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European Commission
Health and Food Safety Directorate-General
Unit 4 Medical Products: quality, safety, innovation
B-1049 Brussels

Subject: **Response to the consultation on the roadmap for the revision of directive 2002/98/EC setting the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components**

Dear Dr van der Spiegel,

The European Haemophilia Consortium (EHC), registered in the EU Transparency Register under identification number 786550013705-85, wishes to submit its comments on the Roadmap outlining the revision process for Directive 2002/98/EC. The EHC is also a member of PLUS, the Platform for Plasma Users, an informal grouping of patient organisations representing people relying either totally or partially on plasma-derived treatments.

We welcome the opportunity to comment on the Directive and appreciate the efforts made by the European Commission to include all interested stakeholders in the revision process, including patient organisations.

We support the decision of the Commission to evaluate the continued relevance and coherence of this legislation. In fact, since its original implementation, not only has the European Union enlarged, but there have been many technical and scientific advances as well.

Assessment criteria

When looking at the high-level questions in the 'relevance' assessment criteria, we would like to suggest to also include a question on whether the terminology used in the legislation should be expanded. In particular, we would like to see a separation between the concept of plasma for plasmapheresis (or transfusion) and plasma for fractionation (or for the manufacturing of plasma-derived treatment).

Under the criteria of 'effectiveness,' we would like to expand the last question to look at whether the legislation, by promoting blood donation, has also contributed to greater access to plasma-derived treatments in Europe. Furthermore, we would like to have an assessment on whether

the original legislation was also able to reduce unnecessary wastage of collected plasma, for instance, with recovered plasma. Finally, we would like to include a question on whether the legislation has increased not only the collection of whole blood but also the collection of plasma through plasmapheresis.

With regard to 'coherence,' we welcome the suggestion to analyse the extent to which the legislation is coherent with other relevant legislations. We also welcome the proposal to analyse whether the requirements of the Directive are suitable when blood is used as a starting material for the manufacturing of medicinal products. In fact, it would be interesting to know whether the implementation of concepts, such as good manufacturing practices and plasma master file (as established by Directive 2003/94/EC), earlier in the blood collection process could facilitate and increase the collection of additional plasma for manufacturing.

Additional comments

We hope that the revised legislation will continue to promote the collection and availability of blood and blood components in Europe, as many patients rely on these substances for survival on a daily basis.

Although plasma-derived medicinal products are not directly regulated by this legislation, we are hoping that the continued promotion of the collection of blood components and, in particular, plasma for fractionation, will result in increased availability of plasma-derived medicines. In this regard, we would like to see the revised regulation encouraging more Member States to develop plasmapheresis programmes.

We remain at your disposal for any further queries,

Yours sincerely,

Amanda Bok

EHC CEO