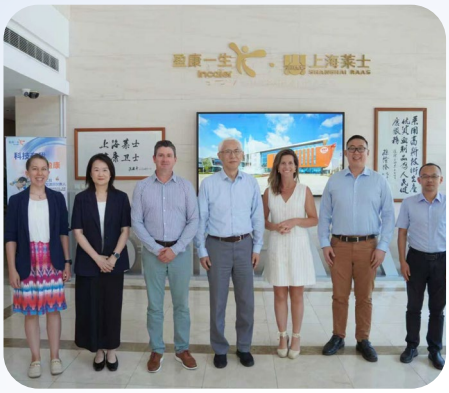
PLASMA PROTEIN
THERAPEUTICS
ASSOCIATION



2025 ANNUAL REPORT

WWW.PPTAGLOBAL.ORG

PLASMA PROTEIN THERAPEUTICS ASSOCIATION

CONTENTS

FROM OUR PRESIDENT

Advancing Access. Strengthening Donor Safety. Shaping Policy.

2025 marked a year of meaningful progress in advocacy, regulatory engagement, donor safety, and global policy influence despite unprecedented geopolitical challenges. Across Europe and the United States, PPTA strengthened the plasma ecosystem through evidence-based leadership, cross-sector partnerships, and strategic engagement with decision-makers.

This progress would not have been possible without the continued commitment, expertise, and collaboration of our member companies and stakeholders, whose leadership and dedication drive innovation and resilience across the plasma sector.

Together, we advanced shared priorities, responded to emerging challenges, and reinforced the essential role of plasma-derived therapies in global health.

Going forward, our commitment remains the same: ensuring safe, reliable access to plasma-derived therapies for patients worldwide — made stronger through the collective efforts of our community.

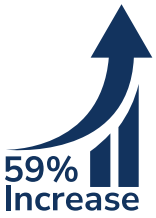
With gratitude,

Anita Brikman

President & CEO, PPTA

UNITED STATES: ADVOCACY, AWARENESS & LEGISLATIVE WINS

ON CAPITOL HILL



Plasma Caucus Growth

The bipartisan **Congressional Plasma Caucus expanded from 29 to 46 members,** reflecting increased policymaker understanding of plasma-derived (PDTs).

Standing Room Only Congressional Briefing

On July 15, PPTA joined with the Congressional Plasma Caucus and the American Plasma Users Coalition to host a **high-impact briefing**, "Plasma-Derived Therapies: A Uniquely American Part of the Pharmaceutical Industry," which attracted a standing room only audience.

100+ Congressional Meetings

PPTA engaged more than **100 Congressional offices**, focusing on committee members of Energy & Commerce, Ways & Means, and Senate Finance to advance awareness of PDTs and their community impact.

TRADE & TARIFFS

Tariff Exemptions Progress

PPTA secured federal language affirming that **"non-patented articles for further pharmaceutical application"** qualify for tariff exemption — reducing cost pressures on manufacturers.

IN THE STATES

Louisiana Legislative Success

Legislation eliminating unnecessary licensing requirements for plasma center lab personnel **passed unanimously** and was signed June 4. Effective August 1, the law streamlines operations and reflects broad bipartisan support.

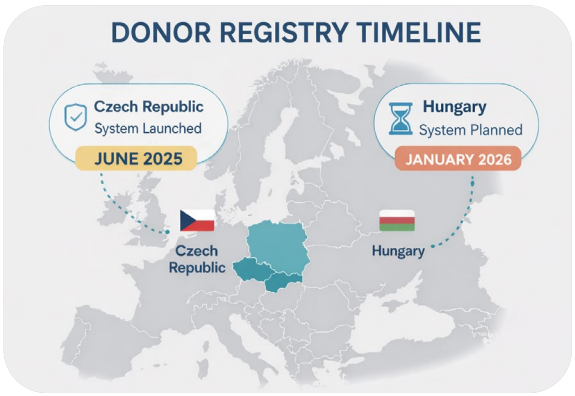
California, New Jersey, and Washington Advocacy

PPTA testified, convened stakeholders, and collaborated with regulators across these states to **advance industry needs** in complex policy environments.

