Global Access Challenges

Global Access to Care in Times of Austerity

If Only My Mother Had Known About Primary Immunodeficiencies

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In the interest of encouraging broad and open discussion of issues relating to plasma protein therapies, collection and fractionation, the Source magazine may contain statements of opinion on such issues. These statements are those of the author and do not necessarily reflect the opinion of PPTA or its members. ©Plasma Protein Therapeutics Association 2014

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CLARIFICATION:
The Transatlantic Trade and Investment Partnership article in the Spring issue of The Source contained on page 17 the sentence “Currently, [plasma collection] centers are subject to inspection by both FDA and EMA, and may be subjected to a third inspection by German national authorities as well.”

That statement should read as follows: Currently (plasma collection) centers are subject to inspection by FDA and European Member State inspectors from countries where US 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.
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We have come a long way! I remember the days when there was a worldwide shortage of immune globulins that generated an enormous amount of media and government attention in the United States. Within weeks after arriving in the U.S., I had the “pleasure” of being interviewed by “60 Minutes”, and in the same year I was an industry witness at two Congressional hearings. I can assure you that this was an experience that I will never forget!

But we all learned many lessons from this. One of the biggest ones is to never forget that we are here to help ensure that patients in need of life-saving therapies have unlimited access to them. Another one is to provide patients with useful information on product access to help them make informed decisions about the medical options.

Only two years after the IVIG problems we had to deal with a worldwide shortage of recombinant Factor VIII. The persons with hemophilia made it very clear that it was better to have information about product access, even it was bad news, than to have no news at all.

In response to the questions raised by users, physicians, patients, regulators, policymakers, and media, we developed, then continuously improved and updated over the next decade, PPTA's North American Data Program. One of the key strengths of this program is its flexibility. For example, during the shortage of recombinant Factor VIII we were able shift quickly to bi-weekly reporting until the crisis passed. The flexibility to address future emergencies is still there.

We have experienced that our system is extremely helpful in times of shortage, but even more valuable when there are rumors about shortages. Sometimes you don’t know where the rumors originate, but they happen all the time. Very unfortunate but it is a part of life. A reliable data system helps to refute rumors and provide factual information in times when unnecessary concerns arise.

We have been able to develop this system first in the United States and all manufacturers, members and non-members, participate. I would like to thank all companies for so diligently providing the necessary data to the third party that collects the data. The third party is necessary because it provides assurance that all data are treated confidentially. The PPTA staff, for example, has no access to company-specific data, and like other stakeholders, only see the aggregate that is available on our website.

We have introduced the same methodology in some European countries. In some countries this is not possible since there are several not-for-profit companies not providing data (yet). We have requested these companies to participate so that we can accomplish the same level of shortage preparedness in different parts of the world.

The current product access situation cannot be compared to what we experienced some 15 years ago. New manufacturing sites have been built, new recombinant suites have opened. Compared to those years, the annual distribution of immune globulins has quadrupled, recombinant Factor VIII has tripled, and plasma-derived Factor VIII and albumin have doubled. All good news because it means that more patients can be treated!

However, there is no room for complacency. If there is an actual shortage, or substantial patient and provider concern regarding a potential shortage, in even one country for whatever reason, everyone needs to know what the facts are. If we work together we can do something about it. I call for the non-participating European companies to accept our invitation!

Jan M. Bult, President & CEO
Two major forces are pulling at opposite ends while, in the middle, patient access to life saving plasma protein therapies is being jeopardized. This situation I just described isn’t happening in one or just a handful of countries; it’s happening all around the world. The tension between unmet patient need and access to plasma protein therapies is evident in many countries. Most countries are just starting to emerge from a global recession.

Under guidance and support from the PPTA Global Board of Directors, the Association evaluated its activities and is expanding its focus on patient access to care in order to have a more global reach. Countries all over the world are experiencing budget austerity and are being forced to make reductions in expenditures. Often times, decision makers, rightly or wrongly, look to metrics to guide them in their cost-cutting endeavors and more often than not, plasma protein therapies are in the top 20 of most expensive drugs administered.

As part of its newly-expanded international focus, PPTA recently delved into patient access to care issues in Poland, Romania, Ecuador, and Columbia. No doubt there will be additional countries that require our attention and in these initial three countries, PPTA has developed the capacity to respond and open the doors to dialogue with the policymakers in countries where access to essential plasma protein therapies is at risk. The following is a brief glimpse of our recent forays in Poland, Romania, Ecuador, and Columbia:

**POLAND**

PPTA became aware that the Ministry of Health (MOH) considered all immunoglobulins (IG) to be equivalent medicinal products, based on the definition in the country’s Reimbursement Act of 2011. Through this, Poland applies a reimbursement mechanism that is similar to the classical way in which many European governments address pricing for generic pharmaceutical drugs. In Poland, any new immunoglobulin therapy introduced to market is treated as if it were a generic to the first immunoglobulin that was marketed in country, without considering the inherent differences in these lifesaving therapies. This translates to a 25 percent decrease in reimbursement levels for any immunoglobulin (both subcutaneous and intravenous) that was not first in market.

PPTA worked with members in Europe and communicated to the Polish MOH the potentially adverse consequences of Poland’s pricing mechanism to patients’ access to care using immunoglobulins. In its letter, PPTA stressed that each
immunoglobulin product is a complex biological with its own unique final formulations, and that individual patients do not tolerate all immunoglobulins uniquely. PPTA’s action opened a dialogue for further discussion with patients, manufacturers, and the government concerning patient needs in the country.

