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The WISH Project

Antibodies from Reconvalescent Donors for the Prevention and Treatment of Virus Infections: Revisiting an Old Concept in Light of the Current Ebola Virus Epidemic

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Contents

3 IN MY VIEW

4 EMA Workshop Focuses on Viral Safety of Plasma-Derived Medicinal Products with Respect to HEV

6 Antibodies from Reconvalescent Donors for the Prevention of Treatment of Virus Infections: Revisiting an Old Concept in Light of the Current Ebola Virus Epidemic

8 The WISH Project

11 Living the “Fullest Life Possible”

14 Rebuilding After Loss: The Joplin, MO, Story

16 Transatlantic Trade and Investment Partnership: PPTA Engages as Negotiations Move Forward

20 INSIDE PPTA

20 The Source Team

22 PPTA European Collectors Committee

23 Revised IQPP Standards

24 A New Tool for Industry: The IQPP Cross Donation Check System

26 The Grifols Academy of Plasmapheresis

27 GLOSSARY

28 UPCOMING EVENTS
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As you read this column, we are finalizing our preparation for the annual International Plasma Protein Congress (IPPC) that this year will be held in Rome, Italy. This Congress has convened for two decades and has evolved to become one of the premier European meetings on the plasma proteins that are used by so many patients and help improve (even save) their lives.

I am very pleased that we have the 2015 meeting in Rome, since Italy shows good initiatives to improve access to these therapies. Not only that, one initiative (that is in more detail described in this edition) has led to the supply of a significant amount of Factor VIII units to the World Federation of Hemophilia as a gift to help persons with hemophilia in parts of the world where access is limited.

The organization of this annual Congress is 100 percent done by PPTA staff, both from the Brussels office and the Annapolis office. It is truly amazing to see how motivated and committed staff is to make this Congress a success. I would like to thank all for that hard work!

Every year we present the Joachim Hilfenhaus Award to an individual who has made an outstanding contribution to the provision of safe and efficacious plasma protein therapies.

I remember Joachim Hilfenhaus as the first Chairman of the European Association of the Plasma Products Industries (EAPPI) Viral Safety Working Group. He was a very respected virologist who worked for Behring in Marburg, Germany. Those who have known him, remember his very characteristic laughter. He was a good scientist, a good human being with a sense of humor. Unfortunately he passed away at a too young age. We are very proud that his name is associated with this prestigious Award that our Association presents every year at the IPPC Congress.

Every year, we get a lot of questions about the location of the next IPPC Congress. We always choose a big city in Europe, try to be close to an airport, and find a hotel that can accommodate all guests. This is not always possible (as this year in Rome) but we do our best.

This year we are doing something new. We are giving the attendants of the IPPC an opportunity to give a preference for the next location. We will provide four options and let the attendants decide. We have never tried this before, but we will see how this works!

Hope to see all of you in Rome!

Jan M. Bult, President & CEO
On October 28-29, 2014, PPTA and member companies participated with regulators, clinicians, and industry in a closed “Workshop on viral safety of plasma-derived medicinal products [PDMPs] with respect to hepatitis E virus [HEV]” organized by the European Medicines Agency (EMA) in London.

It was intended to provide the basis for deciding what further action may be needed, including possible updates of current regulatory guidance and/or development of a new position or reflection paper specifically on the viral safety of PDMPs with respect to HEV. PPTA Pathogen Safety Steering Committee (PSSC) members Thomas R. Kreil (Chair, Baxter BioScience), Albrecht Gröner (CSL Behring), and Rodrigo Gajardo (Grifols) presented the results from studies on the inactivation/removal of HEV, followed by PPTA perspectives on risk assessment for PDMPs and implications for warning statements.

BACKGROUND

HEV, a zoonotic disease present in pig populations around the world, has been transmitted by transfusion of blood components, yet not by PDMPs, although HEV has been detected in plasma for fractionation. Information derived from HEV-associated complications in transfusion and transplantation was reviewed during workshop discussions, as well as the severity of clinical consequences of infection.

ARE PDMPs SAFE WITH RESPECT TO HEV?

Attending regulators stated that there has not been any transmission of HEV through PDMPs. Not a new virus, HEV has been present in e.g. the EU for decades, and thus transmissions should have been observed if there was a potential risk. However, regulators cautioned that HEV infection may be under- and mis-diagnosed, as patients with symptoms are not always tested for HEV, and thus transmissions may be missed.

Based on the virus reduction data presented, attending patient groups [International Patient Organization for Primary Immunodeficiencies (IPOPI), European Haemophilia Consortium (EHC) / World Federation of Hemophilia (WFH), European Liver Patients Association (ELPA)] stated that PDMPs are safe with respect to HEV. EHC/WFH did propose to introduce screening for blood donors to protect hemophilia

BY MARY CLARE KIMBER
available data indicate that the neutralization capacity of HEV antibodies may be limited and of lower avidity. The observation may be explained by preliminary evidence that the non-lipid enveloped HEV may be coated with lipids under certain circumstances, which may render neutralization less effective.

HEV has been circulating in the human population for a long time, regulators indicated that adding product-specific statements on HEV reduction measures would only enable marketing based on a product attribute of theoretical value.

Next steps
Regulators concluded that more data are needed before any final decision-making process can commence. For now, regulatory measures, such as e.g. incentivizing NAT testing or adding warning statements, would not improve product safety. As a first step, EMA plans to publish a workshop report and reflection paper subject to consultation with stakeholders. PPTA will continue to engage EMA and other regulators, as well as the patient community, to ensure that any policy developments rationally reflect ongoing research and understanding of viral safety of PDMPs with respect to HEV.

Mary Clare Kimber, PPTA Senior Manager, Regulatory Policy


Patients that do not have access to recombinant therapies and rely on transfusion products.

**Which steps are efficient to remove/inactivate HEV (which model viruses can be used)?**

There are open questions that need to be addressed before any final conclusion on the efficacy of certain inactivation/removal steps for HEV can be made. Although there is certain confidence based on the available data, particularly with model viruses, only data with HEV itself will be able to confirm today’s assumptions. There is a need for more data generated with HEV as the virus of concern, but the establishment of test systems is difficult, particularly the generation of high titer supernatants.

