The EC outsourced the inquiry to an external consultant and PPTA Europe has been involved throughout the process by providing responses to various questionnaires and valuable data and information for the study. In particular, the European Health Policy Steering Committee (HPSC) has played a key role in providing information for the preparation of a report to the EC. At this time, several points have been identified as important and considerations include: the differentiation between blood for transfusion and plasma for fractionation, donor compensation, self-sufficiency, freedom of choice and EU market for plasma protein therapies. A report from the consultant was received in late August. Following its publication, PPTA has planned a series of outreach meetings to discuss the outcomes and to gather intelligence on other stakeholders’ positions.

Finally, another development that may have a significant impact on the revision of the ‘Blood Directive’ is the legal action taken by Octapharma against the French State earlier in 2012. This case is founded on the fact that the French National Safety Agency for Medicines and Health Products (ANSM) included in its labile products list blood products containing ‘freshly-frozen, leukocyte-depleted, solvent/detergent-treated virus-deactivated plasma’. Octapharma is contesting this decision and referred to the fact that according to the European legislation on medicinal products, labile products prepared with a method involving a industrial process are considered medicinal products and not labile products. Based on this interpretation of the legislation, Octapharma also stated that the ANSM had no right to require additional permissions to put these products on the market.

The French Conseil d’Etat (Council of State) was asked for legal advice on this case and it addressed two questions to the European Court of Justice (ECJ). The first question regards whether two pieces of legislation regulating one product can be both applied or whether only the legislation on medicinal products should be applied when it is stricter than the other legislation. If the Court decides that the medicinal products’ legislation takes precedence, then the Blood Directive would not apply any longer to plasma prepared by an industrial method and intended for transfusion. The question would then be whether this would also be the case for plasma for fractionation. The second question regards certain provisions in the Blood Directive and the EU ‘Treaty’, which allow Member States to maintain stricter rules regarding the quality and safety of blood and blood components. The question is whether these provisions would apply to plasma prepared with an industrial process and, if so, whether these provisions take precedence over Directive 2001/83, including its requirement for pre-market authorization of the product. If the Court decides that this is not justified, then Member States would not be able to impose stricter rules than existing EU legislation, which could have an impact not only on the marketing of these products, but also for example on matters such as donor compensation.

The EC is following the case and it is expected that it will take it into account while revising the blood legislation. PPTA has long advocated for the EC to improve the European market for plasma protein therapies and the Association will follow closely the response of the ECJ which will conclude the matter.

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2 Agence Nationale de Sécurité des Médicaments et des Produits de santé. The ANSM is responsible for publishing technical requirements for labile blood preparations and hemovigilance.
4 The Conseil d’Etat is a body of the French government that provides legal advice on the preparation of legislation.
5 In this case the Blood Directive and the Community Code relating to Medicinal products for Human Use for whole blood which is prepared by a method involving an industrial process and which is intended for transfusion
7 Treaty on the Functioning of the European Union, article 168.

In the case of the Blood Directive, the objective is to ensure that patients across Europe have access to blood and blood components with a consistent level of safety and quality.