

# PLUS

## FORGING A RELATIONSHIP BETWEEN PATIENTS, INDUSTRY AND GOVERNMENT

BY BRIAN O'MAHONY



**PLUS** is a coalition of patient organizations representing a number of disparate, inherited or acquired, serious or life threatening conditions which are routinely treated with plasma protein products. These are hemophilia, primary immune deficiencies, alpha-1 antitrypsin deficiency, Guillain Barré syndrome, hereditary angiodema, idiopathic thrombocytopenic Purpura and von Willebrand disease. The conditions vary enormously in the level of recognition, diagnosis and treatment. Together, these conditions account for some 90,000 known patients in Europe and a probable prevalence of 380,000.

The conditions are disparate, but the main therapies used in all these conditions are manufactured from human plasma. The organizations that represent the patients with these conditions are acutely aware that diagnosis is insufficient for many of the conditions and access to therapy needs to be increased and optimized. Patients in Europe who rely on plasma-derived therapies deserve the opportunity to have access to treatment and the possibility of freedom from the life-threatening consequences of lack of treatment. Access to safe and effective therapy is affected by government or national healthcare priorities, budgets and availability of specific therapies. However, it is also affected by the views of regulatory authorities, the European Union (EU) Commission, industry, the not-for-profit sector, national blood authorities, donors, the World Health Organization (WHO) and other stakehold-

ers. Patient organizations including the European Haemophilia Consortium (EHC), World Federation of Hemophilia (WFH), and International Patients Organisation for Primary Immunodeficiencies (IPOPI) have made both separate and coordinated representations in the past on issues including the Directives in 1989 and 2002 on blood and plasma and have responded to views expressed by stakeholders and others on issues including proposals on self sufficiency, donor deferral measures, donor remuneration and product importation.

In many cases, these views have been set out as a response to proposals or views which were already well advanced or published. We were concerned that directives, guidelines and recommendations which may have a major impact on access to safe and effective plasma therapies have been promulgated in Europe without proactively seeking the views of the relevant patient organizations. This was unacceptable. Our voices, as the users of these lifesaving and enhancing therapies, must be heard and we must be consulted when measures are being drafted, which will have a major impact on our access to therapy. We further recognized that it was impractical to ask the EU

Commission at any level to meet regularly with each of the separate organizations. However, recognizing that we share a common and vital interest in the optimum access to the safest and most efficacious plasma-derived therapies, in 2009 we

formed a broad coalition of seven organizations of plasma users—PLUS.

The genesis of PLUS came from the recommendations of a European Platform for Patient Organisations, Science and Industry (EPPOSI) Conference in December 2007 on *Best Practice on Communicating Risks and the Value of Safety to Patients with Chronic Diseases*. One of the recommendations was that the European Commission should be encouraged to establish condition specific Consultation Groups for chronic diseases. Following this conference we met with the EU Commission officials and with the then EU Health Commissioner and persuaded them to set up such a group with a coalition of organizations representing constant users of plasma products. When they agreed to this proposal, we established PLUS, the Platform of Plasma Protein Users.

### The terms of reference for PLUS are as follows:

- To facilitate the exchange of information towards the building of consensus views when possible among the organizations that represent regular users of plasma, plasma proteins or plasma-derived therapies

- To ensure that the consensus views of the organizations are communicated to the EU Commission, Members of Parliament (MEPs), the Council of Europe and other relevant bodies and individuals.
- To ensure that the collective views of the organizations are proactively considered on a timely basis when Directives, Guidelines and recommendations are being framed in relevant areas
- The collective views expressed on behalf of the organizations in no way detract from each organization's ability or right to express their own individual view on any particular issue. PLUS will express the collective view on an issue when agreed.

The views expressed by PLUS represent the collective position of the membership. The member organizations are EHC, WFH, IPOPI, Alfa Europe, GBS/CIDP Foundation International (GBS/CIDP), Hereditary Angioedema International (HAEI) and the ITP Support Association, which improves the welfare of people with immune thrombocytopenic purpura.