**Are more virus reduction data needed?**

Since there are still many open questions, regulators were adamant that more studies are needed, although regulators may not require data from each company on efficacy of every reduction step in clearing HEV at this stage. While data presented were generally consistent, conflicting data on certain details presented raised some doubts whether the underlying mechanisms are sufficiently understood.

EMA has not required HEV NAT testing for PDMPs, even if rare pools may contain a low viral burden, based on converging evidence from model and target virus reduction studies that support final product safety margins.

Of note, IPOPI was confident about the safety of PDMPs and cautioned that safety measures should be balanced against availability. Unnecessary loss of plasma and unwarranted incurrence of costs should be avoided for products with an excellent record of safety.

**Do serum HEV antibodies neutralize the virus?**

Available data indicate that the neutralization capacity of HEV antibodies may be limited and of lower avidity. The observation may be explained by preliminary evidence that the non-lipid enveloped HEV may be coated with lipids under certain circumstances, which may render neutralization less effective.

**Are risk assessments and/or warning statements needed?**

During the workshop there was general agreement that adding HEV to the warning statement for hepatitis A (HAV) and parvo virus B19 (B19V) in the EMA guidance would not be appropriate at this time, in that the general statement in the current guidance covers any theoretical HEV risk: “the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.” Noting that there have been no transmissions of HEV by PDMPs reported to date, although
Some clinical evidence suggests that antibodies from reconvalescent donors (persons who have recovered from infection) may be effective in the treatment of Ebola virus infections. Different approaches of how to prepare such antibodies for administration to Ebola virus-infected patients while preventing the transmission of other human-pathogenic viruses are discussed here, with more detail available to the interested reader elsewhere¹.

Antibodies from reconvalescent donors, at the time from horses, have been used for the treatment of infectious diseases for little more than one hundred years now, an approach initially pioneered by Emil von Behring and sufficiently impactful to earn him the first Nobel Prize in Medicine. Over time though, driven by the advent of vaccines and antibiotics, this treatment modality has lost some importance, and its current use is limited to primarily niche applications such as antivenoms/antitoxins, and few licensed hyperimmune indications such as for example anti-hepatitis B, or anti-rabies. And while the conceptual value of reconvalescent antibody-based products for the treatment of emerging viruses, such as recently West Nile Virus or pandemic influenza viruses, has been recognized, the required amount of pre- and clinical investigations may have been an insurmountable obstacle to bringing the interventions to use. The situation may be different with the current Ebola virus (EBOV) outbreak in West Africa, in that the scale of human suffering and death combined with the very limited alternative options, i.e. only early stage development products, may make any alternative that could be more immediately available and reasonably promising more desirable. To be respectful of scientific
evidence, the effectiveness of treating EBOV infections with antibodies from reconvalescent donors is not fully proven either, but some limited clinical experience can be interpreted as encouraging, and more recent results from preclinical work also supports the potential utility of the approach.

Beyond the confirmation of efficacy though, concerns all too familiar for the plasma products industry need to be addressed: first and foremost, it is critical to prevent the transmission of other infectious agents that may be harbored by the donors; and secondly, the number of treatment courses that can be made available needs to be reasonably commensurate with the size of the challenge, to allow for broad scale treatment of potentially all those in need, rather than currently only the treatment of foreign aid workers who have risked their lives in a laudable humanitarian effort.

To address the safety aspects, history has proven that testing the donations will be an imperfect solution. Despite the implementation of even elaborate nucleic acid test (NAT) algorithms, non-virus inactivated transfusable blood components still occasionally transmit West Nile Virus in the U.S., and similar situations need to be expected in West Africa—with an HIV-positivity rate in the adult population of approx. 1 percent as reported by UNICEF (United Nations Children’s Fund.) (http://www.unicef.org/infobycountry). The transfer of EBOV antibodies, however, only requires the transfusion of serum or plasma, a component that can be virus-inactivated by a number of proven methods, with the solvent-detergent treatment probably the most effective choice for lipid-enveloped viruses as demonstrated by a PPTA-facilitated industry collaboration2. In one specific embodiment, the production of solvent-detergent plasma was achieved by use of a commercially available disposable set of bags developed for use in a resource-limited blood bank setting3. Against this background it is rather disappointing to see that the World Health Organization (WHO) guidance document on the use of reconvalescent plasma for the treatment of EBOV has stopped short of even mentioning the option of virus inactivation. Instead, it requires the comprehensive testing of donors within 48 hours before transfusion, or for longer periods a complete repeat, which represents a technical and logistical effort to achieve a result of limited value.

For the volume aspect, it is not too difficult to imagine how a basic plasmapheresis infrastructure could be established in West Africa, once the hospital-like infrastructure committed by several countries is available there.

All-in-all, it seems that the use of antibodies from reconvalescent donors may find yet another medical use, and with the support pledged by large philanthropic entities the scientific support for the currently to some degree assumed efficacy is expected to improve soon. For the necessary safety and volume considerations it could have been more effective to also involve the expertise of the plasma products industry, ideally under the auspices of WHO so that its guidance on the use of reconvalescent plasma could have been more comprehensive: the experience this industry has accumulated in both pathogen safety issues as well as volume challenges, could have helped accelerating the availability of a quite possibly helpful intervention in one of the most dire recent infectious disease outbreaks.●

THOMAS R. KREIL, Ph.D., Associate Professor of Virology, Senior Director, Global Pathogen Safety, Baxter BioScience

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4 Use of Convalescent Whole Blood or Plasma Collected from Patients Recovered from Ebola Virus Disease for Transfusion, as an Empirical Treatment during Outbreaks. Interim Guidance for National Health Authorities and Blood Transfusion Services Version 1.0 September 2014; accessed at http://apps.who.int/iris/bitstream/10665/135591/1/WHO_HIS_SDS_2014.8_eng.pdf
The WISH Project

BY FABIO CANDURA, GABRIELE CALIZZANI, AND GIULIANO GRAZZINI

In May 2014, as representatives of the Italian National Blood Centre (CNS), we signed a Memorandum of Understanding with the World Federation of Hemophilia (WFH) to launch a humanitarian programme aimed at reducing the gap between low-income and high-income countries in the access to plasma-derived medicinal products, and based on the not-for-profit distribution of up to 150 million IUs of FVIII over a five-year period. Now, we are in the process of finalizing the definitive project Agreement.