ROMANIA
Romania is another example of a country experiencing budget issues. The government has installed a clawback tax on all pharmaceuticals to finance parts of the health budget deficit. The clawback tax currently amounts to approximately 26 percent of the offset sales and is regularly increased. PPTA is in the process of gathering information regarding the impact on plasma protein therapeutics and will evaluate ways to address the issue with key governmental decision makers.

ECUADOR
In a meeting on January 23, 2015, the National Board for Review and Establishment of Prices for Medicines for Human Consumption approved ceiling prices for medicines which were established in accordance with the provisions of Executive Order No. 400, “Regulation for the Establishment of Pricing for Medicines for Human Use and Consumption.” The ceiling prices were approximately 30 percent lower than the previous prices.

PPTA prepared a communication addressing industry’s concerns and presented it to the Minister of Health. The International Patient Organisation for Primary Immunodeficiencies (IPOPI) reacted to the threat to patient access and also submitted a letter to officials. IPOPI stressed the importance that PID patients have access to the widest range of IG therapies as possible.

COLOMBIA
This January the Colombian MOH proposed across the board reductions in reimbursement for strategic medicines. PPTA and other organizations engaged in opposition to the proposed reduction. PPTA sent a letter to officials in country explaining the potential detriment patient access to plasma protein therapies. The outcome was successful; our latest intelligence indicates that intravenous immunoglobulin (IVIG) is excluded from the reduction.

PPTA will continue to engage in countries around the world where access to plasma protein therapies is threatened. The Association is in the process of developing analytical tools to assist us in making strategic decisions. We will work in tandem with our member companies to identify countries where we can make a difference on behalf of patient access.

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Immunodeficiencies (IPOPI) reacted to the threat to patient access and also submitted a letter to officials. IPOPI stressed the importance that PID patients have access to the widest range of IG therapies as possible.

JULIE BIRKOFER, PPTA Senior Vice President, North America
Health Technology Assessments (HTA) measure the medical, economic, social, and ethical implications concerning the use of new health technologies.\(^1\) HTA has been described as a science-based art, with health policy representing the science and the patient perspective representing art.\(^2\) The current changes in the way HTA balances these two sides when making an access decision for a new technology was discussed in the access to care session during the 2015 International Plasma Protein Congress.

**Access, balancing the SCIENCE WITH THE ART**

**BY NICK HICKS**

**DR. FRANÇOIS MEYER, HAUTE AUTORITÉ DE SANTÉ (HAS)**

Health Technology Assessment, Early Dialogues (ED) and Adaptive Pathways

Ongoing collaboration between the European Medicines Agency (EMA) and HTA authorities will prompt earlier dialogues with key stakeholders and allow companies to make early changes in a technology’s development. This should increase standards in assessment, improve quality and data appropriateness as well as reduce current work duplication. Pathway harmonization proposed under the EUnetHTA\(^3\) Core Model means that previously centralized EMA activities are combined with criteria that were previously under local HTA responsibility. For example, full health economic analysis would be undertaken at the local level without repeating the clinical evaluation previously performed.

Following successful ED pilots, the European Commission (EC) has given HAS additional funding under the SEED initiative (Shaping European Early Dialogues) to coordinate 10 EDs amongst 14 national/regional HTA partners. The main areas of assessment include: patient population, trial design, endpoints, and statistical analysis. SEED’s aim is to create a harmonized methodology which allows a new technology to be assessed with appropriate patient-relevant clinical endpoints. The EMA, payers, and selected patient group representatives act as observers.
“The aim of adaptive licensing (AL) is timely access for patients to treatments that promise to address serious conditions where there is unmet medical need.”

— Dr. François Meyer

“Within each ED. A report with recommendations will be delivered to the EC by the end of 2015.

In addition to structural changes, new developments in pathway design—the A scientific process used to describe and analyse the properties of a health technology—are underway.

“The aim of adaptive licensing (AL) is timely access for patients to treatments that promise to address serious conditions where there is unmet medical need. AL has the potential to overcome the current dilemma seen with promising new drugs which are often refused access because their longer economic benefit has not been sufficiently proven at time of launch,” said Dr. Meyer.

Considering that treatment populations are often fragmented, AL is a form of progressive licensing reflecting the growing patient demand for timely access to innovative therapies. New treatments are given an initial license based on a smaller amount of data from a well-defined population. When cost benefit, efficacy, and safety have been established, the treatment then transitions to a full license. All decision-makers who determine access are involved in the current set of pilots being undertaken: HTA bodies, medical associations & patient groups. There is an increased influence of payers but the AL approach should improve sustainability of industry investment.

“A healthy society is a strong economic society. The current systems must change to ensure a win–win for all stakeholders...”

— Professor Lieven Annemans

Proposed Harmonisation of EMA and HTA

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Chart courtesy of Prof. Annemans, University of Gent
PROFESSOR LIEVEN ANNEMANS, UNIVERISITY OF GENT

Usage of HTA Studies in the Market Access Landscape

HTA processes vary from country to country as national governments attempt to best serve the public health and economic interests of their populations; unfortunately such variation can create inconsistencies in access to certain medicines for patients because key selection criteria are viewed differently by country, e.g. the QALY (Quality Adjusted Life Years) measurement is well accepted by National Institute for Health and Care Excellence but not by Institute for Quality and Efficiency in Health Care (IQWiG). Though attempts are being made to create HTA harmonization, through the International Network of Agencies for Health Technology Assessment4, serious differences still remain in key areas.