Since our inception we have had a number of meetings with the European Commission officials (DG Sanco and DG Enterprise) and we have ensured that PLUS will be proactively consulted when issues such as the review of the blood directive are being scheduled.

The collective view on these vital issues are not formed in a vacuum. PLUS and the organizations constituting PLUS would have engagement with key stakeholders including industry, the not-for-profit sector, WHO, the International Society Blood Transfusion (ISBT) and national blood authorities. We have been concerned that key stakeholders including those who collect blood or plasma, those who manufacture plasma-derived products and authorities such as WHO will set out positions, which can significantly impact the availability of safe and effective therapies in the required amounts without first eliciting the views of the organizations whose members are the major users of their blood, plasma or manufactured products.

Issues such as donor deferral, donor remuneration and self sufficiency tend to elicit definitive statements from stakeholders, which leave little room for the views of patient organizations. Decisions in these vital areas which can have such a profound impact on the therapy available for our members should not be taken in isolation and should not be made without

consulting the representatives of those who use the therapies on a regular basis. We wish to engage with all key stakeholders, to listen, to learn and to proactively contribute the collective views of patient organizations.

Decisions about us should not be made without us. Stakeholders can not know the needs of the patients if they do not engage proactively in dialogue with their representative organizations. It is not a good business model to never elicit the views of your customers. We will be proactive in leading this process. In January of this year, we organized a conference in Dublin, Ireland that brought together many of the key stakeholders. This resulted in two days of focused and positive interaction and discussion. There were clearly different views expressed on many issues yet the process was positive and mutually respectful. The result was a statement of principles, the Dublin Consensus Statement, which was agreed to by 14 of the 15 individual participants (with the exception being the donor organization). This was then sent back to their organizations for their decision on endorsement, non endorsement or agreement in principle with some qualifications. This statement, to paraphrase former British Prime Minister Winston Churchill, was not the end but the end of the beginning. It is clear from the meeting that a dialogue between all key stakeholders can take place in an atmosphere which allows for both debate and mutual respect.

From the comments received to date, there is clear agreement on many issues. Outstanding issues will be the focus of future meetings because all present recognized the importance of this dialogue and indeed of this process being led by the patient organizations. We pledge to continue this process of inclusive dialogue, to do our utmost to bring stakeholders together and to give them an opportunity to understand the concerns and priorities of the patient organizations represented by PLUS. We further pledge that we will not act in the interests of any sector or stakeholder except our constituent patient organizations. We seek constructive engagement. We welcome dialogue, clarification and information.

We will listen respectfully to all, engage with all and ensure that all are aware of our collective views on these vital issues. ☺

*BRIAN O'MAHONY is a representative of the PLUS Steering Group and is Chief Executive of the Irish Haemophilia Society*



## Brian O Mahony

**B**rian O'Mahony is the Chief Executive of the Irish Haemophilia Society. He represents the society on the statutory National Haemophilia Council and he is the Vice Chair of the Tender Commission established by the Irish Government for the Procurement of factor Concentrates. He previously served as Chair of the Irish Haemophilia Society for 17 years and as President of the WFH for 10 years. He continues to work as a volunteer with WFH and he assists several national member organizations on an ongoing basis in areas such as strategic planning, and lobbying. Among his activities are writing, advocating, and facilitating training. His publications for WFH include Monographs on Advocacy, Developing Haemophilia Organisations and a Guidebook on National Tender systems. A medical scientist by profession, he is a Fellow of the Institute of Biomedical Sciences (UK) and a Fellow of the Academy of Medical Laboratory Sciences (Ireland) He has post-Graduate qualifications in Management and in Occupational Health and Safety. He spearheaded the advocacy initiatives in Ireland, which resulted in the availability of prophylaxis for children access to optimal quantities of treatment products for all persons with hemophilia. From 1993-2006 there was a four fold increase in per capita use of clotting factors. The Irish Hemophilia Society also has a formal role in decisions on National haemophilia health care policy. He is a member of the steering committee of the European Haemophilia Consortium and the plasma users coalition (PLUS), which advocates on plasma and blood related issues with the European Commission on behalf of several non-governmental organisations. Brian O'Mahony has severe haemophilia B.