consensuses over the years - their voice and message should be heard.

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References