The initiative, the WISH Project (World Federation of Haemophilia and the Italian National Blood Centre for a Sustainable Supply for Haemophilia patients), is born from both parties’ strong commitments to collaborate in ensuring an effective response to the therapeutic needs of patients, who would otherwise not have adequate access to treatment.

A formal working group—the Joint Steering Committee (JSC) composed of WFH, CNS, and Italian Regions representatives—will be established. The JSC will, as required, call upon experts from governmental institutions, donor associations and federations, scientific societies, patient organizations, industry, and other relevant stakeholders.

Main tasks of the JSC will be to: define criteria for the recipient country selection process; identify the recipient countries; support the implementation of haemophilia care networks in recipient countries, including the education and training of local professionals; monitor the activities of the specific projects and verify compliance with timelines and deadlines; provide technical and scientific advice/support; and monitor financial aspects related to the projects. Kedrion, as the current partner of the Italian Regions, has actively promoted the development and success of the project by committing to cover the regulatory and logistics costs of shipping the product to the recipient country. The Industry
Main tasks of the JSC will be to: define criteria for the recipient country selection process; identify the recipient countries; support the implementation of haemophilia care networks in recipient countries, including the education and training of local professionals; monitor the activities of the specific projects and verify compliance with timelines and deadlines; provide technical and scientific advice/support; and monitor financial aspects related to the projects.

(ies) [so far Kedrion], which is (are) the collector(s) of plasma from the Italian Regions, the manufacturer(s) of the finished product and the marketing authorisation holder(s), handling the stock and the shipment from Italy to the recipient countries, will therefore be technical expert(s) and observer(s) in the JSC.

Quality and safety of blood and blood products, and of all transfusion medicines activities, are the primary concerns of the Italian National Blood System (INBS), and self-sufficiency of blood and blood products (including plasma-derived medicinal products) from voluntary and non-remunerated donation (VNRD) is recognized by the Nation as a primary goal.

Since 2008, amongst the INBS main stakeholders—the regional blood services, donors associations and federations, scientific societies and patient organizations—there has been a growing awareness on the need to promote an ethical, transparent, and sustainable use of the surplus of plasma-derived clotting factor concentrates from Regional toll fractionation agreements. This has led to the introduction of specific regulatory amendments (Ministerial Decrees, April 2012; State-Regions Agreement, February 2013) enabling the possibility for both intermediates and final products in excess of regional and national demand to be non-profit exported, in some cases even recovering production costs, within specific agreements, programs or projects.

Since then, a number of donations have been made to countries including Afghanistan, Albania, Armenia, Egypt and India, thereby opening the window to opportunities offered by the collaboration with the WFH.

The potential lack of use of clotting factors concentrates (or intermediates) represents an ethical issue, as well as a financial waste. The allocation of excess products to developing countries, in which access to concentrates is prevented by financial constraints, would allow the Italian Regions to recover their costs, creating a context in which a planned surplus production for humanitarian purposes could be organized. Provided that this surplus is completely neutral from an economic point of view for Italian Regions, it addresses the issue of an ethical and rational utilization of medicinal products manufactured from the gift of millions of Italian donors, by preventing possible waste.

The partnership between CNS and WFH aims to provide recipient countries with medium- to long-term products supply by means of product donation, or the development of ethical, transparent, and sustainable (i.e. cost saving or cost-recovery) options to provide access to not for profit plasma-derived Factor VIII products. With reference to the cost-recovery option, recipient countries could be asked to partially refund the Italian Regions only of the costs associated with product manufacturing. Specifically, each year an agreed amount of the identified total product could be made available. During the first year, products would be delivered as a humanitarian aid donation. Thereafter, products would be progressively made available on a production costs-recovery basis, at prices that would be significantly lower than average market prices. Such an agreement would require a formal commitment, on the part of recipient countries, to establish and implement a long-term national haemophilia care programme.

Will WISH come true? It is a strong commitment to the haemophilia community and a considerable engagement for the Italian blood system.

FABIO CANDURA, GABRIELE CALIZZANI, and GIULIANO GRAZZINI are representatives of the Italian National Blood Centre

Alain Weill, left, World Federation of Hemophilia President, and Gabriele Calizzani, Italian National Blood Centre, at the WFH 2014 World Congress in Melbourne, Australia.
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I became weaker as my stress level escalated. I spent about six agonizing hours in the emergency room, being seen by every neurologist, student, resident, fellow, and nurse. For a 14-year-old girl, the last thing I wanted was to be different. I finally had a spinal tap which confirmed my diagnosis and a couple of days later I had an electromyography (EMG) and nerve conduction test. During my five day hospital stay I received several rounds of IVIG and showed immediate improvement. My life, however, would never be the same.

I continued to have relapses every eight weeks, which changed my original diagnosis to chronic inflammatory demyelinating polyneuropathy (CIDP). In time I became aware of the signs of a relapse such as difficulty gripping a pen, feeling sensitivity in my fingertips, and the prevailing foot drop, before they were observable to anyone else. I finally came to terms with my condition after meeting other people who could relate to me at my first symposium. I was determined to live a healthy life and become more in touch with the connection between my body and mind.

With the practicing of Iyengar Yoga, a healthy diet, and the support of my loving husband and parents, I have not had a relapse in close to five years. I am an Early Intervention Special Education Teacher and the Chair for the Pittsburgh Walk & Roll. Every day I awake with my condition and live the fullest life possible.

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The summer before I turned 14 was one of literal ups and downs. My knees and elbows were scraped and bruised from several falls. The signs that something was wrong were increasing day-by-day. I was dropping things and having difficulty opening bottles. When the scariest moment came; falling off my bike and being unable to stand up, my mother immediately called my pediatrician.

Thankfully, my pediatrician recognized the seriousness of my symptoms and referred me to a pediatric neurologist. Days later, I was getting ready to see Dr. Rajiv Varma but my condition had deteriorated dramatically. My mom had to help me get dressed because I was unable to lift my arms above my head, and earlier that day I had fallen down the stairs. After a lengthy evaluation and many questions, Dr. Varma diagnosed me with Guillain-Barre Syndrome. From there, I was taken by my parents to the emergency room at Children’s Hospital in Pittsburgh.