The approval of new medicines has traditionally followed a linear path, with HTA following after regulatory involvement. At the HTA and payer side, the present pathways for obtaining price and reimbursement are not always transparent, nor do they allow engagement with all stakeholders. Moreover, sub optimal data sharing is often seen. Finally there is still a lot of “cost myopia” observed among payers, whereby budget impact is the main criterion rather than value for money. Solutions will require a fundamental change at organizational levels between regulators and assessors and the industry viewpoint should also be considered.

“A healthy society is a strong economic society. The current systems must change to ensure a win–win for all stakeholders, the industry being financially recognized for innovative treatments which maximize the patients’ health whilst recognising the limits of what is socially acceptable in terms of cost and priorities,” said Prof. Annemans.

Changes include: (i) earlier assessment for a treatment’s likely cost benefit in a specific population based on its Target Product Profile5, (ii) harmonisation of the present roles of the regulator and the HTA bodies/payers when evaluating the different criteria that matter for market access (see diagram) and (iii) more effective post marketing surveillance increasing the need for registries. Patient groups will take on a more active role in registry development by providing the unique patient insight earlier in the development and assessment process.

PROFESSOR ALBERT FARRUGIA, UNIVERSITY OF WESTERN AUSTRALIA

HTA and Market Approval: Should The Twain Ever Meet?

Rather than efficiencies, a closer alignment of market authorization and HTA will not be good for patients or wider society. Bringing the two processes together to share common elements will not increase timely access to treatments. The lenses used by HTA and the regulators are different; the regulators’ lens is of efficacy and safety while HTA views clinical effectiveness and cost effectiveness. Depending on the lens, different decisions can be drawn from the same evidence.

“The convergence between Marketing Authorization and HTA could be seen to be driven by financial expediency and bureaucratic inefficiency, potentially resulting in conflict of interest and role confusion. Furthermore, the danger of the ascendancy of HTA bodies into the clinical space is influencing the design of clinical trials that might not be always in the patient’s best interest.” said Prof. Farrugia.

The N-of-1 clinical trial is the most robust future investigative methodology, with a patient receiving alternately the experimental treatment and the comparator (placebo or treatment). The ultimate goal of an N-of-1 trial is to determine the optimal or best intervention for an individual patient using objective data-driven criteria. Yet differences between regulators and HTA bodies must be overcome before such approaches are used. The EMA views the N-of-1 trial in appropriate diseases favourably, a view not all together shared by IQWiG for example.

CONCLUSION

Ensuring patients’ timely access to safe, innovative quality treatment lies at the very heart of current health policies. Fundamental changes in the way potential new treatments are assessed at the European and national levels are bringing in new ways of working for balancing the science with the art. Whether such changes will work remains to be seen.

NICK HICKS, Director of Commutateur Advocacy Communications

References

3 http://www.eunethta.eu/outputs/methodological-guideline-reapharmaclinical-endpoints
4 http://www.inahta.org/ accessed 31 march 2015
5 TPP is a document that the industry uses to ensure that a potential new medicine meets key scientific, medical and technical information and so guides its development to meet regulatory and assessor requirements.
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I was born into an inland shipping family in Holland and lived on a working barge until I was 8. One morning when I was about 3, I was not able to stand. At the time there was an outbreak of polio and although I believe I was vaccinated, it turned out that I had indeed contracted polio and for the next four years had to wear steel calipers and very tight, high boots. I do believe that this is not uncommon for a person with a primary immune deficiency (PID) and the virus apparently remains in the body, which sometimes can flare up again in later years.

At about 6, I started to suffer quite badly from cystitis, but as I was living on the barge, which at that time was on the River Rhine in Germany, it was not always easy to get medical help very quickly. I had to wait until we were back in Holland before I was taken to a doctor, who recommended that I should stay in hospital for a kidney rinsing. As you can imagine, being a small child and having to stay in hospital and undergo a very painful procedure was not all a positive experience. I remember crying a lot. In those days there certainly was no understanding or willingness to accommodate the wishes of the parent or the child; even the visiting hours were very limited. I could not wait to get out of there, and eventually was discharged after 10 days, only to wake up the following morning with a severe case of chicken pox. I was so afraid that I would have to go back into hospital! Thank goodness I do not remember much about this, only that my mother told me much later that the doctor was afraid that since the chicken pox were in my eyes it could have resulted in blindness.

At 8, I was sent to a special school for children who live on a barge—called a Schipperschool in Dutch. I was no longer wearing the leg braces; otherwise it would have been even
more difficult to cope with the curriculum, and of course, living on land for the first time in my life. The first health problems to appear were the most horrendous boils at the back of my knees. As soon as one healed another appeared. It was called Hong Kong flu at the time and I had to stay in bed for weeks. The coughing started around this time and occasionally diarrhea. At the same time, my mother was showing very similar symptoms and was diagnosed with bronchitis and losing a lot of weight, but no one thought that we could be having the same condition. I presume my mother was actually suffering from malabsorption. Years later, when I was visiting a gastroenterologist for months on end to find out why I was always suffering from diarrhea—never getting a definitive diagnosis despite numerous procedures to examine the intestines and bowel—I began to despair. At the same time, my lungs were causing a major problem too, and so I underwent many X-rays and scans, and tried multiple antibiotics. Because the coughing was so bad that it kept me awake at night, I turned to an over-the-counter product—an expectorant, which I drank by the bottle each night, not to be recommended! A few years earlier, my mother had suffered a thrombotic embolism. I was with her when this happened so when the same thing happened to me I was not really frightened because I knew what it was. I was given months of warfarin and heparin medication. Years of continued ill health continued until I ended up in hospital for about 3-4 weeks with pneumonia; first in one lung, then in the other. A friend suggested I was immunodeficient and suggested that I ask for an antibody test. Well, would you believe it, three days later the results were back, and within no time I started intravenous immunoglobulin. To finally be told that you are suffering from a chronic condition which will not go away and that you will have to be on this therapy for the rest of your life, is quite a shock. Then questions come into your head: What will happen if there is a problem with the plasma supply? Have my children inherited this? Will I be able to live a normal life? How long will I live? Will it affect my work? Will I be able to travel? What about life insurance? The questions are endless.

