Outcome of the PPTA Roundtable Event in the European Parliament

BY KARL PETROVSKY, DIRECTOR, HEALTH POLICY EUROPE, PPTA

On Feb. 21, PPTA organized a roundtable discussion at the European Parliament on "The Growing Need of Plasma-Derived Medicinal Products (PDMPs) in the European Union." The roundtable was hosted and opened by Member of the European Parliament (MEP) Mr. Ramon Tremosa i Balcells, ALDE/Spain. MEP Nicola Caputo, S&D/Italy co-opened the event, and MEP José Inacio Faria, EPP/Portugal held the concluding remarks. The objectives of the event were threefold: (1) raise awareness about the industry and the growing need for Source plasma, (2) engage with stakeholders on the EU level to explain the importance of Source plasma and to increase knowledge of the diseases treated by PDMPs, and (3) demonstrate that PPTA remains a trusted adviser in the event the European Blood Directive is opened for reconsideration. During this multi-stakeholder roundtable discussion, patients, health care professionals, policymakers, and industry representatives presented on how to ensure appropriate access to PDMP treatment. The ongoing evaluation of the EU Blood Directive provided a timely opportunity to discuss plasma collection in Europe and how to help ensure access to treatment for European patients. Forty-five participants attended the event, the majority of whom came from the institutional side, including the European Commission and six Permanent Representatives from EU Member States.

The roundtable was structured in three sessions:

- **Session 1** offered industry representatives an opportunity to share information about the collection of Source plasma and the manufacture of PDMPs.
- **Session 2** addressed the importance of access to treatment from the perspective of patients and medical doctors.
- **Session 3** explored ways to ensure the EU's legal framework encourages the collection of Source plasma.

The main highlights were:

- **Session 1:** For the first time, information about the plasma protein therapeutics sector was presented in detail at the EU Parliament. Oliver Schmitt from CSL Behring, who serves as chair of PPTA's EU Board, presented the manufacturer's side, while Takeda's Matthias Gessner, chair of PPTA's European Plasma Alliance, described the complex aspects of plasma collection.

Dr. Keller provided an overview on the plasma collection system in Germany, which, according to the Transfusion Law, is based on the concept of "voluntary unpaid donations" and includes a fair compensation for donor expenses ("Aufwandsentschädigung").

- **Session 2:** Jean-Philippe Plançon, European Patient Organisation for Dysimmune and Inflammatory Neuropathies (EPODIN), described the challenges patients with dysimmune and inflammatory neuropathies currently face and their need for access to treatment. Any future revisions to the EU Blood Directive should consider the growing need for plasma in the EU and around the world. Dr. Nizar Mahlaoui, Necker Hospital, Paris, focused on accessibility issues for patients affected by primary immunodeficiencies (PIs). Dr. Mahlaoui noted that no alternative therapy for PI patients exists, so all stakeholders, including patients, doctors, industry, and politicians, should collaborate to increase plasma collection and to ensure patients receive the best standard of care.
- **Session 3:** Martine Pergent, Platform of Plasma Protein Users (PLUS), illustrated the situation in Europe from the perspective of patient organizations, with a particular focus on PIs. Considering immunoglobulin (Ig) is the only treatment for PI, she highlighted the importance of EU legislation being focused on patients as well as on plasma donors to meet the clinical needs for PDMPs. The legislation should cover quality and safety but also the availability of blood and plasma, while differentiating between the two. In addition, Ms. Pergent requested that the legal framework provide clear definitions to support better coordination of blood and plasma collection.

On the industry side, Jan M. Bult, PPTA, stated that the protection of human health is a fundamental right enshrined in article 35 of the EU Charter of Fundamental Rights, which is reiterated several times in the Blood Directive. Patients in need of PDMPs are entitled to benefit from the fundamental right to receive treatment. However, the EU legislation from 2002 is inadequate to meet patients' needs, as there is no definition of key concepts and no clear recognition of plasma specificities.

Ortwin Schulte, Head of Unit Health Policy, German Permanent Representation to the EU, focused on the upcoming German EU presidency (July–December 2020). The potential revision of the EU Blood Directive and the EU health technology assessment dossier are key topics that will be discussed under the upcoming, rotating EU Presidencies. Turning to the specifics of the blood directive legislation, Mr. Schulte stated that this policy area is particularly complex due to the technical aspects and the corresponding bioethical challenges. However, each EU Presidency has the opportunity to focus on identified pressing issues. According to Mr. Schulte, plasma collection is one of those pressing issues that is highly politicized.

An important highlight of the Question & Answer session was the contribution of Dr. Konstantin Keller, German Ministry of Health. Dr. Keller provided an overview on the plasma collection system in Germany, which, according to the Transfusion Law, is based on the concept of "voluntary unpaid donations" and includes a fair compensation for donor expenses ("Aufwandsentschädigung"). Different plasma collection methods are in place in Germany, and stakeholders such as the Red Cross, University/community hospitals, and industry are even "obliged by law to collaborate in order to ensure sufficient supply of blood products and to avoid shortages." Dr. Keller concluded that although a high quantity of plasma is collected in Germany covering approximately 110 percent of its needs, more needs to done in the future to keep potential donors engaged in plasma donations.

CONCLUSION

In his concluding remarks, MEP Faria pointed to the consensus of the participants regarding the urgent need for increased plasma collection in the EU to make sure patients have access to appropriate PDMP treatment. The MEP thanked the speakers and the audience for their engagement in this roundtable and encouraged PPTA, as well as all other stakeholders, to make their voices heard in the upcoming EU Parliament legislature. ●