PLASMA PROTEIN THERAPEUTICS ASSOCIATION

2026 MID-YEAR IMPACT REPORT

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LETTER FROM THE PRESIDENT & CEO

Dear Reader,

As we reach the midpoint of 2026, I am pleased to reflect on the progress that PPTA and its members have made during the first half of the year, and the momentum we are building for the months ahead.

Across our advocacy efforts, we have continued to strengthen relationships with policymakers and stakeholders who recognize the vital role plasma-derived medicines play in healthcare. Through sustained engagement at the federal, state, and international levels, we are advancing policies that support a safe and sustainable plasma ecosystem, while elevating awareness of the patients who depend on these lifesaving therapies.

Our work in the United States and Europe remains focused on fostering a regulatory and legislative environment that supports innovation, donor well-being, patient access and long-term supply resilience of plasma and plasma-derived medicines. At the same time, we continue to collaborate with partners around the world to address shared challenges, promote donor safety, and reinforce the importance of these unique medicines within evolving healthcare systems.

The global landscape continues to present uncertainty and complexity. Yet the need for our work has never been clearer. Every policy discussion, every advocacy effort, and every partnership is ultimately driven by a common purpose: ensuring patients have access to the therapies they need, when they need them.

Thank you for your continued support, engagement, and commitment to our mission. Together, we will continue to build on this progress and advance the interests of patients, donors, and the plasma community throughout the remainder of the year and beyond.

Warm Regards,

Anita Brikman
President & CEO
Plasma Protein Therapeutics Association (PPTA)

North America

ADVANCING FEDERAL ADVOCACY ON MOST FAVORED NATION

During the first half of the year, PPTA maintained a strong and coordinated advocacy campaign focused on addressing concerns surrounding Most Favored Nation (MFN) drug pricing policies and their potential impact on patient access to plasma-derived therapies. The Association met with members of the Congressional Plasma Caucus and engaged directly with leaders at the Centers for Medicare & Medicaid Services and across the Administration, ensuring that the industry's perspective remained central to ongoing policy discussions.

A significant milestone was the submission of comprehensive industry comments on both the GLOBE and GUARD proposals. These comments outlined key concerns regarding patient access, treatment continuity, and the broader implications for the plasma protein therapeutics sector. PPTA also strengthened its advocacy efforts by partnering with patient organizations, helping to amplify patient voices and reinforce shared concerns with policymakers.

ADVANCING FEDERAL ADVOCACY ON MOST FAVORED NATION

One of the most impactful advocacy initiatives of the year was the **April Stakeholder Roundtable Organization (SRO) Briefing on MFN**. The briefing on Capitol Hill convened policymakers, stakeholders, and advocates to discuss the potential consequences of MFN policies and served as a critical platform for education and engagement. **The event generated significant interest and helped establish MFN as a key policy priority for the industry.**

PPTA's "26 in '26" Congressional Fly-In represented another major success. During the Fly-In, Association leaders met with 26 congressional offices, including influential legislators such as Energy and Commerce Committee Chairman Brett Guthrie (R-KY), Senate Majority Leader John Thune (R-SD), Senate Finance Committee Chairman Mike Crapo (R-ID), and other congressional leaders. **These meetings reinforced the industry's priorities and expanded engagement with key decision-makers on Capitol Hill.**

EXPANDING STATE-LEVEL ADVOCACY EFFORTS

PPTA continued to build momentum at the state level, achieving meaningful progress in California while laying the groundwork for future success in New Jersey.

In **California**, revised legislation supporting plasma collection was introduced that substantially reduced projected implementation costs for the California Department of Public Health. This strategic revision helped strengthen support for the bill, which successfully advanced through two legislative committees during the first half of the year. PPTA continues to advocate for passage and is actively working to secure a vote before the full Assembly. **The advancement of this legislation represents one of the organization's most significant state advocacy achievements to date in 2026.**

In **New Jersey**, legislation was introduced and discussions were initiated with the New Jersey Department of Health. While the effort remains in the early stages, PPTA has established productive engagement with state officials and continues to build support for the initiative heading into 2027.

Europe

EUROPE: KEY MILESTONES (JANUARY–JUNE 2026)

January: Hungary National Donor Registry Enters into Force: The Hungarian National Donor Registry officially entered into force in January 2026, marking a significant advancement in donor health and safety by enhancing donor tracking and enforcing donation frequency requirements. The Registry also supports the continuous and safe supply of lifesaving plasma-derived medicines. PPTA and the European Plasma Alliance welcomed this important step towards strengthening plasma collection and supply resilience in Europe.

