

PPTA Position Paper European Commission's Legal Proposal on Information to Patients

The Plasma Protein Therapeutics Association (PPTA)¹ welcomes the European Commission's Public Consultation on a *Legal Proposal for Information to Patients* and is pleased to submit here below key recommendations and ideas on behalf of the plasma protein industry.

EU standard for the information made available

PPTA believes there should be a common European standard for information that is to be provided to patients so that patients can expect the same level of information no matter which country they live in. A simple standard would be that they should receive all relevant information to make an informed decision on treatment with their physician in ambulatory or hospital care. The information should be given to the patient by healthcare professionals.

The WHO has in 2007 published its 15th List of Essential Medicines to be used globally. The WHO list is intended to provide guidance to individual countries in determining which medicines are considered to be essential and in subsequently prioritizing their healthcare resources. Included in that list are both coagulation factors and immunoglobulins, both of which are utilised in the treatment of plasma protein related disorders (e.g. haemophilia, primary immunodeficiencies and auto-immune disorders). It is therefore unfortunate that information and thereby the access to these therapies are subject to diverging standards in different member states.

Who should provide the information?

PPTA's member companies are uniquely capable of providing factual and useful information to patients. The healthcare professional could ideally serve as an intermediary.

Patients with plasma protein disorders are suffering from mostly rare and chronic diseases which require their co-operation in what can be complex treatments. Most patients become experts in their condition and the treatments available. The producers are uniquely placed to provide the detailed information that patients need, as the conditions that are treated are not only rare but also often left undiagnosed or misdiagnosed due to the lack of specialist knowledge available. Overall, we are convinced that industry has an important role to play in providing information to strengthen the doctor-patient relationship. Currently this is often not possible due to legal restrictions in place. Equally industry is open to provide information on treatment at the request of patients.

¹ PPTA is the primary advocate for the world's leading producers of plasma-derived and recombinant analogue medicinal products. The medicines produced by PPTA members are used to treat patients suffering from rare life-threatening and/or life-impairing disorders and serious medical conditions including bleeding disorders (e.g. Haemophilia), immune system deficiencies (e.g. Primary Immunodeficiencies), auto-immune diseases, burns and shock.

Unnecessary bureaucracy

PPTA strongly supports the suggestion that any procedures introduced will be kept simple, in line with the principles of Better Regulation. This is vital to ensure patients' access to timely and high quality information.

Necessary legal definition of information to patients

It is recognised, also by the European Commission, that criteria need to be defined regarding what type of information to patients may be promotional and what type may be unbiased information strictly for "informational" purposes. It is therefore crucial that such criteria are elaborated. Since industry is an important stakeholder in this issue, it is suggested that the elaboration of these criteria is undertaken by the European Commission in close collaboration with relevant stakeholders including relevant and directly concerned patient groups, industry and therefore PPTA.

Technology issues

The study published by DG SANCO on Member State information practices highlights the fact that many EU citizens use the internet to research illnesses and treatment options, and also to liaise with their public authorities. However, the statistics also demonstrate that nearly half of EU citizens do not have access to the internet. This says that any solution cannot be primarily internet based.

The internet is very useful for researching plasma protein disorders and the treatments available. Whilst we believe that the healthcare professionals should be the first port of call for help and information, people can and do choose to search on the internet. As the web is unregulated there is the possibility for inaccurate or biased information to be published as fact. The PPTA believes that patients should be helped to be directed to the correct sources of information via the existing EU Commission web portal on health information.

Specific recommendations

Beyond the issues addressed above, PPTA is convinced that several areas should be enhanced at EU level, in order to help patients to become better informed about their conditions. Related topics that could be covered in the Commission's proposal are:

- EU-wide **disease specific patient registries** that would help patients to be better coordinated and communicate with their patient communities, alongside the main goal of improving treatment levels.
- Easy to access **centralized information on reference centres** that would be particularly useful in plasma protein disorders, so that patients can quickly access the relevant information about their condition and patient communities that can provide support.
- **Public/private partnerships** in education/awareness programmes that would help to better understand symptoms of specific illnesses, e.g. plasma protein disorders, and to improve the competency of patients and their advocacy groups.
- **Improving the understanding of symptoms** for rare plasma protein deficiency disorders for the medical community in order to improve diagnosis and therefore the

level of treatments. The information that can be made available to patients will naturally be improved through better knowledge.

- Encouraging the use of **electronic media and interactive technologies** to disseminate and share patient information

PPTA would welcome the opportunity to further discuss these recommendations and engage into a constructive dialogue with the decision makers currently focusing on this legal proposal with the aim to ultimately provide better and more efficient information to patients.