EU Commission Stakeholder Event: EVALUATION OF THE BLOOD, TISSUE, AND CELLS LEGISLATION

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The famous Italian adage « *chi va piano va sano* » (slowly but safely) might not be true when it comes to the modernization of the Blood Directive in Europe. Indeed, analyzing the blood and plasma sector takes a considerable amount of time for the EU Commission while patients are waiting for sustainable solutions for their future.

On Sept. 20, the EU Commission organized a stakeholder event gathering 206 participants, including 163 representatives from different organizations and 43 individual citizens. This meeting was an important step along the long road to evaluate the legislation in question as it allowed the different stakeholders to express positions and to participate in debates publicly.

After the opening of the event by Martin Seychell, Deputy Director General, DG-Santé, and the introduction to the evaluation by Anna-Eva Ampélas, Head of Unit, Medical Products, Quality, Safety and Innovation, Stefaan Van der Spiegel, Head of Sector, presented several key figures related to the different donations of Substances of Human Origin (SoHO). It was good news to see him mention specific EU collection figures for plasma for manufacturing (8 million liters). Indeed, this indicates an increased understanding of the importance of plasma protein therapies among EU Commission members resulting from all the constructive exchanges that PPTA has had with them in recent years.

The meeting was divided into five sessions, each with four speakers who presented their views with only one slide and each session included a 40-minute debate with the audience.

The sessions addressed the following issues:

1. The key importance of donors—The gift of life
2. Regulatory oversight of the sectors—How to ensure safety and quality
3. Availability and sufficiency—Are patients getting the blood, tissues, and cells they need?
4. Legal consistency and coherence—Regulatory pathways for Substances of Human Origin
5. A changing world—Technological, societal, epidemiological, and international developments

PPTA was invited to present its views in Session Four, which again provided the opportunity to highlight that "ensuring

a high level of human health protection" (Art. 35 of the EU Charter of Fundamental Rights) involves the duty to protect patients. When developing recommendations on ethical aspects related to donation practices, several stakeholders (e.g., the Council of Europe in Strasbourg) too often forget to consider the specificities of the plasma donation process and the life-threatening conditions that affect the patients in need of plasma-derived medicinal products.

Johan Prevot, representing the Platform of Plasma Protein Users (PLUS), explained that the major current safety issue for patients is the risk of lack of supply of plasma-derived medicinal products. Indeed, in Europe more than 40 percent of plasma-derived medicinal products are made out of plasma collected in the United States and, at the same time, clinical needs are growing globally. Thus, it is time for the EU to encourage more efficient plasma collection practices (plasmapheresis) on a larger scale and to define "compensation" so such practice can be established more generally. Indeed, compensating donors for time and inconveniences, similar to the Tissue and Cell Directive (2004/23/EC), would allow the collection of much higher quantities of plasma. Alice Simonetti, from the International Federation of Blood Donor Organizations (IFBDO), made a remarkable new statement supporting the possibility to compensate certain donors. It is an important development to see more and more stakeholders understand a new system has to be put in place in the EU to ensure patients can get the treatments they need.

However, we have to see the reality, and there is still a long road before things can be changed in the EU. Several countries are not ready to vote for a change (e.g., France, Italy), and several stakeholders do not want to acknowledge the reality of a growing clinical need for plasma protein therapies, as expressed by some representatives during the meeting, to the point that Laura Savini from the European Haemophilia Consortium (EHC) had to make an intervention referring to the scientific work done to evaluate the clinical usage of plasma proteins and to establish clinical guidance for their usage (e.g., Wildbad Kreuth recommendations). Ensuring that countries and the EU Parliament could approve some potential future changes to the legislation is quite a challenge. This will only be possible if countries have a clear understanding of the blood and plasma sectors and show an open-minded attitude. Public opinion will play a major role as well. Therefore, ongoing dialogue and education is essential; awareness about our sector is needed now more than ever.

The sectors related to the donations of SoHO are incredibly complex and contain political and technical elements that need to be reviewed or updated. At the same time, the public blood sector is redefining certain activities due to the decrease of blood usage (Patient Blood Management) while more plasma is needed in the world. For the EU Commission, understanding all these aspects in order to provide a modern legal framework is a huge amount of work for a limited staff. Andrzej Rys, Director, DG-Santé, confirmed at the end of the meeting that potential collaboration with external entities (e.g., World Health Organization, Council of Europe) is envisaged for some aspects but not yet decided. This is indeed risky if some of these stakeholders are not ready in their structure to have a robust and unbiased process to evaluate and propose recommendations.

PPTA company representatives actively participated in the debates during the meeting: Stephan Walsemann, M.D., Ph.D., (Chair, European Plasma Alliance; KEDPLASMA GmbH); Dr. Matthias Gessner (Shire AG); and Kristen Seidel, M.D. (CSL Plasma GmbH). They shared the sentiment that the industry is available to engage in constructive dialogue for scientific questions or other issues where industry expertise would be valuable, as long as there is an official balanced process to include the input of the private industry.

As a final note, it is important to consider that the EU Commission is determining legislation that will be adapted on the basis of the added value the EU can bring. This is certainly the case for the blood and plasma sector, where standards and harmonization are key aspects, but the decision to review the Blood Directive (2002/98/EC) has not been taken yet. It was made apparent during the day that if there are improvements to be made, it will take quite a lot of time at the EU level. With all due respect for the evaluation process, patients and their families are hoping they will not reach a crisis situation in the coming years. We hope the same. •

Source: EU Commission