January-April: Advancing National Advocacy in Germany: PPTA's advocacy efforts in Germany focused on the revision of the GKV Contribution Rate Stabilization Act, a reform package aimed at generating approximately €16 billion in public savings through increased pharmaceutical rebates. Through sustained engagement with policymakers and stakeholders, PDMPs included on Germany's critical medicines list have, to date, been exempted from the proposed rebate increases. This outcome preserves the current mandatory rebate rate and helps avoid significant additional financial burdens for the sector, supporting continued patient access to critical therapies. Advocacy activities included formal recommendations submitted to the Federal Ministry of Health, participation in public consultations, and increased media engagement. A March press release generated coverage across 45 national media outlets, while PPTA's perspectives were featured in Politico Germany in April.

January-March: Expanding Public Visibility in Greece: From January onwards, PPTA strengthened its media outreach in Greece, securing coverage in many national news outlets and increasing awareness of the role of plasma-derived therapies and the importance of a sustainable plasma ecosystem.

SHAPING EUROPEAN POLICY AND REGULATORY DISCUSSIONS

- April: Publication of Revised Stockpiling Policy Paper: PPTA published a revised edition of its policy paper, *Perverse Consequences of Systemic Stockpiling of Plasma-Derived Medicinal Products in Europe*. The paper's recommendations were formally submitted to the Organisation for Economic Co-operation and Development (OECD) and are expected to inform the OECD's forthcoming guidance to governments on "smart stockpiling" approaches.

Europe

- March-April: Engagement on International Trade and Market Access: PPTA submitted evidence and policy input to the European Commission's Directorate-General for Trade regarding restrictions affecting exports of PDMPs to China, contributing industry expertise on trade barriers and data requirements.

- May: Influencing the EU Critical Medicines Act: PPTA's engagement throughout negotiations on the EU Critical Medicines Act contributed to the inclusion of safeguards ensuring that future contingency stock requirements remain proportionate and aligned with the principles of transparency and solidarity. These provisions help reduce the risk that national stockpiling measures could unintentionally disrupt the availability of critical medicines, including PDMPs, across Europe.

- June: Contributing to the EU Biotech Act: PPTA submitted its position to the European Commission's public consultation on the Biotech Act and conducted targeted political outreach. Proposed amendments were shared with Members of the European Parliament and national representations, ensuring that the specific needs of PDMPs were reflected in ongoing policy discussions.

ELEVATING THE VOICE OF THE PLASMA SECTOR

- April: Record Participation at IPPC 2026: PPTA achieved its highest-ever attendance at the International Plasma Protein Congress (IPPC) 2026. New initiatives included a dedicated pre-event engagement with patient organizations and highly attended sessions that strengthened dialogue across the plasma community.

- April: European Parliament Engagement: Speaking at an event hosted by the Alpha-1 Europe Alliance in the European Parliament, PPTA highlighted the importance of strengthening European resilience and progressing toward greater self-sufficiency in plasma supply.

Europe

- June: Friends of Europe: Reimagining Healthcare Systems: At a high-level *Friends of Europe* event, PPTA highlighted the unique manufacturing and supply-chain characteristics of PDMPs and underscored the need for tailored policy approaches as the EU advances pharmaceutical and biotechnology initiatives. The discussion reinforced the importance of practical implementation, prevention, equity, and long-term policy planning in strengthening medicine supply and innovation.

- June: European Parliament Event on Rare Diseases and Innovation: At the EPODIN event in the European Parliament, PPTA emphasized the importance of resilient and differentiated supply-chain policies, highlighting the central role of plasma supply in ensuring the availability of PDMPs and supporting patient access across Europe.

CONTINUED MOMENTUM

One of the most significant achievements of the first six months of the year was **PPTA's successful advocacy in Germany, which helped secure the special status of PDMPs on the German critical medicines list from proposed pharmaceutical rebate increases under the GKV reform**. This outcome protects the sector from substantial additional financial burdens and supports the continued availability of essential PDMPs for patients. Alongside this policy success, record participation at IPPC 2026 and increased media visibility across Europe further strengthened the sector's influence and profile.

Asia

PPTA EXECUTIVES VISIT INDIA

In early March, Anita Brikman, PPTA President & CEO, and Joshua Penrod, PPTA Senior Vice President of Global Plasma & Technical Advocacy, joined PPTA consultant Dr. Ranjeet Ajmani for a series of meetings across India with regulators, public health experts, blood bank leaders, patient advocates, clinicians, and plasma fractionation professionals.