I am happy to say that after just three months of receiving this miracle treatment, I felt so much better. I joined the national patient organization in the UK and learned so much from other patients and the parents of patients that I felt compelled to become involved. David Watters, at the time chief executive of IPOPI (International Patient Organisation for Primary Immunodeficiencies), became my tutor in all PID-related matters. When he asked if I would be interested in joining IPOPI, I did not hesitate. He introduced me into a world that is still inspiring me every day with its quest to ensure that as many patients as possible are diagnosed, and of course, most importantly, have access to safe, effective and affordable treatments. I would like to think that I can show patients that you can do everything you want to do, despite having a primary immunodeficiency.

Eleven years later, I continue to work very closely with IPOPI’s dedicated board members, Johan Prevot, IPOPI executive director, and his staff. Together we are making a difference. There are many more established patient organizations across the world, which in itself means more
Economic pressures and conflicts have put our patients and their health care professionals at additional risk. The need for collecting data on patients’ health, quality of life, burden of the disease, and type of treatment is greater than ever.

patients are diagnosed and treated. None of this would be possible without the dedication of those incredible immunologists, other specialists, and nurses. IPOPI works very closely with all stakeholders in the PID community.

During the last decade IPOPI has changed and I feel very privileged to have been part of this transformation. So much has been done but there is still so much more that needs to be done. In certain countries of the world, patients still have to pay for their own Ig therapy—and that’s if they are fortunate enough to be able to pay or to acquire the products at all. Access to clinics and expertise is not easy, even in countries where one would expect these services to be in place. Economic pressures and conflicts have put our patients and their health care professionals at additional risk. The need for collecting data on patients’ health, quality of life, burden of the disease, and type of treatment is greater than ever. Some of us are fortunate to have a choice of treatment while others are still struggling to have any treatment at all. As patients we are ultimately looking for a cure and with the development of Bone Marrow Transplant (BMT) and gene therapy, this has been made possible for some patients. One of my future hopes is to have a BMT facility in every country.

Working together with other plasma user organizations has given our patients a better platform for advocacy and access to the political arena where decisions are made affecting the availability of this rare but most valuable medicine: human plasma. Meetings have taken place in the EU Parliament and the World Health Organization. Collaborative action can be very powerful and we as patients have to be vigilant as to what is happening to the whole issue of blood/plasma collection so that decisive action can be swiftly taken.

The recently published Principle of Care document will give patient organisations and their immunologists an opportunity to advocate for this “gold standard of treatment” in their countries. This was made possible because so many international experts contributed to this paper and Professor Helen Chapel for ensuring publication. There will be many discussions regarding this document, especially at IPOPI’s 2nd International Primary Immunodeficiencies Congress Nov. 5-6 in Budapest, with a focus on Clinical Care and Diagnosis.

I could continue writing about all the needs in the different countries, the problems experienced, the enthusiasm of the patients, but the one thing that unites us all is the Health, Quality of Life and Treatment availability for our patients.

Just one final word. My mother died when she was 53-years-old...before I was diagnosed. We will never know if she also had a PID.

JOSE DRABWELL, President, IPOPI
1989 was a pivotal year for John Walsh and his family. That was the year that he and his twin brother, Fred, found out there was a name for the symptoms—infections, shortness of breath—that had plagued them for the previous five years.

“I’ll never forget it,” said John. “Fred called me and said, ‘I’ve got good news and I’ve got bad news.’ ”

“Give me the good news,” he recalled saying. “He told me, ‘The good news is we have a genetic condition: Alpha-1 Antitrypsin.’ ”

“The bad news is that this is what mom had.’ ”

Alpha-1 has had a significant impact on the Walsh family. In addition to John and Fred, they have a sister who is an Alpha and another who is a carrier. When they were 13, they lost their 46-year-old mother to the condition.

As president and chief executive officer of the Alpha-1 Foundation, John Walsh has dedicated the last 20 years to advocating on behalf of others living with the condition and finding a cure. Today the Alpha-1 Foundation has invested $54 million to support Alpha-1 Antitrypsin Deficiency research and programs at 100 institutions in North America, Europe, the Middle East, and Australia. Additionally, the Foundation works with the National Institutes of Health, Food and Drug Administration, and industry to expedite the development of improved therapies. Along the way, Walsh, who is also a cofounder of the organization, says the relationships he has made along the way have given him a second family because, “once you meet another Alpha, you realize you’re not alone.”
What was life like before your diagnosis?
Life before was exciting. I’d just returned from eight years in Saudi Arabia and was opening a business. My life changed when I was diagnosed because I realized I had to take some responsibility and become involved. At the time, the only research being conducted was a National Institutes of Health (NIH) longitudinal disease progression study as a Phase 4 requirement with market surveillance requirement for the introduction of the first orphan drug for Alpha 1 and augmentation therapy.