EUROPE: STRENGTHENING SYSTEMS & ADVANCING ACCESS

Securing Recognition in the EU CMA

PPTA successfully ensured that the **diversity of pharmaceutical supply chains** — including the highly specialized nature of plasma-derived medicinal products (PDMPs) manufacturing — was recognized in European Parliament amendments. If maintained in the final Critical Medicines Act (CMA) text, this milestone can **reduce inappropriate stockpiling obligations** and support **uninterrupted patient access**.

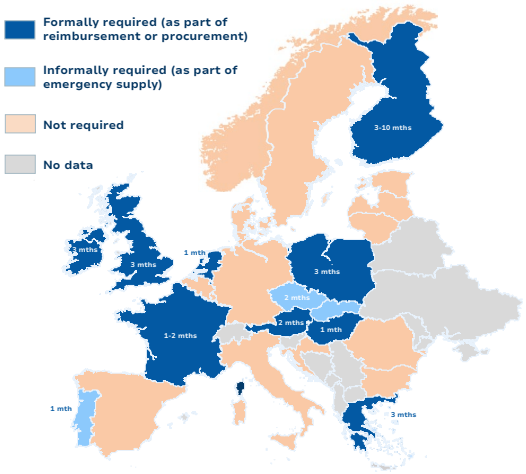


New Research on PDMP Reimbursement & Access

PPTA presented new comparative research at the International Society for Pharmacoeconomics and Outcomes Research conference **(ISPOR Europe 2025)**, mapping reimbursement, cost-containment, and stockpiling policies across EU countries. The analysis offers an evidence base to inform national decision-making and identify access challenges.

Advancing Donor Safety Through New National Registry Systems

National donor registry systems were launched or advanced in the **Czech Republic (2025)** and **Hungary (launch planned for 2026)**. These systems enhance donor protection and better align countries with upcoming EU-level requirements.



2025 REGULATORY HIGHLIGHTS

DATA-DRIVEN OUTCOMES

CORE | COHORT OF REPEAT DONOR EXPERIENCES STUDY

CORE Study Ready for Launch

The Cohort of Repeat Donor Experiences (CORE) Study received Institutional Review Board approval and is preparing for a March 2026 start of the pilot study. The primary aim of this study is to assess the associations between plasmapheresis, biochemical markers, and health outcomes at different donor frequency levels. This study aims to generate findings applicable to adults aged 18-74 years who meet eligibility criteria for plasmapheresis donation.

Elevating PPTA Scientific Credibility

PPTA increased participation in scientific workshops, collaboration with scientific bodies on various clinical and infectious disease issues, and regulatory discussions, expanding its role as a **data-driven thought leader**.

New Viral Marker Data Platform

A new member website now enables streamlined viral marker uploads, improving data capture and future analytical capacity.

ENGAGEMENT WITH REGULATORY AGENCIES

Centers for Medicare & Medicaid Services (CMS) & Clinical Laboratory Improvement Amendments (CLIA): Protecting Plasma Center Operations

PPTA secured enforcement discretion and clarifications around laboratory director and consultant requirements, avoiding **more than $5 million** in anticipated industrywide costs and delays.

$5+ MILLION SAVED
in pathologist annual rates, retainer fees, and more

FDA

Responding to a Transforming Agency

With major structural shifts at the U.S. Food and Drug Administration (FDA) in 2025, PPTA provided **continuous leadership** on Precheck, HBsAg testing updates, pandemic preparedness, immunoglobulin indication expansion, and manufacturing topics — ensuring member priorities remain front-and-center.