While there is significant work ahead, the visit reinforced a strong spirit of collaboration and a shared commitment to improving patient care across the region. As India continues to expand its role in the global plasma ecosystem, partnerships like these will remain critical to advancing access, strengthening quality, and supporting better outcomes for patients. PPTA's meetings in India reflect the organization's continued commitment to working with stakeholders around the world to help improve the availability of safe, high-quality plasma-derived medicines.

North America Regulatory

ADVANCING PATIENT ACCESS THROUGH REGULATORY ENGAGEMENT

During the first half of 2026, the team maintained strong engagement with U.S. regulators and policymakers to advance initiatives that support patient access to plasma-derived therapies. A key milestone was the successful coordination of the **Annual FDA Liaison Meeting** in February, which brought together industry leaders and FDA officials to discuss emerging regulatory priorities and opportunities to address unmet patient needs.

A central focus of the meeting was the exploration of regulatory pathways and flexibilities that could facilitate the addition of a second indication for patients with secondary immunodeficiency (SID) to therapies already approved for primary immunodeficiency (PID). These discussions represented an important step toward expanding treatment options and improving access for patients whose clinical needs may not be fully addressed under current labeling frameworks.

Building on this momentum, PPTA is currently preparing for this summer's webinar, titled "**Beyond Labels: Ensuring Access to IG Therapy for Secondary Immunodeficiency.**" The educational program will convene leading physicians, researchers, and regulatory experts to examine the challenges facing SID patients and discuss opportunities to improve access to immunoglobulin therapies. The distinguished panel includes representatives from major academic medical centers and regulatory agencies in North America and Europe, helping to foster cross-sector dialogue on this important issue.

North America Regulatory

SUPPORTING SCIENTIFIC STANDARDS AND OPERATIONAL EXCELLENCE

Significant progress was made on initiatives aimed at strengthening scientific standards and supporting operational improvements across the industry. Working closely with stakeholders, PPTA revised and updated the Red Cell Immunization Guidance Document to ensure alignment with current scientific knowledge, industry best practices, and evolving regulatory expectations.

In parallel, PPTA completed the drafting of CLIA Flex Studies protocols in partnership with key stakeholders. These protocols support efforts to recategorize the total protein test performed using digital refractometer technology and establish a foundation for future regulatory submissions and implementation activities.

LAUNCH OF THE CORE PILOT STUDY

The most significant accomplishment during the first six months of the year was the successful training and launch of the CORE pilot study.

Following extensive planning, protocol development, and stakeholder coordination, the pilot study was initiated at ADMA BioCenters and Takeda BioLife plasma centers. The pilot was designed to rigorously test study protocols, operational processes, and data collection procedures under real-world conditions before broader implementation. By validating every component of the study in advance, the pilot helps ensure that potential challenges are identified and addressed before the launch of the full study.

This proactive approach is expected to improve study quality, increase operational efficiency, and strengthen the reliability of future results. The successful launch reflects the collaborative efforts of participating organizations and represents a major milestone in advancing research capabilities across the plasma industry.

Europe Regulatory

REGULATORY POLICY AND STAKEHOLDER ENGAGEMENT

Throughout the first half of 2026, the Association maintained a strong presence in European regulatory discussions, engaging extensively with key institutions to ensure industry perspectives were reflected in evolving policy and regulatory frameworks.

A major area of focus was collaboration with the European Directorate for the Quality of Medicines & HealthCare (EDQM) on data harmonization initiatives. The team actively participated in discussions and submitted responses to consultations, contributing technical expertise to efforts aimed at improving consistency and efficiency across regulatory data requirements.