The Alpha-1 Foundation evolved from the support groups that were formed at the NIH registry study sites. The support groups connected with each other and created the Alpha-1 Association in 1991, focusing on patient advocacy, support, and education. When the National Heart Lung and Blood Institute (NHLBI) announced that the longitudinal study was ending in 1994 and there would no further research on Alpha-1, we took the responsibility to found the Alpha-1 Foundation. (Walsh, along with Susan Stanley and Sandy Lindsey, created the foundation with endorsement from the Alpha-1 Association. The two organizations later merged in 2014.)

What are some things the Alpha-1 Foundation does?
We created AlphaNet, a not-for-profit organization focused on developing and implementing a comprehensive health management program and developing a recurring source of revenue to support the research mission of the Foundation. AlphaNet expanded its role to include development of patient health management tools, creating a culture of adherence to medications and participation in clinical research.

From an educational standpoint, the reference materials created by the Foundation and AlphaNet have been translated into nine languages and made available to the Alpha-1 Global community. The Foundation has created the largest national registry in the world of individuals with Alpha-1, the largest repository of DNA and tissue available to the international research community and continues to expand the Clinical Resource Center Network with more than 80 Centers across the country.

What research has you most excited?
We’re very proud that we’ve funded research that has resulted in therapeutic development in the biotech industry with specific targets being explored now. We’re starting clinical trials in some liver disease therapies for Alpha-1 that are the direct result of funding we did in 1998-99. It’s clear that one of the big accomplishments of the Foundation is to keep and expand the research community focused on Alpha-1. Because we have a registry, they can recruit for a clinical trial within 6-10 weeks and we have a strong advocacy platform in Washington D.C. working with not only Congress and Centers for Medicare and Medicaid Services on access issues, but the Food and Drug Administration (FDA) on regulatory issues and NIH on research. We’ve really been able to make progress on getting more therapies approved, particularly augmentation therapy where we previously had a shortage and now there’s an adequate supply. For liver disease in Alpha-1, there is also a gene therapy in development and we’re hoping we can get an aerosol delivery of augmentation therapy within five years.

According to the Alpha-1 Foundation, the average lifespan of an Alpha-1 patient used to be 54. You’re 66. How is your health?
I’ve been on augmentation therapy since 1993 and I’ve never smoked. I saw how my mom suffered—she didn’t smoke but she needed supplemental oxygen just to breathe—and was an incredible inspiration to us. We didn’t want our families to go through what we went through. So, I never smoked and I didn’t have a lot of environmental exposures. Today, I have about 34 percent of normal lung function and I have to use oxygen when I fly, sleep, and when I exercise but I don’t need it daily. It’s very clear that the combination of comprehensive health management and augmentation therapy has had a significant impact on our quality of life and longevity.

What are the organizations biggest challenges going forward?
Access is a huge concern. The challenge by the Office of the Inspector General—of the validity of patient assistance programs, is appalling and frightening. A lot of individuals can’t afford their copays and in some cases, can’t afford their premiums. To ignore people that need help is—in my view—criminal and we’ve got a huge battle in front of us and we’re working closely with them. So our main advocacy concern remains access. We also remain focused on making sure the FDA continues to recognize rare diseases are different from chronic conditions and the importance of having more flexible clinical trial designs and more flexible biomarker guidelines because of the size of our community.

JOHN WALSH, President and CEO of the Alpha-1 Foundation
This year marks the 20th anniversary of the European Medicines Agency (EMA). The EMA is an agency of the European Union (EU) located in London. The EU was established following World War II to bring together the individual countries of Europe under a legal structure to promote a “peaceful, united and prosperous Europe.”¹ The EMA is one of the agencies that carry out technical, scientific or managerial tasks that help the EU institutions make and implement policies. Specifically, the EMA is responsible for the scientific evaluation of applications for European marketing authorization for medicinal products submitted for approval under what is called a “centralized procedure.”²

The centralized procedure is one way of seeking marketing authorization in Europe, and certain medicinal products (e.g., those that are biotechnologically derived and ones that are designated as orphan medicines) must follow the centralized procedure. The other ways to gain marketing authorization in Europe are “national” (one member state) and “mutual recognition”/“decentralized” (at least two member states). Under the centralized procedure, companies submit one single marketing authorization to the EMA to allow marketing of the approved medicinal product throughout Europe.

The EMA was established in 1995. As the EU has grown in scope of authority and membership, the EMA has also grown in terms of its responsibilities. It now has a 20-year track record of ensuring the efficacy and safety of medicines for humans and animals across Europe, and promoting research and innovation. Today, seven EMA scientific committees and

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¹ The Source, Summer 2015

² The Source, Summer 2015
more than 30 working parties provide scientific expertise for the regulation of medicines by drawing on a pool of several thousand European scientific experts.3

The regulation of plasma protein therapies as medicinal products involves the workings of multiple committees and working parties. The primary committee for regulation of plasma protein therapies is the Committee for Medicinal Products for Human Use with the assistance of the Blood Products Working Party and the Biologics Working Party. Other committees play important roles. Some of these include the Committee for Orphan Medicines, the Pediatric Committee, and the Pharmacovigilance Risk Assessment Committee; all of which have been established more recently as the enactment of various EU laws expands the scope and responsibilities of the EMA. From an agency that started with the primary goal of facilitating a European-wide marketing authorization procedure, the EMA had evolved to addressing a life-cycle approach to regulating medicinal products.

