Outcomes of the EDQM Meeting in Strasbourg

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In January, PPTA staff participated in a three-day Symposium on Plasma Supply Management in Strasbourg, France, organized by the European Directorate for Quality of Medicines (EDQM).

The purpose of this scientific meeting was to collect evidence-based data supporting the revision of the 20th edition of the "Guide to the Preparation, Use, and Quality Assurance of Blood Components with Regard to Plasmapheresis."

PPTA, which had also been part of the scientific organizational committee, was given the opportunity to present data and insight regarding the collection of plasma in the EU. PPTA's role in assisting the EDQM address these important issues has been important in terms of representing the industry and helping to develop initiatives for global plasma sufficiency and access to finished products for patients. Specifically, with regard to the Association's role on the agenda and at the meeting, PPTA staff and industry experts alike presented on the experiences of the private sector and donor motivation, the use of recovered plasma in Europe, technical recommendations for the evaluation of donor suitability, strategies on the protection of iron stores in plasma donors, data on donor adverse reactions, and the industry's ongoing efforts in plasmavigilance.

It was the first time that stakeholders from patient groups and donor associations, as well as public and private sector collection establishments, came together to discuss the current issues in an open dialogue. This dialogue provided a more complete picture of the current situation. The industry was able to establish itself as a credible part of the discussion and an expert in the field of plasma collection with its long-term experience focusing on patient safety and donor health. Only a week after the "PLUS Consensus Principles on Strategies to encourage Blood and Plasma Donation in Europe" in Estoril, Portugal, the patients emphasized again that any policies aimed at increasing blood and plasma collection should ensure that it is both patient- and donor-centered with the goal of meeting clinical needs. They presented the newest Consensus Statement developed in Estoril and signed by many organizations.

It has been recognized that human plasma is a crucial component for the manufacturing of lifesaving therapies on which patients with rare and chronic diseases depend heavily. It was also recognized that the need for plasma has increased in recent years and there is a need to foster and support collection systems in Europe.

The outcomes of the symposium will be translated into general recommendations for the editorial committee of the guide. PPTA and the European Plasma Alliance will continue to be official stakeholders in the extended expert group and offered their availability for any additional input in the activities of the TS093 core working group. It was noted that the collaboration between the EDQM and the European Commission was intensified, which may have an impact on the potential revision of the European Blood Directive. Regarding the timeline, the draft of the 20th edition is expected to be published for public consultation in July 2019. The final text will then be approved for at the end of 2019. •