Kristen Weaver is determined to live a healthy life and “become more in touch with the connection between my body and mind.”

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Living the “FULLEST LIFE POSSIBLE”

BY KRISTEN WEAVER

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Every day, in cities around the world, people are doing amazing things. They’re creating, innovating, adapting, building, imagining. What about a bank? Shouldn’t we be equally ingenious? Strive to match our clients’ vision, passion, innovation? At Citi, we believe that banking must solve problems, grow companies, build communities, change lives.

Citi Prepaid Cards has used our passion and innovation to provide the plasma industry with a secure, easy payment answer for donor compensation. Citi Prepaid remains committed to our clients, just as our clients are committed to helping people live healthier, happier lives through research, therapy and treatment.

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October 11 - 17, 2015

The purpose of International Plasma Awareness Week (IPAW) is:
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On May 22, 2011, Joplin, Mo., was rocked by a catastrophic EF5, multiple-vortex tornado. It is a day forever marked in the minds of Joplin-area residents. Lives were lost, families were disrupted. The town’s BioLife Plasma center was ravaged. Following is a story of how one town’s plasma center employees, in the heartland of the country, responded swiftly with courage and with the help of their colleagues around the country.

Shortly after the tornado passed, every BioLife employee was contacted by the company. Those staffers who were reached by phone first asked about their colleagues and if there was anything that they could do to help. For those needing a hand, assistance was plentiful. The company provided items for those who needed them: food, plastic tubs, laundry detergent, and clothes for the families’ children; as well as helped clear debris, or performed errands for those who lost vehicles.

The day after the tornado hit, even before the gravity of the situation really set in for employees, regional management traveled to Joplin to make sure everything that was needed was available. The damage to the center was assessed and the recovery process began. The company’s leadership team met that day to discuss the situation, including assessing employee status and individuals’ needs. In a matter of days, the company’s support departments put together plans to support the Joplin center team, including providing employees the means to sustain their livelihoods and focusing on getting families and loved ones back on their feet. This included a wide array of tools and services such as grief counseling, tetanus vaccines, and loans for access to cash.
Offers for help came in from BioLife centers all over the country. At company headquarters in Deerfield, Ill., a donation truck was put together to be driven to Joplin. The truck collected so many donations in just two days they had to swap out for a bigger truck and also use an SUV to pack the remainder of the items.

While the center was being rebuilt, employees worked at neighboring Baxter centers. Every morning, Joplin employees met at the center site and traveled by van; some to work in Springfield, Mo., some in Fayetteville, Ark., and some in Broken Arrow, Okla. Other Joplin team members traveled to work at company locations outside of the region.

The company committed to helping the Joplin community to rebuild as well. For example, BioLife organized a fundraiser and raised more than $3,000 from selling T-shirts to purchase trees, which were planted in the areas where the tornado had left the landscape bare.

Additionally, the Baxter Foundation provided $10,000 to the American Red Cross in Joplin.

The newly rebuilt facility began processing donors again on November 2, 2011, less than six months after the devastating tornado crossed its path. To be a part of the Joplin community again and to resume doing what we do best—collecting plasma for those in need—was both gratifying and appreciated for center staff.

LINDA BORDONARO, Senior Marketing Communications Associate, Baxter BioLife

The May 2011 multiple-vortex tornado in Joplin, Mo., shut down the city’s BioLife Plasma Center for nearly six months.
The ongoing Transatlantic Trade and Investment Partnership (TTIP) negotiations provide an important opportunity for the plasma protein therapies industry to challenge regulatory barriers on both sides of the ocean that raise costs, reduce innovation, and ultimately impede patient access to care.

As the global association representing both U.S. and European fractionators of plasma protein therapies, as well as source plasma collectors, PPTA is uniquely well situated to deliver key industry messages to the TTIP negotiators, and will continue to do so as the discussions move forward.

**TTIP BACKGROUND**

The TTIP negotiations benefit from a favorable starting point, as the U.S. and the E.U. are already extremely agreeable trading partners, with an enormous volume of commerce between them. Nevertheless, there is room for improvement. Although formal trade barriers, such as tariffs and import quotas, between the two jurisdictions are few, conflicting regulatory structures, policies, and rules continue to impose costs without corresponding benefits. This is the space in which the TTIP negotiations are intended to have an impact, with the ultimate goal of making trade between the U.S. and the E.U. as seamless as trade within the U.S. and the E.U.

With this goal in mind, a working group was established in 2011 to explore the feasibility of a U.S.-E.U. free trade
agreement. The group recommended that bilateral negotiations commence and TTIP was born. In February 2013, U.S. President Barack Obama and E.U. Commission President José Manuel Barroso announced that TTIP negotiations would begin the following July. Since that time there have been six rounds of negotiations—direct talks between the responsible U.S. and E.U. trade authorities—with the most recent taking place in Brussels on July 14-18, 2014.

The scope of the TTIP negotiations is broad, and encompasses six primary categories of issues: (1) quantitative trade restrictions (e.g., tariffs and import quotas); (2) rules for the conduct of business and commercial activities (e.g., customs and dispute settlement rules); (3) regulatory regimes for industrial products; (4) regulatory regimes for agricultural products, (5) regulatory regimes for services; and (6) regulatory regimes for intellectual property. Of these, the most important for the plasma protein therapies industry is the issue of regulatory regimes for industrial products—specifically, pharmaceutical products, which were identified as a sub-category requiring individual attention early on.

The technical details of how pharmaceutical products will be addressed remain to be determined. It has been suggested that these products should be addressed in a bio-pharmaceutical chapter or annex within TTIP’s overall framework for regulatory convergence. This was the approach taken, for example, in the U.S.-Korea Free Trade Agreement. Regardless of the particular mechanism, it is clear that the issues are daunting, as conflicting U.S and E.U. regulatory regimes continue to be a top tier issue for the pharmaceutical industry. As a starting point, while the U.S. has a single regulator for the pharmaceutical industry—the Food and Drug Administration (FDA)—this is not the case in Europe. Although the European Medicines Agency (EMA) takes a leading role on many issues, substantial responsibilities remain with the regulatory regimes of individual Member States. U.S. and European regulation differs in such fundamental areas as manufacturing processes, active ingredients, and clinical trials. With all of these issues in play, a further concern of the plasma protein therapeutics industry is ensuring that its narrower, sector-specific issues are not overlooked in the discussion of “pharmaceuticals” writ large.