The plasma protein therapies industry is global. It is important that regulatory bodies in different regions of the world not be isolated. In 2001, the EMA and the U.S. Food and Drug Administration agreed to work together in many critical areas. Both also participate in the International Conference on Harmonization. While legal and regulatory structures differ, and regional differences exist in epidemiology and risk assessment and perception, the collaboration of the regulatory agencies has proved to enhance understanding in a more global way.

The EMA has had an exciting path from 1995 to 2015. It has grown in size, authority, responsibilities, and expertise over these past 20 years. PPTA applauds the scientific expertise and openness of the EMA and wishes the EMA a most heartfelt congratulations for its impressive 20-year history.

MARY GUSTAFSON, PPTA Vice President, Global Regulatory Policy

References
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PPTA Updates: A Global Focus

BY JAN M. BULT

The single most important priority for our industry is to manufacture safe and effective plasma protein therapies for patients worldwide and to assist them in ensuring that these therapies are available in all sites of care.

To achieve this it is obvious we have many challenges to overcome. These challenges are different and require targeted approaches. To best address the various issues in the different parts of the world, PPTA has redefined its strategic priorities and reviewed its organizational structure. This article will give you some insight on how we are dealing with the complex issues that we are facing.

STRATEGIC PRIORITIES
The PPTA strategic priorities are defined as follows:

**Access to Care**
Ensure access to care through advocacy, education and appropriate reimbursement policies

**Free Trade**
Eliminate trade barriers and other discriminatory practices to achieve open access to plasma protein therapeutics globally

**Regulatory & Quality Policy**
Advocate regulatory and quality policies that reflect the special nature of plasma protein therapies and promote a harmonized approach

**Communication & Advocacy**
Be the trusted resource when information about plasma protein therapies is needed

**Plasma**
Ensure the availability of safe, sufficient, high quality plasma for fractionation

The Association has established offices in North America and Europe; however, this does not mean that the issues that we are dealing with are limited to these regions. Just in the last two years we have seen many issues come up in different countries that require serious attention like in: Argentina, Belgium, Brazil, Canada, China, Columbia, Ecuador, Germany, India, Japan, Netherlands, Mexico, Portugal, Poland, Romania, and Turkey. This list by no means all inclusive, but is an illustration of the regional spread of the many issues that we are dealing with in the world.

The increasing number of international issues required us to take a fresh look at our organizational structure and make the necessary adjustments. PPTA as a global Association will from now on organize its activities in three main areas: Health Policy, Medical/Regulatory, and Source. This approach will ensure us greater efficiency and faster response to challenges.

Another thing we will do is to build an international
support group. This group will collect, in a standardized manner, the information that we need to effectively manage the various issues in the world. The information will be available to the different divisions and to the members. The needs of our members and stakeholders are totally different today than when the Association started and the creation of the international support group will help us to be more responsive to these needs. The international support group will:

- Systematically conduct country analyses that will help us to prioritize
- Build a regulatory repository of all relevant regulations for the various countries
- Conduct a systematic analysis of the various reimbursement policies
- Develop and maintain informational and advocacy toolkits

The Health Policy Group will focus on the activities in North America, Europe, and the Rest of the World. We all know that most of the messages that we need to convey are similar in different parts of the world, but there will be regional variation. The new construction will allow us to be more efficient in the development of the right argument in the right place.

Another important group will be Medical / Regulatory. The addition of a Medical Director will allow us to be more responsive to the growing amount of issues that require input from a medical expert.

The Association has established offices in North America and Europe; however, this does not mean that the issues that we are dealing with are limited to these regions. Just in the last two years we have seen many issues come up in different countries that require serious attention.

The third group is Source and remains unchanged. The organization will be governed by the Global Board of Directors. The role of the Board is one of a supervisory Board and not an operational Board. The Global Board will be involved in setting priorities, approving major initiatives, and reviewing activities.

The North American, European and Source Boards remain active with their responsibilities to provide oversight to the activities in the regions/divisions.

The new structure has already been implemented and we are expecting more efficiency and efficacy. I hope that you will soon experience the new PPTA.

JAN M. BULT, PPTA President & CEO
NEWS FROM AROUND THE GLOBE

New IQPP Standard Approved

BY SONIA BALBONI

PPTA has launched an International Quality Plasma Program (IQPP) Standard for recording donor adverse events (DAEs). The new standard serves as a foundation for establishing industry-wide requirements for adverse event definitions and classifications. The standard was developed when industry recognized a growing need for specifying DAE definitions so that each company could record events using like parameters.

Why the need for a standard? All IQPP certified centers have processes in place to monitor, manage, and document DAEs. Companies across the United States and Europe possess complex systems, but no two systems are alike, and each company uses different factors to define their events. “Companies use similar terminology to describe certain events; however their definitions are not uniform,” said Dr. Marilyn Rosa-Bray, chief medical officer, Grifols Plasma Operations, member, PPTA Medical Policy Committee (MDPC). “Therefore, although a company can analyze its own data, and has the statistical power to draw assumptions considering their large number of donations, until now it has been challenging to aggregate data across the industry. Having a standard categorization and definition language will allow the industry to develop more comprehensive conclusions regarding the true industry profile [for adverse events].”