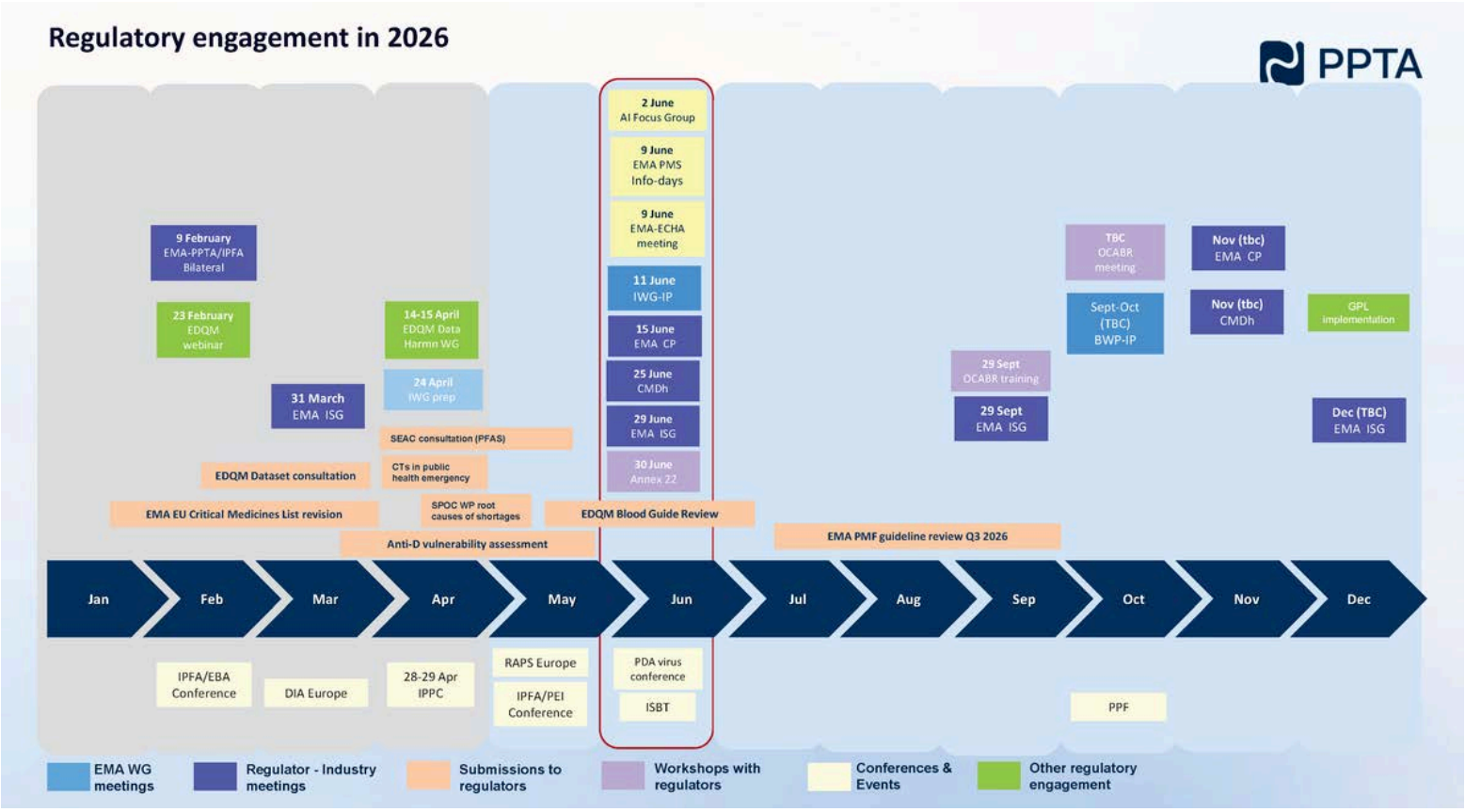
The annual meeting with the European Medicines Agency (EMA) provided an important opportunity to discuss strategic priorities, emerging regulatory developments, and issues affecting the plasma sector. In addition, the team engaged closely with EMA on several initiatives related to medicine shortages and supply resilience, including vulnerability assessments, development of the Critical Medicines List, and efforts to classify and better understand the root causes of shortages. These activities helped reinforce the industry's role as a key stakeholder in strengthening Europe's healthcare supply chain.

Europe Regulatory

RESPONDING TO KEY CONSULTATIONS

In addition to ongoing stakeholder engagement, the team actively participated in several important regulatory consultations. Responses were submitted on proposals related to clinical trials during health emergencies, while additional work was undertaken to prepare industry input on emerging PFAS-related regulatory initiatives.

Collectively, these activities demonstrate the team's continued commitment to providing scientific expertise, supporting evidence-based policymaking, and ensuring that the unique considerations of plasma-derived therapies are represented in European regulatory discussions.



Upcoming PPTA Events

INTERNATIONAL PLASMA AWARENESS WEEK

PLASMA POWERS POSSIBILITY

Save the Date for **#IPAW2026**

OCTOBER 5-9 2026

www.plasmaweek.org

Save the Date

for the 2026 Plasma Protein Forum & Business Forum*

PLASMA PROTEIN FORUM

November 3–4, 2026

Concludes at 12 PM on the 4th

BUSINESS FORUM

November 4, 2026

1–5 PM

**Business Forum is for members only*

Alexandria, VA

pptaglobal.org/forum

Save The Date

for IPPC 2027 in **Barcelona, Spain**

20-21 April, 2027

#IPPC2027

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