INDUSTRY-SPECIFIC ISSUES

The prioritization of potential issues to be addressed through the TTIP negotiations continues to evolve, but a number of long-standing industry concerns appear to be particularly well suited to resolution, or at least substantial forward progress, through trade discussions.

One such issue is multiple, overlapping, and duplicative inspections of source plasma collection centers. Currently, (plasma collection) centers are subject to inspection by FDA and European Member State inspectors from countries where U.S. plasma is used for further manufacturing. While in most cases these are national inspectors, in Germany the inspections are carried out by Länder (regional) authorities. This does little to improve the quality or safety of the collected plasma, but adds significantly to the cost of collection center operations. The cost of a single visit by a European inspector to a U.S. plasma collection center, for example, is typically in excess of $10,000. With such inspections scheduled every 2-3 years, the costs quickly add up both within individual companies’ center networks and industry-wide. Harmonization of audit checklists and protocols or, even better, mutual recognition of inspections would dramatically improve the situation. These sensible steps would also yield substantial benefits for regulators, who are stretched to carry out their current responsibilities with limited inspections budgets and personnel.

Although formal trade barriers, such as tariffs and import quotas, between the two jurisdictions are few, conflicting regulatory structures, policies, and rules continue to impose costs without corresponding benefits.

A related issue that could usefully be considered simultaneously is development of a regulatory pathway for U.S. acceptance of source plasma collected in Europe. Currently, the issue of duplicative plasma collection center inspections is primarily a U.S. concern for the simple reason that plasma collected in Europe cannot be sold in the U.S. Consequently, there is little need for FDA inspection of European centers. The TTIP discussions provide an important opportunity for these two issues to be considered together, in such a manner that both the U.S. and E.U. negotiating teams could walk away from a compromise with important benefits. Indeed, the TTIP discussions could provide the impetus needed to spur a re-examination of U.S. regulatory policies that, though necessary and appropriate when cases of variant Creutzfeldt-Jakob disease peaked in the United Kingdom 15 years ago, may no longer reflect a careful, science-based assessment of the safety-related risk.

As noted previously, because traditional trade restrictions between the U.S. and the E.U. are already few in number, the TTIP negotiations are focused primarily on so-called “non-tariff barriers.” This potentially provides an opening for the industry to renew its long-standing opposition to national self-sufficiency policies. Although it is increasingly clear that such policies are not in the public interest, they continue to be strongly supported by some European policymakers,
as exemplified most recently by the 2013 Rome Declaration on Achieving Self-Sufficiency in Safe Blood and Blood Products. PPTA and the industry have been consistent in pointing out that national self-sufficiency policies do not reflect current manufacturing practices and economics of scale, cannot satisfy clinical need, and, most importantly, are not supported by patients. The TTIP negotiations provide an opportunity to make the further point that they are often protectionist. In addition to being bad public health policy, these efforts are bad trade policy, and are often rooted in a desire to protect a national plasma collection and/or fractionation monopoly from robust competition on a level playing field.

The issue of differing U.S. and E.U. rules on data privacy is much bigger than plasma protein therapies, or even pharmaceuticals as a whole, but could also be usefully addressed through the TTIP negotiations. Although the protection of personal information, particularly health information, is an important priority, it must be balanced against the competing priority of protecting the public health. The TTIP negotiations provide an important opportunity to strike the correct balance here—a balance that would permit PPTA’s IQPP Standards Program to be truly global, or at least “transatlantic,” in nature. Currently, European data privacy regulations prevent the use of two electronic databases critical to full implementation of the IQPP Program: the National Donor Deferral Registry (NDDR), which ensures the safety of collected source plasma, and the Cross Donation Check System (CDCS), which ensures the safety of plasma donors. Eliminating this regulatory disconnect would deliver immediate benefits to European patients and donors. The prospects for European compromise here are, helpfully, improved by the fact that implementation of a European NDDR—an important public health safeguard—would seem to further bolster the case for U.S. acceptance of European plasma.

**PPTA ENGAGEMENT TO DATE**

On May 21, 2014, in conjunction with the fifth round of TTIP negotiations, a Stakeholder Forum was convened in Arlington, Va. PPTA participated in the discussions pertaining to the pharmaceutical industry and provided an overview of the industry’s priorities in the areas of regulatory harmonization and market access. Due to severe time constraints, the PPTA presentation focused largely on two issues—duplicative inspections of plasma collections centers and protectionist national self-sufficiency policies—but also provided an overview of the industry’s broader TTIP agenda. The presentation was accompanied by submission of a more detailed written statement, which the TTIP negotiators and their staffs have taken under advisement.

PPTA will continue to monitor the TTIP negotiations as they move forward, with the goal of distinguishing the concerns and priorities of the plasma protein therapies industry from those of the broader pharmaceutical sector. In addition to participating in future Stakeholder Forums as they are scheduled, PPTA will engage in targeted outreach to the key U.S. and E.U. negotiators, including officials at the both the Office of the U.S. Trade Representative and the European Commission’s Directorate General for Trade.

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**JOHN DELACOURT, PPTA Vice President, Legal Affairs**
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In the early 1970s, members of the source plasma collection industry first recognized the need for representation through a trade association. These initial discussions resulted in the formation of the American Blood Resources Association (ABRA), the first trade association representing the interests of the for-profit compensated plasma collection sector. As the industry evolved through the 1980s and into the 1990s, the needs for a trade association evolved as well, resulting in the combined efforts of fractionators and collectors and culminating, in 2002, in the formation of the Plasma Protein Therapeutics Association.

The Source Division of PPTA is the direct link to the history of Association involvement, through the lineage of ABRA. ABRA spurred the advent of the International Quality Plasma Program (IQPP), an intense focus on regulatory policy and issues advocacy, and outreach to plasma collection centers, donors, stakeholders, and the public at large.