The Source Board of Directors recognized the need to harmonize the lexicon for DAEs. So, the Board asked the MDPC to develop common definitions for DAEs. The next question was how to ensure that all companies would follow the definitions consistently. Here, the Board turned to the IQPP Standards Committee. The Committee reviewed the definitions and discussed the operational aspects of a plasma center’s internal systems for recording DAEs. They developed a new standard with requirements that centers use the agreed definitions and meet other criteria.

Industry now has a mechanism to make sure that DAE information is recorded consistently and, if needed, aggregated by PPTA. Since companies will be using the same parameters to define DAEs for the first time, industry can use accurate data to develop analyses of issues and address them in a timely and meaningful way. “The standard takes into consideration each organization’s diverse processes and provides an uncomplicated recording procedure we can all align to,” said 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. “Industry now holds a valuable instrument for upholding vigilance when it comes to donor health and safety.”

SONIA BALBONI, PPTA Senior Manager, Source & Standards

Industry now has a mechanism to make sure that DAE information is recorded consistently and, if needed, aggregated by PPTA. Since companies will be using the same parameters to define DAEs for the first time, industry can use accurate data to develop analyses of issues and address them in a timely and meaningful way.
PPTA held the 21st International Plasma Protein Congress March 10-11 in Rome. More than 330 physicians, scientists, policymakers, and patients from around the globe attended the conference, considered Europe’s premier event for the plasma protein therapeutics industry.

The conference opened with a panel devoted to current Italian health policy considerations, which featured Dr. Paolo Marcucci, Dr. Giuliano Grazzini, Dr. Lorenzo Montrasio, and Dr. Patrick Robert. Dr. Marcucci, PPTA’s Chairman of the Global Board of Directors, highlighted the Association’s mission “to promote the availability of and access to safe and effective plasma protein therapies for all patients in the world” and acknowledged the source plasma donor as a “key element of the strength of our industry.” He also recognized the significance of the recent decision in Italy to open the market “for custom manufacturing,” noting the “importance of the patient relationship and the continued exchange of ideas and opinions between industry and patient organizations.” Dr. Grazzini explained the complex situation in Italy with regards to the collection of blood and plasma and presented the multiple efforts to collect blood and plasma in an effort to stimulate self-sufficiency in Italy.

The Regulatory Panel featured various perspectives, including Dr. Jay Epstein who gave an overview of U.S. Food and Drug Administration policies that affect plasma and plasma protein therapies; Dr. Anneliese Hilger on the European Medicines Agency (EMA); Dr. Tommaso Paoli on the Epidemiology and Industry; and Dr. Micha Nübling of the World Health Organization, who spoke on the EMA epidemiological guideline. Dr. Epstein reported that there will be a policy change on the deferral of male donors who have had sex with men (MSM) with a guidance document being developed with an expected implementation date in 2016. Dr. Nübling noted that a new epidemiology guideline will be published later this year. Two goals of that guideline will include removing burdens of reporting; and seeking harmonization between plasma master files by using standard window periods and incidence estimates for first-time donors.

PPTA invited PLUS (Platform of Plasma Protein Users) to organize a panel to talk about access. Brian O’Mahony of the European Haemophilia Consortium spoke on the importance for physicians and patients to work together towards the common goal of access to safe, efficacious, and cost-effective plasma protein therapies. He also shared an inspiring video of 9-year-old Adam, a young hemophiliac proudly showing himself infusing. To see video, visit YouTube and search “Adam’s Self Infusion Video.”

During her presentation, Jose Drabwell of International Patient Organisation for Primary Immunodeficiencies (IPOPI), provided a comprehensive update her organization’s achievements internationally on behalf of access to care. Alpha-1 representative Dr. Frank Willersinn—a patient and medical doctor—spoke of the difficulties in access to therapies in Europe, saying,
More than 330 physicians, scientists, policymakers, and patients from around the globe attended the conference, considered Europe’s premier event for the plasma protein therapeutics industry.

“quality of life is more important than expectancy of life.” In addition, he noted that although access to Alpha-1 proteinase inhibitor is good in most countries in the European Union, there remain several countries that do not reimburse for the treatment. The global scope of the Alpha-1 Foundation was covered by Gonny Gutierrez with an emphasis on research and diagnosis, awareness, and an extensive advocacy network.

The final session of the 2015 addressed international perspectives. Cesar Garrido of Venezuela spoke on the need to close the gap between the number of Latin American patients estimated to have hemophilia and those actually diagnosed with the disease. According to Mr. Garrido, there are approximately 58,000 people living in 19 Latin American countries who have hemophilia compared to the 28,000 who have been diagnosed.

Prof. Aziz Bousfiha centered his talk on Primary Immune Deficiency (PID). He spoke of the need for African doctors to receive more training and awareness so they can properly diagnose PID and other immunodeficiencies. He noted that availability of IVIG in Africa is a challenge.

Alan Chit rounded out the panel with a comprehensive presentation on China covering political, regulatory and patient access to care issues. Given the 1.36 billion population, there is significant potential to be a major market for plasma protein therapies. However, some barriers involving trade and regulations exist; many of these are based on cultural beliefs and lack of information pertaining to the safety and efficacy of plasma products available today. Mr. Chit noted a cultural tenet in which many Chinese believe that blood is a life source that gives energy, making some reluctant to donate. In turn, this contributes to a lack of a stable supply which compromises patient care. It is estimated that currently only “50 percent of the needed plasma is actually collected.”

The 2016 IPPC will be held in Barcelona and the 2017 event will be in Prague.