FDA Red Blood Cell Immunization Protocol Update

FDA agreed to modernize 1995 guidance — reducing donor/RBC qualification periods from **12 months to 3 months**, easing pathways for programs like Anti-D.

EUROPE: DEEPENED REGULATORY ENGAGEMENT

Throughout 2025, PPTA **strengthened partnerships** with the European Commission, European Centre for Disease Prevention and Control (ECDC), European Medicines Agency (EMA), and European Directorate for the Quality of Medicines & HealthCare (EDQM), positioning the Association as a trusted expert in a rapidly evolving regulatory environment.

Growing Collaboration with ECDC

PPTA expanded its role as an **expert resource** for infectious disease monitoring and risk assessment, supporting ECDC's increasing focus on substances of human origin (SoHO) and their supply chains.

Broader Engagement with the EMA

PPTA's **collaboration with EMA** extended well beyond traditional marketing authorization and lifecycle management. Engagement now includes:

- Quality and safety standards
- Inspections
- Shortage reporting
- Clinical immunoglobulin guidance
- Epidemiological data and the Plasma Master File

Throughout 2025, PPTA ensured that regulatory evolutions consider the specificity of plasma collection and PDMP manufacturing systems.

Significant Progress with EDQM

One of the year's most promising developments was PPTA's **strengthened relationship with EDQM.** PPTA contributed expertise to EDQM working groups covering:

- Batch release
- Donor eligibility and donor health (Blood Guide)
- Plasma supply
- Anti-D immunoglobulin
- Data requirements

This engagement helped elevate PDMP-specific considerations in technical guidance and standards.

Learn more about how PPTA engages with global regulatory authorities to influence patient access.

INTERNATIONAL PLASMA AWARENESS WEEK (IPAW) 2025

International Plasma Awareness Week (October 6–10) united donors, patients, policymakers, and plasma professionals around the theme “Plasma Powers Possibility,” highlighting the **essential role of plasma-derived therapies and the donors who make them possible.**

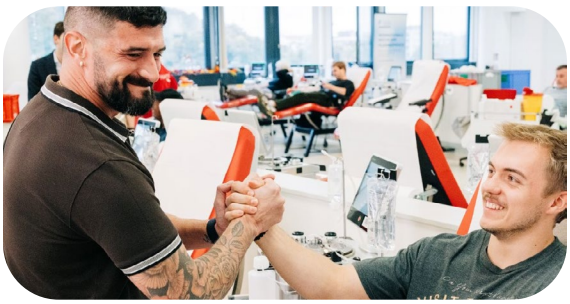
PPTA partners across the globe used campaign materials — including social media graphics, explainers, and donor recognition tools — to amplify awareness and celebrate the impact of donation. The campaign hub, plasmaweek.org, supported hundreds of organizations in sharing consistent, evidence-based messaging.

Europe

In Europe, IPAW launched a **high-level policy discussion in Brussels** focused on the unique supply chain needs of PDMPs within the upcoming Critical Medicines Act. PPTA also collaborated with **Haema and the GBS/CIDP Foundation International** to bring patients and donors together in Berlin, generating strong media engagement across the region.

INTERNATIONAL PLASMA AWARENESS WEEK

PLASMA POWERS POSSIBILITY



John, (left) an MMN patient from Gibraltar, said of the visit, “ This was by far the most significant moment in my MMN journey so far, and one I’ll carry with me always.”

North America

North American efforts centered on media outreach, community engagement, and patient storytelling. PPTA President & CEO Anita Brikman hosted a **patient-focused webinar** and appeared on **television and radio** to highlight the importance of donor participation. Local coverage in key plasma regions broadened the campaign's reach.

Watch the webinar:

Jana Mattheu, mother of a primary immunodeficiency patient, and Dr. Michael Keller, a pediatric immunologist at Children's National Hospital, helped bring greater attention to IPAW and the importance of donating plasma via a video interview with local news stations.