The PPTA Source Division boasts seven fine staffers who proudly support membership in a variety of areas. Source staff administers the day-to-day of IQPP and related issues. This includes processing of information to confirm compliance with standards; for example, the analysis of viral marker reporting data. It also includes managing a network of six IQPP inspectors, scheduling audits, reviewing audit reports, and answering questions from new centers applying for initial certification. Source staff field questions from members and the general public about the requirements in the IQPP standards. Additionally, Source staff administers the IQPP Standards Committee which oversees development of the standards and the certification program in general. We also engage in the many cross-cutting issues involving plasma collection, including regulatory advocacy in Europe and the United States.

IQPP stands as a central pillar for virtually all of the PPTA Source activities. Built around the goal of voluntary industry improvement that began in the 1990s, the program has been an important—and growing—component of bettering the industry and the way it’s been portrayed. Much of the
NEWs FROM AROUND THE GLOBE

The complexity of the scope of our work continues to increase, as the connections involving a globalized industry become more intricate.

The entire industry’s advocacy activities, including stakeholder outreach, legislative initiatives, regulatory policy, and others are built around IQPP. Work involving the standards is woven into the activities and happenings across the Association, and takes pride of place in the development of educational literature and outreach regarding the industry and plasma donation.

With members on both sides of the Atlantic, and a widespread basis of many issues to manage, PPTA Source staff work with a wide variety of experts and thought leaders from many different countries and in different parts of the Association. On any given day, the PPTA Source Division can be spread across the United States and Europe, with one staff member active on a regulatory issue in the United States, another meeting with patient groups in a different city, another handling a donation education campaign in Europe, and yet another addressing a global issue involving the debate on self-sufficiency and donor compensation. The following is a sample of some of the activities engaged in by the PPTA Source staff:

- Advocacy in Ontario, Canada, opposing legislation banning donor compensation.
- Developing the Cross-Donation Check System in the United States to aid IQPP-certified centers in further protection of the well-being of donors.
- Undertaking a project to rationalize value added tax (VAT) policies in Europe.
- Developing a systematic approach toward discussion of the ethics of compensated plasma donation.
- Responding to media and related inquiries regarding the industry, safety of plasma, and the practice of donor compensation.
- Creating the next phases of International Plasma Awareness Week, celebrated in several different countries and at hundreds of plasma collection centers. In addition, major workshop events were held simultaneously in Berlin and on Capitol Hill in Washington to carry out the mission of further education.
- Finalizing revisions to IQPP standards to address global relevancy.
- Processing and management of industry demographic, viral marker, and related information.

For 2015, the Source Division looks to build on the successes of 2014 and further advocate on behalf of the industry. The complexity of the scope of our work continues to increase, as the connections involving a globalized industry become more intricate. Proposed trade agreements, such as the Trans-Atlantic Trade and Investment Partnership, could have a significant and positive impact on plasma collection and fractionation. Recognition of the needs of patients around the world is a further, critically important matter, understood by the industry as a matter of clinical, medical, and public health priorities. Continued optimization of already-high levels of safety and efficacy within the industry provides an excellent springboard for demonstrating the value of the industry and its vast contribution to high-impact therapies for chronically ill people. The Source team is a powerful resource for members and continues to serve effectively as a fierce advocate on behalf of the industry.

JOSHUA PENROD, PPTA Vice President, Source
The European Plasma Collectors Committee (EPCC) was founded in 2001 to advocate for plasma collection in Europe to foster patients’ access to plasma derived medicinal products. The role of the EPCC is to provide input to European Union (EU) National Regulatory Authorities and policymakers and to improve the landscape for plasma collection in Europe. At the time of its foundation, plasma collection took place predominantly in Germany and Austria. Today, EPCC members are also engaged in the collecting of source plasma for further manufacture in the Czech Republic and Hungary.

The EPCC, led by chair Dr. Stephan Walsemann, is composed of 12 European Source Member companies that operate 87 plasma collection facilities in Germany, Austria, Hungary, and the Czech Republic. In 2013, they collected more than 2.3 million liters of plasma for further manufacture.

In the past months, the committee has focused on a tax project. Members experienced issues with the non-harmonized value-added tax (VAT) system in Germany. Currently, according to some German States, plasma for fractionation is exempted from the VAT, such as blood and blood components for therapeutic use. Together with a tax specialist, a PPTA position paper was drafted with the objective of starting the dialogue with local tax authorities on insisting on the fact that plasma for fractionation is a starting material for industrial use and as such should be applicable to VAT.

In light of a potential review of the current EU Blood Directive 2002/98, PPTA’s European Health Policy Steering Committee invited representatives of the EPCC to participate in different workshops on how to differentiate blood for transfusion and plasma for further manufacturing in order to provide input for a new legislative proposal.

The EPCC’s efforts to be recognized by the European Commission as a stakeholder were rewarded when the committee was formally introduced to that organization. Furthermore, the European Blood Alliance reached out to EPCC representatives to get involved in a project of the European Directorate for the Quality of Medicines & Healthcare.

Due to the difficulties in finding physicians in some areas of Germany, the EPCC supported a project that would allow physicians to delegate some tasks to qualified medical staff. Several outreach activities to politicians made it possible that a draft bill of the Ministry of Health now includes a proposal that should facilitate the assignment of qualified non-medical professions to perform delegated medical services.

This year, the committee will continue to strengthen the role of the EPCC as a stakeholder and to encourage plasma collection in the EU Member States.

Source plasma donation is an important activity that contributes to saving lives. For many with rare diseases, plasma derived medicinal products are the only therapies available to treat these chronic conditions. Unfortunately, diagnosis and treatment is still suboptimal in many EU Member States and many patients have no or limited access to plasma protein therapies. It is therefore important to raise awareness of stakeholders that more plasma for fractionation is needed to mitigate the current limitations.
Revised IQPP Standards

BY SONIA BALBONI

PPTA is proud to announce that several revisions to IQPP standards have been implemented. The revisions are the product of work that began with a special task force engaged to provide input on the global applicability of the voluntary IQPP Standards Program. The work was then continued by the IQPP Standards Committee, and the proposed changes underwent an extensive public review process. The revisions were then presented to the Source Board of Directors for final approval. Over 450 centers in North America and Europe are certified for their compliance to the requirements in the IQPP standards.