JENNIFER GARVIN, PPTA Manager, Communications

Winner: Professor Ann Gardulf, center, receives the 2015 Hilfenhaus Award from Oliver Schmitt, CSL Behring GmbH, at right; and Bruno Santoni, PPTA Executive Director, Europe.

Prof. Ann Gardulf honored with 2015 Hilfenhaus Award

Each year, PPTA recognizes an individual who has made a significant contribution to patient access to safe plasma protein therapies with the prestigious Hilfenhaus Award.

This year’s award was presented to Prof. Ann Gardulf, Ph.D., a leading researcher in the administration of subcutaneous immunoglobulin. Dr. Gardulf began her career in 1982 and her diverse experience in treating patients with Primary Immune Deficiency includes a background as a registered nurse. She received her doctorate from Karolinska Institutet in Stockholm in 1994.

PPTA has recognized industry leaders such as Dr. Gardulf with the Hilfenhaus award since 1998. The award is named in honor of Dr. Joachim Hilfenhaus, a well-respected virologist who unfortunately passed at a too young age in 1996. Dr. Hilfenhaus was the first Chairman of the Industry Experts Working Group on viral safety and he worked for Behringwerke in Marburg.

The 2015 award was presented by Oliver Schmitt of CSL Behring GmbH and a member of the PPTA Europe Board, who congratulated Dr. Gardulf on her achievements. Upon receiving the award, Dr. Gardulf thanked the PPTA for “this prestigious award” and noted that she is proud to be the “first R.N. to receive the award.”
The Patient Notification System (PNS) is provided at no cost and is a 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 therapies with direct input from consumers.

HOW THE SYSTEM WORKS
Anyone interested in participating registers with the Patient Notification System and provides general contact information, including their preferred methods of notification. Registrants have the opportunity of being notified by: E-mail, telephone, or fax - which ever is most convenient for them. Please consider e-mail as your method of notification for the following reasons:

- E-mail is instantaneous
- E-mail is trackable
- E-mail is accessible, even on travel

If a therapy is withdrawn or recalled, the company involved immediately contacts Stericycle Inc. which then directly notifies the registrant. Every effort will be made to notify registrants within 24 hours. Each registrant will also receive a letter by first-class mail to ensure receipt of the information.

For current information on therapy recalls or withdrawals. To maximize the usefulness of the system, it is important for consumers to keep accurate infusion logs and record the lot number, therapy name, and manufacturer for all therapies used.

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.

In addition, consumers can go online to:
www.patientnotificationsystem.org

or call a 24-hour, toll-free number:
1-888-UPDATE-U
(1-888-873-2838)
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.

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To find out more about Citi Prepaid Cards please visit citiprepaid.com

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### Glossary of Terms

<table>
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<th>AL – ADAPTIVE LICENSING</th>
<th>IQPP – INTERNATIONAL QUALITY PLASMA PROGRAM</th>
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<tr>
<td>BMT – BONE MARROW TRANSPLANT</td>
<td>IQWIG – INSTITUTE FOR QUALITY AND EFFICIENCY IN HEALTH CARE</td>
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<td>DAE – DONOR ADVERSE EVENT</td>
<td>IVIG – INTRAVENOUS IMMUNOGLOBULIN</td>
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<td>EC – EUROPEAN COMMISSION</td>
<td>MDPC – PPTA MEDICAL POLICY COMMITTEE</td>
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<tr>
<td>ED – EARLY DIALOGUES</td>
<td>MOH – MINISTRY OF HEALTH</td>
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<td>EHC – EUROPEAN HAEMOPHILIA CONSORTIUM</td>
<td>MSM – MEN WHO HAVE SEX WITH MEN</td>
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<td>EMA – EUROPEAN MEDICINES AGENCY</td>
<td>NHLBI – NATIONAL HEART LUNG AND BLOOD INSTITUTE</td>
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<td>EU – EUROPEAN UNION</td>
<td>NIH – NATIONAL INSTITUTE OF HEALTH</td>
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<td>FDA – U.S. FOOD AND DRUG ADMINISTRATION</td>
<td>PID – PRIMARY IMMUNE DEFICIENCY</td>
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<tr>
<td>HAS – HAUTE AUTORITÉ DE SANTÉ</td>
<td>PLUS - PLATFORM OF PLASMA PROTEIN USERS</td>
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<td>HTA – HEALTH TECHNOLOGY ASSESSMENT</td>
<td>PNS – PATIENT NOTIFICATION SYSTEM</td>
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<td>IG – IMMUNOGLOBULIN</td>
<td>PPTA – PLASMA PROTEIN THERAPEUTICS ASSOCIATION</td>
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<tr>
<td>IPOPI – INTERNATIONAL PATIENT ORGANISATION FOR PRIMARY IMMUNODEFICIENCIES</td>
<td>QALY – QUALITY ADJUSTED LIFE YEARS</td>
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<tr>
<td>IPPC – INTERNATIONAL PLASMA PROTEIN CONGRESS</td>
<td>SEED – SHAPING EUROPEAN EARLY DIALOGUES</td>
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<td></td>
<td>STAMP – SAFE AND TIMELY ACCESS TO MEDICINES FOR PATIENTS</td>
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The serology product range is not available for blood screening settings in Angola, Argentina, Bahamas, Bangladesh, Canada, Guyana, Iraq, Korea D.R., Latvia, Lesotho, Lithuania, Malaysia, Philippines, South Korea, Uganda, and the United States. For all other countries, please contact your local Roche representative to check availability.

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