Watch the video here:

A Shared Message

Across all activities, the message remained clear: **Plasma donation saves lives**, and continued donor engagement is essential to ensuring reliable access to **lifesaving therapies for patients worldwide**.

MARK YOUR CALENDARS FOR IPAW 2026: OCTOBER 5-9

Visit plasmaweek.org to learn more

ON THE HORIZON FOR 2026

PPTA's 2026 priorities will continue to advance patient access, plasma availability, and understanding of plasma ecosystems worldwide. These priorities include:

1. Advocate for Differentiated & Proportionate Policy Approaches

PPTA will work to ensure regulatory obligations recognize the sector's unique characteristics. Focus areas include:

- Exemption from the **Global Benchmark for Efficient Drug Pricing (GLOBE)** and **Guarding U.S. Medicare Against Rising Drug Costs (GUARD)** models, which would impose Most-Favored Nation (MFN) style pricing in the Medicare program
- Critical Medicines Act (CMA) implementation
- Proposed Biotech Act
- EMA and EDQM technical alignment

2. Support the Transition to the EU SoHO Regulation

PPTA will strengthen national collaborations to ensure a smooth transition to the new SoHO framework by:

- Protecting operational continuity
- Mitigating risks to plasma collection and PDMP manufacturing
- Strengthening societal acceptance and public trust

3. Amplify PDMP Access Research Across the EU

Building on the 2025 reimbursement and access study, PPTA will:

- Share findings with national governments and health authorities
- Develop country-specific policy papers
- Support targeted advocacy to address access inequalities for PDMPs

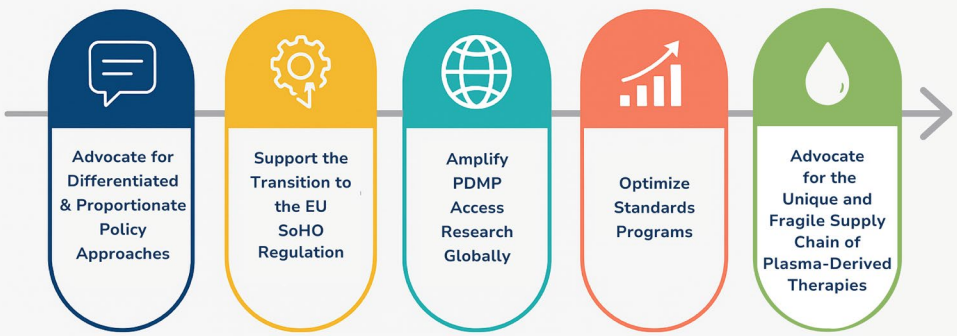
4. Optimize Standards Programs

PPTA will work with members to refine, modernize, and streamline standards programs — maintaining their essential role in safety and quality while improving efficiency and member value.

5. Advocate for the Unique and Fragile Supply Chain of Plasma-Derived Therapies

PPTA will continue to cultivate champions on Capitol Hill who understand the plasma sector, patient access, and potential impact of tariffs.

2026 ROADMAP



PLASMA PROTEIN THERAPEUTICS ASSOCIATION

WWW.PPTAGLOBAL.ORG

@PPTAEUROPE

@PPTAEUROPE

@PLASMAPROTEINS

@PLASMA-PROTEIN-THERAPEUTICS-ASSOCIATION

@PPTAGLOBAL

PPTA NORTH AMERICA
601 New Jersey Ave NW, Suite 750
Washington, D.C. 20001
UNITED STATES
PHONE: +1.202.789.3100

147 Old Solomons Island Road, Suite 100
Annapolis, MD 21401
UNITED STATES
PHONE: +1.202.789.3100

PPTA EUROPE
Boulevard Brand Whitlock 114 /b4
1200 Brussels BELGIUM
PHONE: +32.2.705.5811

INTERNATIONAL QUALITY PLASMA PROGRAM

QSEAL
QUALITY STANDARDS OF EXCELLENCE, ASSURANCE & LEADERSHIP