“PPTA and its member companies have revised the IQPP voluntary standards to ensure they continue to be meaningful and applicable. With these new changes, adherence to the IQPP Standards Program shows that plasma centers are committed to excellence, to the safety of our donors and to the collection of high-quality plasma worldwide,” remarked Ileana Carlisle, Vice president, Plasma Operations & Logistics, Biotest Pharmaceuticals, chair of the IQPP Standards Committee and a member of the PPTA Source Board of Directors.

IQPP standards help ensure the highest level of quality and safety of human source plasma. IQPP certification is obtained via a rigorous inspection by an independent third party, and through demonstrated compliance with voluntary standards.

The revised standards are:

- IQPP Community-Based Donor Standard, Version 4.0
- IQPP Cross Donation Management Standard, Version 2.0
- IQPP Donor Education Standard, Version 3.0
- IQPP Personnel Education and Training Programs in Plasmapheresis Establishments Standard, Version 4.0
- IQPP Professional Plasma Collection Facility Standard, Version 3.0
- IQPP Qualified Donor Standard, Version 4.0
- IQPP Quality Assurance Standard, Version 4.0

The revisions supersede the previous versions in their entirety.

The Patient Notification System is a free, confidential, 24-hour communication system providing information on plasma-derived and recombinant analog therapy withdrawals and recalls.

The system was created to provide consumers with a single, convenient, and confidential source for up-to-date withdrawal and recall information. Led by the Plasma Protein Therapeutics Association (PPTA), the Patient Notification System was developed by the manufacturers of plasma protein therapies with direct input from consumers.

To make accessing the PNS site easier for users, the Association has developed a QR code which is a machine-readable code and will allow users to scan a barcode with a smart phone and immediately be taken to the PNS website to register.
A New Tool for Industry: The IQPP Cross Donation Check System

BY SONIA BALBONI

PPTA has launched a novel database to assist companies in diminishing the chance of cross donation. The Cross Donation Check System (CDCS) is intended to streamline plasma centers’ implementation of requirements related to cross donation. In particular, the CDCS was commissioned by PPTA’s Source Board of Directors to assist with implementation of the International Quality Plasma Program (IQPP) Cross Donation Management Standard. It was not difficult for the Board to recognize the need for such a system. In some plasma centers, companies had to hire full-time staff just to manage the paperwork involved with conducting donor checks in accordance with the IQPP standard. Yet the Board considered the standard, implemented in 2010, so valuable in protecting donor health that there was no question of diminishing the donor check requirements. “Conducting checks in accordance with the Cross Donation Management Standard is a vital component of a company’s process for taking care of our donors,” stated Larry Moss (The Interstate Companies and member, Source Board of Directors). Thus entered the CDCS.

Through the CDCS, center personnel can enter basic information about a potential donor into an online database. The CDCS then conducts a query; if the individual’s information matches information in the database, the CDCS will reply that a potential match was found. The response time for queries is only three seconds. This significantly frees up time for center staff, which they can now use to conduct other essential duties. Mike Taormina (Biotest Pharmaceuticals Corporation) is a member of the PPTA Information Technology Task Force (ITTF) which worked on developing the requirements for the System. He observes, “Everyone involved has been excited to see the end result: quick, paperless checks for potential cross donations. The plasma industry has a new tool to further ensure donor safety.”

After the Board called for the CDCS, PPTA conducted a bidding process, and the Board selected Haemonetics to develop and implement the system. Haemonetics began its work in Fall 2013, and the CDCS went live this February. The CDCS is unique because, unlike most plasma company information technology (IT) products, the system had to be designed to meet the needs of many companies, each with different business practices, operational styles, and technological capabilities. It could be accurate to say that the CDCS was developed “by committee.” The ITTF designed the technical requirements for the CDCS and provided the technological expertise for staff to work with Haemonetics on the development, design and implementation phases. Then the PPTA IQPP Standards Committee reviewed the requirements from an operational perspective.

The layers of approval for the design and development process were a hurdle, but the ITTF was not daunted. Initially there was a lot of back and forth among members of the ITTF.
“We value plasma donors for their contributions toward saving patients’ lives. It is important that industry has this new tool to further ensure that the donor experience goes smoothly and safely.”

— Randy Furby, CSL Plasma and Member, Source Board of Directors.

1 Cross Donation is a donation pattern in which a donor exceeds the maximum allowable donation frequency by donating at more than one plasma center. (See the IQPP Cross Donation Management Standard, v2.0.)

2 The seven-day increments are related to regulatory requirements for cross donation.

SONIA BALBONI, PPTA Senior Manager, Source & Standards

While at the beginning there was much discussion among the ITTF on the CDCS requirements, the group was able to quickly come to agreement and resolve issues. Once the specifications were agreed to and Haemonetics identified as the vendor, the ITTF held periodic teleconferences to review the requirements and tweak where necessary.

The IQPP Standards Committee was fortunate to be able to rely on the expertise of the individuals on the ITTF for the development of the system. In addition to their technical knowledge, these industry veterans each held an in-depth knowledge of the plasma collection business, and showed great facility in understanding their own companies’ procedures for managing the donor intake process. Some of the task force members got their start on the donor floor, or had previously worked in operations or as center managers. This enabled the ITTF members to quickly identify a potential pitfall in the CDCS design, and address it before it became a problem for the plasma collection process. In turn, the staff at Haemonetics really understood the business, which made dialogue with the task force that much more meaningful.

Once the CDCS was developed and designed, a beta test was conducted at the CSL Plasma and Biotest Pharmaceuticals centers in San Antonio. This allowed the team to work out any kinks in the system. Following a successful beta test, the system was submitted to the Food and Drug Administration (FDA) and cleared for use. Then future users were given access to a special validation site, where they and center staff could familiarize themselves with the CDCS environment, and adapt their company processes as needed. Finally, the CDCS underwent a trial period in the live environment, with about 50 centers participating. The trial period allowed users to really get a feel for how things would be when all 425-plus centers began participating.

At last, when members were comfortable that the CDCS was ready for the big time, the System went “live” on February 2.
The Grifols Academy of Plasmapheresis

The Grifols Academy of Plasmapheresis (Academy) is a training resource designed to give its plasma donor center employees access to quality educational training opportunities and career development. Academy courses cover specific medical fields, GMP, operations, quality systems, and the development of other skills for solid leadership.

In January, Grifols announced that the Academy is the recipient of accreditation from the Accrediting Council for Continuing Education and Training, a nationally-recognized authority on quality continuing education or training programs.

Grifols established the Academy in 2009 in order to provide employees with technical skills and scientific knowledge on the plasma management process dedicated to continuous improvement through lifelong learning and innovation. The new accreditation ensures employee participants will receive continuing education units (CEU) that can be used to meet the requirements of their specialized professional licenses and certifications.

“Receiving ACCET accreditation has been a long-term goal of the Academy, and to achieve this is a testament to Grifols’ dedication to ensuring quality education programs for our employees,” said Beth Eacret, Academy director. “Additionally, this accreditation will bring much deserved national recognition to the Grifols Academy in the specialized field of human plasma science.”

Since the Academy’s inauguration, more than 4,000 participants have benefited from training opportunities at campuses in Arizona, Indiana, and satellite sites; more than 5,000 participants have utilized on-line self-study classes. In 1998, ACCET became the only recognized accrediting agency to be certified as an ISO 9001:2008-Quality Management System, under the international standards established by the International Organization for Standardization.

Grifols will continue to encourage employee education and development as a strategical asset and is expected to extend these programs in the future outside of the company to offer knowledge forums to patients, scientific and medical communities in plasma industry.
# Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ABRA</td>
<td>AMERICAN BLOOD RESOURCES ASSOCIATION</td>
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<td>CDCS</td>
<td>CROSS DONATION CHECK SYSTEM</td>
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<tr>
<td>CEU</td>
<td>CONTINUING EDUCATION UNITS</td>
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<tr>
<td>CIDP</td>
<td>CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY</td>
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<td>CNS</td>
<td>ITALIAN NATIONAL BLOOD CENTRE</td>
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<td>EAPPI</td>
<td>EUROPEAN ASSOCIATION OF THE PLASMA PRODUCTS INDUSTRIES</td>
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<td>EBA</td>
<td>EUROPEAN BLOOD ALLIANCE</td>
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<td>EBOV</td>
<td>EBOLA VIRUS</td>
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<tr>
<td>EC</td>
<td>EUROPEAN COMMISSION</td>
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<td>EDQM</td>
<td>EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES &amp; HEALTHCARE</td>
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<td>EHC</td>
<td>EUROPEAN HAEMOPHILIA CONSORTIUM</td>
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<td>ELPA</td>
<td>EUROPEAN LIVER PATIENTS ASSOCIATION</td>
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<td>EMA</td>
<td>EUROPEAN MEDICINES AGENCY</td>
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<td>EMG</td>
<td>ELECTROMYOGRAPHY</td>
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<td>EPCC</td>
<td>EUROPEAN PLASMA COLLECTORS COMMITTEE</td>
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<td>FDA</td>
<td>FOOD AND DRUG ADMINISTRATION</td>
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<td>HAV</td>
<td>HEPATITIS A VIRUS</td>
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<td>HEV</td>
<td>HEPATITIS E VIRUS</td>
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<tr>
<td>HPSC</td>
<td>HEALTH POLICY STEERING COMMITTEE</td>
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<td>JSC</td>
<td>JOINT STEERING COMMITTEE</td>
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<tr>
<td>INBS</td>
<td>ITALIAN NATIONAL BLOOD SYSTEM</td>
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<td>IPAW</td>
<td>INTERNATIONAL PLASMA AWARENESS WEEK</td>
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<td>IPOPI</td>
<td>INTERNATIONAL PATIENT ORGANISATION FOR PRIMARY IMMUNODEFICIENCIES</td>
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<td>IPPC</td>
<td>INTERNATIONAL PLASMA PROTEIN CONGRESS</td>
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<td>IT</td>
<td>INFORMATION TECHNOLOGY</td>
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<td>ITTF</td>
<td>INFORMATION TECHNOLOGY TASK FORCE</td>
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<tr>
<td>IQPP</td>
<td>INTERNATIONAL QUALITY PLASMA PROGRAM</td>
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<td>NAT</td>
<td>NUCLEIC ACID TEST</td>
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<tr>
<td>NDDR</td>
<td>NATIONAL DONOR DEFERRAL REGISTRY</td>
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<td>NRA</td>
<td>NATIONAL REGULATORY AUTHORITY</td>
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<td>PDMP</td>
<td>PLASMA-DERIVED MEDICINAL PRODUCT</td>
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<td>PPTA</td>
<td>PLASMA PROTEIN THERAPEUTICS ASSOCIATION</td>
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<tr>
<td>PSSC</td>
<td>PATHOGEN SAFETY STEERING COMMITTEE</td>
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<td>TTIP</td>
<td>TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP</td>
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<td>UNICEF</td>
<td>UNITED NATIONS CHILDREN’S FUND</td>
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<td>VAT</td>
<td>VALUE-ADDED TAX</td>
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<td>VNRED</td>
<td>VOLUNTARY NON-REMUNERATED DONOR</td>
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<td>WFH</td>
<td>WORLD FEDERATION OF HEMOPHILIA</td>
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<tr>
<td>WHO</td>
<td>WORLD HEALTH ORGANIZATION</td>
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Upcoming Events

March

22–25  41st Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT)
       Istanbul, Turkey

26–28  Hemophilia Federation of America (HFA) Symposium
       St. Louis, Missouri

June

11–14  20th Congress of European Hematology Association (EHA)
       Vienna, Austria

16–17  PPTA Plasma Protein Forum
       Washington, DC

25–27  Immune Deficiency Foundation (IDF) 2015 National Conference
       New Orleans, Louisiana

27–July 1  25th Regional Congress of the International Society of Blood Transfusion (ISBT)
           London, England, UK

September

1–3    4th Annual Bioplasma World Asia 2015
       Shanghai, China

October

11–17  International Plasma Awareness Week (IPAW)

24–27  Annual Meeting of the American Association of Blood Banks (AABB)
       Anaheim, California

25    PPTA Business Forum
       Anaheim, California

November

5–6    International Primary Immunodeficiencies Congress (IPIC)
       Budapest, Hungary
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